
**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 September 30, 2020

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 October 26, 2020, the registrant had 150,424,035 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

	September 30, 2020	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 806,678	\$ 177,254
Marketable securities	476,324	146,401
Accounts receivable, net	206,606	130,667
Inventory	80,427	61,724
Prepaid expenses and other current assets	36,592	40,913
Total current assets	1,606,627	556,959
Long-term Assets:		
Property, plant and equipment, net	456,455	455,325
Operating lease right-of-use assets	129,837	126,444
Goodwill	1,237,672	1,203,197
Intangible assets, net	871,660	1,143,550
Other long-term assets, net	52,119	20,293
Total assets	\$ 4,354,370	\$ 3,505,768
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 26,061	\$ 25,973
Accrued liabilities	182,945	193,329
Operating lease liabilities, current portion	10,746	7,891
Debt, current portion	1,319	834
Other current liabilities	31,761	8,467
Total current liabilities	252,832	236,494
Long-term Liabilities:		
Convertible notes, net	1,554,967	803,605
Long-term debt, less current portion	22,643	24,032
Other long-term liabilities	62,821	34,911
Operating lease liabilities, less current portion	124,007	118,665
Total liabilities	2,017,270	1,217,707
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at September 30, 2020 and December 31, 2019	—	—
Common stock, \$0.01 par value Authorized—400,000,000 shares issued and outstanding—150,373,486 and 147,625,696 shares at September 30, 2020 and December 31, 2019	1,505	1,477
Additional paid-in capital	3,865,990	3,406,440
Accumulated other comprehensive income (loss)	1,084	(100)
Accumulated deficit	(1,531,479)	(1,119,756)
Total stockholders' equity	2,337,100	2,288,061
Total liabilities and stockholders' equity	\$ 4,354,370	\$ 3,505,768

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue	\$ 408,363	\$ 218,805	\$ 1,025,052	\$ 580,718
Operating expenses				
Cost of sales (exclusive of amortization of acquired intangible assets)	95,061	52,335	254,559	146,301
Research and development	31,471	34,714	107,653	96,471
Sales and marketing	136,481	86,196	423,092	265,325
General and administrative	115,589	80,538	336,265	208,067
Amortization of acquired intangible assets	23,430	748	70,199	2,256
Intangible asset impairment charge	209,666	—	209,666	—
Total operating expenses	611,698	254,531	1,401,434	718,420
Other operating income	—	—	23,665	—
Loss from operations	(203,335)	(35,726)	(352,717)	(137,702)
Other income (expense)				
Investment income, net	2,523	9,093	5,532	23,417
Interest expense	(23,582)	(13,209)	(71,647)	(47,911)
Total other income (expense)	(21,059)	(4,116)	(66,115)	(24,494)
Net loss before tax	(224,394)	(39,842)	(418,832)	(162,196)
Income tax benefit (expense)	4,510	(683)	7,109	230
Net loss	\$ (219,884)	\$ (40,525)	\$ (411,723)	\$ (161,966)
Net loss per share—basic and diluted	\$ (1.46)	\$ (0.31)	\$ (2.76)	\$ (1.26)
Weighted average common shares outstanding—basic and diluted	150,155	129,567	149,346	128,344

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net loss	\$ (219,884)	\$ (40,525)	\$ (411,723)	\$ (161,966)
Other comprehensive loss, before tax:				
Unrealized gain on available-for-sale investments	(405)	(2,697)	1,159	1,431
Foreign currency adjustment	—	—	25	—
Comprehensive loss, before tax	(220,289)	(43,222)	(410,539)	(160,535)
Income tax expense related to items of other comprehensive loss	—	643	—	(341)
Comprehensive loss, net of tax	\$ (220,289)	\$ (42,579)	\$ (410,539)	\$ (160,876)

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	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	\$ 3,406,440	\$ (100)	\$ (1,119,756)	\$ 2,288,061
Equity component of convertible notes, net of tax and issuance costs	—	—	346,641	—	—	346,641
Settlement of convertible notes, net of tax	—	—	(64,199)	—	—	(64,199)
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	—	—	—	—	(105,697)	(105,697)
Accumulated other comprehensive loss	—	—	—	(1,617)	—	(1,617)
Balance, March 31, 2020	149,446,864	\$ 1,495	\$ 3,763,328	\$ (1,717)	\$ (1,225,453)	\$ 2,537,653
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	—	—	—	—	(86,142)	(86,142)
Accumulated other comprehensive income	—	—	—	3,206	—	3,206
Balance, June 30, 2020	149,980,798	\$ 1,501	\$ 3,819,798	\$ 1,489	\$ (1,311,595)	\$ 2,511,193
Exercise of common stock options	140,145	1	4,469	—	—	4,470
Compensation expense related to issuance of stock options and restricted stock awards	249,197	2	41,474	—	—	41,476
Issuance of common stock for business combinations	3,346	1	249	—	—	250
Net loss	—	—	—	—	(219,884)	(219,884)
Accumulated other comprehensive loss	—	—	—	(405)	—	(405)
Balance, September 30, 2020	150,373,486	\$ 1,505	\$ 3,865,990	\$ 1,084	\$ (1,531,479)	\$ 2,337,100

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	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	\$0.01 Par Value				
Balance, January 1, 2019	123,192,540	\$ 1,232	\$ 1,716,894	\$ (1,422)	\$ (1,035,763)	\$ 680,941
Equity component of convertible notes, net of tax and issuance costs	—	—	268,390	—	—	268,390
Shares issued to settle convertible notes	2,158,991	22	182,413	—	—	182,435
Settlement of convertible notes	—	—	(300,768)	—	—	(300,768)
Exercise of common stock options	235,278	2	3,648	—	—	3,650
Issuance of common stock to fund the Company's 2018 401(k) match	86,532	1	7,408	—	—	7,409
Compensation expense related to issuance of stock options and restricted stock awards	3,410,481	35	16,131	—	—	16,166
Net loss	—	—	—	—	(82,939)	(82,939)
Accumulated other comprehensive income	—	—	—	1,656	—	1,656
Balance, March 31, 2019	129,083,822	\$ 1,292	\$ 1,894,116	\$ 234	\$ (1,118,702)	\$ 776,940
Equity component of convertible notes, net of issuance costs	—	—	(22)	—	—	(22)
Exercise of common stock options	78,793	1	1,347	—	—	1,348
Compensation expense related to issuance of stock options and restricted stock awards	104,845	1	20,142	—	—	20,143
Purchase of employee stock purchase plan shares	93,588	1	4,136	—	—	4,137
Net loss	—	—	—	—	(38,502)	(38,502)
Accumulated other comprehensive income	—	—	—	1,488	—	1,488
Balance, June 30, 2019	129,361,048	\$ 1,295	\$ 1,919,719	\$ 1,722	\$ (1,157,204)	\$ 765,532
Settlement of convertible notes	26	—	1	—	—	1
Exercise of common stock options	178,628	2	1,389	—	—	1,391
Compensation expense related to issuance of stock options and restricted stock awards	278,180	2	24,346	—	—	24,348
Purchase of employee stock purchase plan shares	3	—	—	—	—	—
Stock issuance costs	—	—	(409)	—	—	(409)
Net loss	—	—	—	—	(40,525)	(40,525)
Accumulated other comprehensive loss	—	—	—	(2,054)	—	(2,054)
Balance, September 30, 2019	129,817,885	\$ 1,299	\$ 1,945,046	\$ (332)	\$ (1,197,729)	\$ 748,284

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)

	Nine Months Ended September 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (411,723)	\$ (161,966)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	53,345	21,920
Loss on disposal of property, plant and equipment	930	880
Unrealized gain on equity investments	(1,183)	—
Deferred tax benefit	(7,976)	(341)
Stock-based compensation	111,075	60,657
Loss on settlement of convertible notes	7,954	10,558
Amortization of convertible note debt discount and issuance costs	55,222	30,778
Amortization of deferred financing costs and other liabilities	(3,614)	(2,421)
Amortization of premium on short-term investments	1,040	(6,229)
Amortization of acquired intangible assets	70,199	2,256
Intangible asset impairment charge	209,666	—
Non-cash lease expense	11,041	2,681
Changes in assets and liabilities:		
Accounts receivable, net	(73,642)	(36,871)
Inventory, net	(18,472)	(14,525)
Operating lease liabilities	(6,135)	(2,628)
Accounts payable and accrued liabilities	(7,608)	16,279
Other assets and liabilities	34,959	(7,382)
Net cash provided by (used in) operating activities	25,078	(86,354)
Cash flows from investing activities:		
Purchases of marketable securities	(890,012)	(604,129)
Maturities and sales of marketable securities	559,907	1,449,330
Purchases of property, plant and equipment	(47,782)	(130,970)
Business combination, net of cash acquired	(6,658)	—
Investments in privately held companies	(10,610)	—
Other investing activities	(244)	(530)
Net cash provided by (used in) investing activities	(395,399)	713,701
Cash flows from financing activities:		
Proceeds from issuance of convertible notes, net	1,125,547	729,477
Proceeds from exercise of common stock options	15,408	6,389
Proceeds in connection with the Company's employee stock purchase plan	9,799	4,137
Payments on settlement of convertible notes	(150,054)	(493,356)
Other financing activities	(938)	(90)
Net cash provided by financing activities	999,762	246,557
Net increase in cash, cash equivalents and restricted cash	629,441	873,904
Cash, cash equivalents and restricted cash, beginning of period	177,528	160,430
Cash, cash equivalents and restricted cash, end of period	\$ 806,969	\$ 1,034,334

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

	Nine Months Ended September 30,	
	2020	2019
Supplemental disclosure of non-cash investing and financing activities		
Property, plant and equipment acquired but not paid	\$ 7,209	\$ 16,933
Unrealized gain on available-for-sale investments, before tax	\$ 1,159	\$ 1,431
Issuance of 136,559 and 86,535 shares of common stock to fund the Company's 401(k) matching contribution for 2019 and 2018, respectively	\$ 12,007	\$ 7,409
Issuance of 2,159,017 shares of common stock upon settlement of convertible notes	\$ —	\$ 182,435
Retirement of equity component of convertible notes settled	\$ (64,199)	\$ (300,768)
Issuance of 386,293 shares for business combination	\$ 28,847	\$ —
Supplemental disclosure of cash flow information:		
Interest paid	\$ 9,239	\$ 4,944

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 for other types of cancer, 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, 2019 included in the Company’s Annual Report on Form 10-K (the “2019 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, 2019 has been derived from audited financial statements, but does not contain all of the footnote disclosures from the 2019 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 2019 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 convertible notes, 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 2019 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 COVID-19 outbreak, which the World Health Organization has classified as a pandemic, has prompted governments and regulatory bodies throughout the world to enact broad precautionary measures, including “stay-at-home” orders, restrictions on the performance of “non-essential” services, public gatherings and travel. Health systems, including key markets where the Company operates, have been, or may be, overwhelmed with high volumes of patients suffering from COVID-19. Even in areas where “stay-at-home” restrictions have been lifted and the number of cases of COVID-19 has declined, many individuals remain cautious about resuming activities such as preventive-care medical visits. Medical practices continue to be cautious about allowing individuals, such as sales representatives, into their offices. Many individuals continue to work from home rather than from an office setting. The Company cannot forecast when the COVID-19 pandemic will end or the extent to which practices that have emerged during the pandemic will continue once it subsides.

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

The extent to which COVID-19 impacts the Company's business and financial results will depend on numerous evolving factors including, but not limited to: the magnitude and duration of COVID-19, the extent to which it will impact worldwide macroeconomic conditions including interest rates, employment rates and health insurance coverage, the speed of the anticipated recovery, access to capital markets, and governmental and business reactions to the pandemic. 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 September 30, 2020 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.

Despite the Company's efforts, 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.

Coronavirus Aid, Relief, and Economic Security Act ("CARES Act")

In April 2020, the Company received \$23.7 million from the United States Department of Health and Human Services ("HHS") as a distribution from the Public Health and Social Services Emergency Fund provided for in the CARES Act. The fund payments are grants, not loans, and HHS will not require repayment provided the funds are utilized to offset expenses incurred to address COVID-19 or to replace lost revenues. The Company accepted the terms and conditions of the grant in May 2020 and recognized the entire \$23.7 million during the nine months ended September 30, 2020, due to lost revenue attributable to COVID-19, which is reflected in other operating income in the condensed consolidated statement of operations. The Company cannot predict the extent to which it might receive any additional funds to be paid out under the Provider Relief Fund, and to what extent the financial impact of receiving such funds might offset the broad implications of the COVID-19 pandemic, which include increases in the Company's costs and lost revenues.

Cash and Cash Equivalents

The Company considers cash on hand, demand deposits in bank, money market funds, and all highly liquid investments with an original maturity of 90 days or less to be cash and cash equivalents.

Marketable Securities

Management determines the appropriate classification of debt securities at the time of purchase and re-evaluates such designation as of each balance sheet date. Debt securities carried at amortized cost are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Debt securities not classified as held-to-maturity are classified as available-for-sale. Available-for-sale securities are carried at fair value. The unrealized gains and losses, net of tax, on the Company's debt securities are reported in other comprehensive income. Marketable equity securities are measured at fair value and the unrealized gains and losses, net of tax, are recognized in other income (expense) in the condensed consolidated statements of operations. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity computed under the straight-line method. Such amortization is included in investment income, net. Realized gains and losses and declines in value as a result of credit losses on available-for-sale securities are included in the condensed consolidated statements of operations as investment income, net. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in the condensed consolidated statements of operations as investment income, net.

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

The Company's 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. Investments in which the Company has the ability and intent, if necessary, to liquidate, in order to support its current operations (including those with a contractual term greater than one year from the date of purchase), are classified as current.

The Company periodically evaluates its available-for-sale debt securities in unrealized loss positions to determine whether any impairment is a result of a credit loss or other factors. This evaluation includes, but is not limited to, significant quantitative and qualitative assessments and estimates regarding credit ratings, significance of a security's loss position, adverse conditions specifically related to the security, and the payment structure of the security.

Allowance for Doubtful Accounts

The Company estimates an allowance for doubtful accounts against accounts receivable using historical collection trends, aging of accounts, current and future implications surrounding the ability to collect such as economic conditions, and regulatory changes. The allowance for doubtful accounts is evaluated on a regular basis and adjusted when trends, significant events or other substantive evidence indicate that expected collections will be less than applicable accrual rates. At September 30, 2020 and December 31, 2019, the allowance for doubtful accounts recorded was not material to the Company's condensed consolidated balance sheets. For the three and nine months ended September 30, 2020 and 2019, there was an immaterial amount of bad debt expense written off against the allowance and charged to operating expense.

Inventory

Inventory is stated at the lower of cost or net realizable value. The Company determines the cost of inventory using the first-in, first out method ("FIFO"). The Company estimates the recoverability of inventory by reference to internal estimates of future demands and product life cycles, including expiration. The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale, no longer meet quality specifications, or has a cost basis in excess of its estimated realizable value and records a charge to cost of sales for such inventory as appropriate.

Direct and indirect manufacturing costs incurred during process validation with probable future economic benefit are capitalized. Validation costs incurred for other research and development activities, which are not permitted to be sold, have been expensed to research and development in the Company's condensed consolidated statements of operations.

Inventory consisted of the following:

(In thousands)	September 30, 2020	December 31, 2019
Raw materials	\$ 33,842	\$ 24,958
Semi-finished and finished goods	46,585	36,766
Total inventory	<u>\$ 80,427</u>	<u>\$ 61,724</u>

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

Property, Plant and Equipment

Property, plant and equipment are stated at cost and depreciated using the straight-line method over the assets' estimated useful lives. Land is stated at cost and does not depreciate. Additions and improvements are capitalized, including direct and indirect costs incurred to validate equipment and bring it to working conditions. Revalidation costs, including maintenance and repairs are expensed when incurred.

Software Development Costs

Costs related to internal use software, including hosting arrangements, are incurred in three stages: the preliminary project stage, the application development stage, and the post-implementation stage. Costs incurred during the preliminary project and post-implementation stages are expensed as incurred. Costs incurred during the application development stage that meet the criteria for capitalization are capitalized and amortized, when the software is ready for its intended use, using the straight-line basis over the estimated useful life of the software, or the duration of the hosting agreement.

Investments in Privately Held Companies

The Company determines whether its investments in privately held companies are debt or equity based on their characteristics, in accordance with the applicable accounting guidance for such investments. The Company also evaluates the investee to determine if the entity is a variable interest entity ("VIE") and, if so, whether the Company is the primary beneficiary of the VIE, in order to determine whether consolidation of the VIE is required. If consolidation is not required and the Company does not have voting control of the entity, the investment is evaluated to determine if the equity method of accounting should be applied. The equity method applies to investments in common stock or in substance common stock where the Company exercises significant influence over the investee.

Investments in privately held companies determined to be equity securities are accounted for as non-marketable securities. The Company adjusts the carrying value of its non-marketable equity securities for changes from observable transactions for identical or similar investments of the same issuer, less impairment. All gains and losses on non-marketable equity securities, realized and unrealized, are recognized in investment income, net in the condensed consolidated statements of operations.

Investments in privately held companies determined to be debt securities are accounted for as available-for-sale or held-to-maturity securities, in accordance with the applicable accounting guidance for such investments.

Derivative Financial Instruments

The Company hedges a portion of its foreign currency exposures related to outstanding monetary assets and liabilities using foreign currency forward contracts. The foreign currency forward contracts are included in prepaid expenses and other current assets or in accrued liabilities in the condensed consolidated balance sheets, depending on the contracts' net position. These contracts are not designated as hedges, and as a result, changes in their fair value are recorded in other income (expense) in the condensed consolidated statements of operations. There were no gains or losses recorded for the three and nine months ended September 30, 2020 and 2019. As of September 30, 2020 and December 31, 2019, the Company had open foreign currency forward contracts with notional amounts of \$18.2 million and \$17.9 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 September 30, 2020 and December 31, 2019.

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Intangible Assets

Purchased intangible assets are recorded at fair value. The Company uses a discounted cash flow model to value intangible assets. The discounted cash flow model requires assumptions about the timing and amount of future net cash flows, risk, the cost of capital, terminal values and market participants.

Patent costs are capitalized as incurred, only if the Company determines that there is some probable future economic benefit derived from the transaction. A capitalized patent is amortized over its estimated useful life, beginning when such patent is approved. Capitalized patent costs are expensed upon disapproval, upon a decision by the Company to no longer pursue the patent or when the related intellectual property is either sold or deemed to be no longer of value to the Company. The Company determined that all patent costs incurred during the three and nine months ended September 30, 2020 and 2019 should be expensed and not capitalized as the future economic benefit derived from the patent costs incurred cannot be determined.

Acquired In-process Research and Development (IPR&D)

Acquired IPR&D represents the fair value assigned to research and development assets that have not reached technological feasibility. The value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenues from the projects and discounting the net cash flows to present value. The revenues and cost projections used to value acquired IPR&D are, as applicable, reduced based on the probability of success. IPR&D projects acquired in a business combination that are not complete are capitalized and accounted for as indefinite-lived intangible assets until completion or abandonment of the related R&D efforts. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If a project is abandoned, all remaining capitalized amounts are written off immediately. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market the resulting products. Such approvals require completing clinical trials that demonstrate the products effectiveness. Consequently, the eventual realized value of the IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods.

Capitalized IPR&D projects are tested for impairment annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The Company considers various factors for potential impairment, including the current legal and regulatory environment, current and future strategic initiatives and the competitive landscape. Adverse clinical trial results, significant delays in obtaining marketing approval, the inability to bring a product to market and the introduction or advancement of competitors' products could result in partial or full impairment of the related intangible assets.

Goodwill

The Company evaluates goodwill for possible impairment in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 350 on an annual basis during the fourth quarter, or more frequently if events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Qualitative factors considered in this assessment include industry and market conditions, overall financial performance, and other relevant events and factors affecting the Company's business. Based on the qualitative assessment, if it is determined that the fair value of goodwill is more likely than not to be less than its carrying amount, the fair value of a reporting unit will be calculated and compared with its carrying amount and an impairment charge will be recognized for the amount that the carrying value exceeds the fair value.

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Impairment of Long-Lived Assets

The Company evaluates the fair value of long-lived assets, which include property, plant and equipment, finite-lived 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. Refer to Note 5 for discussion of the impairment charges recorded during the nine months ended September 30, 2020.

Fair Value Measurements

The FASB has issued authoritative guidance that requires fair value to be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under that standard, fair value measurements are separately disclosed by level within the fair value hierarchy. The fair value hierarchy establishes and prioritizes the inputs used to measure fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs. Observable inputs are inputs that reflect the assumptions that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

Convertible Notes

The Company accounts for convertible notes that may be settled in cash or equity upon conversion by separating the liability and equity components of the instruments in a manner that reflects the Company's nonconvertible debt borrowing rate. The Company determines the carrying amount of the liability component of the convertible notes by using assumptions that market participants would use in pricing a debt instrument, including market interest rates, credit standing, yield curves and volatilities. Determining the fair value of the debt component requires the use of accounting estimates and assumptions. These estimates and assumptions are judgmental in nature and could have a significant impact on the determination of the debt component, and the associated non-cash interest expense.

Leases

The Company acts as lessee in its lease agreements, which include operating leases for corporate offices, laboratory space, warehouse space, vehicles and certain laboratory and office equipment, and finance leases for certain equipment and vehicles.

The Company determines whether an arrangement is, or contains, a lease at inception. At the beginning of fiscal year 2019, the company adopted ASC Topic 842. The Company records the present value of lease payments as right-of-use ("ROU") assets and lease liabilities on the condensed consolidated balance sheets. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments based on the present value of lease payments over the lease term. Classification of lease liabilities as either current or non-current is based on the expected timing of payments due under the Company's obligations.

As most of the Company's leases do not provide an implicit interest rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The incremental borrowing rate is the rate of interest that a lessee would have to pay to borrow on a collateralized basis over a similar term and at an amount equal to the lease payments in a similar economic environment. In order to determine the appropriate incremental borrowing rates, the Company has used a number of factors including the credit rating, and the lease term. Certain vehicle leases include variable lease payments that depend on an index or rate. Those lease payments are initially measured using the index or rate at the lease commencement date.

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The ROU asset also consists of any lease incentives received. The lease terms used to calculate the ROU asset and related lease liability include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. “Reasonably certain” is assessed internally based on economic, industry, company, strategic and contractual factors. The leases have remaining lease terms of 1 year to 15 years, some of which include options to extend the lease for up to 10 years, and some of which include options to terminate the lease within 1 year. Operating lease expense and amortization of finance lease ROU assets are recognized on a straight-line basis over the lease term as an operating expense. Finance lease interest expense is recorded as interest expense on the Company’s condensed consolidated statements of operations.

The Company accounts for leases acquired in business combinations by measuring the lease liability at the present value of the remaining lease payments as if the acquired lease were a new lease for the Company. This measurement includes recognition of a lease intangible for any below-market terms present in the leases acquired. The below-market lease intangible is included in the ROU asset on the condensed consolidated balance sheets and are amortized over the remaining lease term. The Company has not acquired any leases with above-market terms.

The Company has taken advantage of certain practical expedients offered to registrants at adoption of ASC 842. The Company does not apply the recognition requirements of ASC 842 to short-term leases. Instead, those lease payments are recognized in profit or loss on a straight-line basis over the lease term. Further, as a practical expedient, all lease contracts are accounted for as one single lease component, as opposed to separating lease and non-lease components to allocate the consideration within a single lease contract.

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)	September 30,	
	2020	2019
Shares issuable in connection with acquisitions	157	—
Shares issuable upon exercise of stock options	2,429	2,199
Shares issuable upon the release of restricted stock awards	4,654	3,902
Shares issuable upon conversion of convertible notes	20,309	12,197
	<u>27,549</u>	<u>18,298</u>

Accounting for Stock-Based Compensation

The Company requires all share-based payments to employees, including grants of employee stock options, restricted stock, restricted stock units and shares purchased under an employee stock purchase plan (if certain parameters are not met), to be recognized in the financial statements based on their grant date fair values. Forfeitures of any share-based awards are recognized as they occur.

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Revenue Recognition

Revenues are recognized when the satisfaction of the performance obligation occurs, in an amount that reflects the consideration the Company expects to collect in exchange for those services. To determine revenue recognition for the arrangements that the Company determines are within the scope of FASB ASC Topic 606, Revenue from Contracts with Customers, the Company performs the following five steps: (1) identify the contract(s) with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when (or as) the entity satisfies a performance obligation. See Note 2 for further discussion.

Foreign Currency Transactions

Prior to 2019, the Company's international subsidiaries' functional currency was the local currency and assets and liabilities were translated into U.S. dollars at the period-end exchange rate or historical rates, as appropriate. Condensed consolidated statements of operations were translated at average exchange rates for the period, and the cumulative translation adjustments resulting from changes in exchange rates were included in the Company's condensed consolidated balance sheet as a component of additional paid-in capital. In 2019 and 2020, the Company's international subsidiaries use the U.S. dollar as the functional currency, resulting in the Company not being subject to gains and losses from foreign currency translation of the subsidiary financial statements. The Company recognizes gains and losses from foreign currency transactions in the condensed consolidated statements of operations. Net foreign currency transaction gains or losses were not material to the condensed consolidated statements of operations for the periods presented.

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 including the amortization of acquired intangible assets, which is now presented as a separate line item on the Company's condensed consolidated statements of operations and was previously included in cost of sales, research and development, and general and administrative expenses. Due to these reclassifications, the Company is no longer presenting gross margin on the Company's condensed consolidated statements of operations.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The updated guidance requires companies to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets, including trade receivables. The updates also require available-for-sale debt security credit losses to be recognized as allowances rather than a reduction in amortized cost. The guidance was adopted by the Company on January 1, 2020. The requirements of the ASU did not result in the recognition of a material allowance for current expected credit losses, as the Company's analysis of collectability looks at historical experience as well as current and future implications surrounding the ability to collect. Adoption of the updated guidance did not have a material impact on the Company's condensed consolidated financial statements.

In April 2019, the FASB issued ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments –Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*. The updated guidance provides clarity regarding measurement of securities without readily determinable fair values. The guidance was adopted on January 1, 2020 and did not have a material impact on the Company's condensed consolidated financial statements.

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In August 2018, the FASB issued ASU 2018-15, *Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40)*. The update provided guidance for evaluating the accounting for fees paid by a customer in a cloud computing arrangement that is a service contract. The guidance was adopted on a prospective basis, beginning on January 1, 2020 and it did not have a material impact on the Company's condensed consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820); Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. The guidance provided an update to the disclosure requirements for fair value measurements under the scope of ASC 820. The updates were adopted on January 1, 2020 and did not have a material impact on the Company's condensed consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808)*. The update provided additional guidance regarding the interaction between Topic 808 on Collaborative Arrangements and Topic 606 on Revenue Recognition. The guidance was adopted on January 1, 2020 and did not have a material impact on the Company's condensed consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The update simplifies the accounting for income taxes through removing exceptions related to certain intraperiod allocations and deferred tax liabilities; clarifying guidance primarily related to evaluating the step-up tax basis for goodwill in a business combination; and reflecting enacted changes in tax laws or rates in the annual effective tax rate. The amended guidance is effective for interim and annual periods in 2021, however early adoption is permitted. The guidance was early adopted on January 1, 2020 and did not have a material impact on the Company's condensed consolidated financial statements.

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*. The updated guidance provides optional expedients for applying the requirements of certain topics in the codification for contracts that are modified because of reference rate reform. In addition to the optional expedients, the update includes a general principle that permits an entity to consider contract modifications due to reference rate reform to be an event that does not require contract remeasurement at the modification date or reassessment of a previous accounting determination. The updated guidance is effective for all entities as of March 12, 2020 and through December 31, 2022. The Company adopted the guidance upon issuance on March 12, 2020. There was no impact on the Company's condensed consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In August 2020, The Financial Accounting Standards Board issued 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, the new guidance modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the computation of diluted EPS. 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 is currently evaluating the impact of this guidance on its consolidated financial statements.

(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.

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The core principle of ASC 606 is that the Company recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to collect in exchange for those goods or services. The Company recognizes revenues from its products in accordance with that core principle, and key aspects considered by the Company include the following:

Contracts

The Company's customer is primarily the patient, but the Company does not enter into a formal reimbursement contract with a patient. The Company establishes a contract with a patient in accordance with other customary business practices which is the point in time an order is received from a provider and a patient specimen has been returned to the laboratory for testing. Payment terms are a function of a patient's existing insurance benefits, including the impact of coverage decisions with Center for Medicare & Medicaid Services ("CMS") and applicable reimbursement contracts established between the Company and payers. However, when an order is received for a patient with no active insurance or insurance that does not cover the Company's testing services, the Company requires payment from the patient prior to the commencement of the Company's performance obligations. The Company's consideration can be deemed variable or fixed depending on the structure of specific payer contracts, and the Company considers collection of such consideration to be probable to the extent that it is unconstrained.

Under the Company's Laboratory Service Agreements ("LSA") and Laboratory Reference Agreements ("LRA") the Company contracts with a direct bill payer who is the customer for an agreed upon amount of laboratory testing services for a specified amount of time at a fixed reimbursement rate, and certain of the Company's LSAs obligate the customer to pay for testing services prior to result.

Performance obligations

A performance obligation is a promise in a contract to transfer a distinct good or service (or a bundle of goods or services) to the customer. The Company's contracts have a single performance obligation, which is satisfied upon rendering of services, which culminates in the release of a patient's test result to the ordering healthcare provider. Or, in the context of some of the Company's LSAs, the satisfaction of the performance obligation occurs when a specimen sample is not returned to the laboratory for processing before the end of the allotted testing window. The Company elects the practical expedient related to the disclosure of unsatisfied performance obligations, as the duration of time between providing testing supplies, the receipt of a specimen sample, and the release of a test result to the ordering healthcare provider is far less than one year.

Transaction price

The transaction price is the amount of consideration that the Company expects to collect in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration expected to be collected from a contract with a customer may include fixed amounts, variable amounts, or both.

Fixed consideration is derived from the Company's LSA, LRA, and direct bill payer contracts that exist between the Company and the direct bill payers who assume the downstream patient billing. The contracted reimbursement rate is deemed to be fixed as the Company expects to fully collect all amounts billed under these relationships. Variable consideration is primarily derived from third party and patient billing and can result due to several factors such as the amount of contractual adjustments, any patient co-payments, deductibles or patient adherence incentives, the existence of secondary payers, and claim denials.

The Company estimates the amount of variable consideration using the expected value method, which represents the sum of probability-weighted amounts in a range of possible consideration amounts. When estimating the amount of variable consideration, the Company considers several factors, such as historical collections experience, patient insurance eligibility and payer reimbursement contracts.

The Company limits the amount of variable consideration included in the transaction price to the unconstrained portion of such consideration. In other words, the Company recognizes revenue up to the amount of variable

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consideration that is not subject to a significant reversal until additional information is obtained or the uncertainty associated with the additional payments or refunds is subsequently resolved. Differences between original estimates and subsequent revisions, including final settlements, represent changes in the estimate of variable consideration and are included in the period in which such revisions are made. Revenue recognized from changes in transaction prices was \$0.5 million and \$1.2 million for the three months ended September 30, 2020 and 2019, respectively. Revenue recognized from changes in transaction prices was \$9.1 million and \$4.6 million for the nine months ended September 30, 2020 and 2019, respectively.

The Company monitors its estimates of transaction price to depict conditions that exist at each reporting date. If the Company subsequently determines that it will collect more or less consideration than it originally estimated for a contract with a patient, it will account for the change as an increase or decrease in the estimate of the transaction price (i.e., an upward or downward revenue adjustment) in the period identified.

When the Company does not have significant historical experience or that experience has limited predictive value, the constraint over estimates of variable consideration may result in no revenue being recognized upon release of the performance obligations associated with the Company's tests, with recognition, generally occurring at the date of cash receipt.

Allocate transaction price

The transaction price is allocated entirely to the performance obligation contained within the contract with a customer.

Point in time recognition

The Company's single performance obligation is satisfied at a point in time. That point in time is defined as the date the Company releases a result to the ordering healthcare provider, or, in the context of some of the Company's LSAs, that point in time could be the date the allotted testing window ends if a specimen sample is not returned to the laboratory for processing. The point in time in which revenue is recognized by the Company signifies fulfillment of the performance obligation to the patient or direct bill payer.

Disaggregation of Revenue

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Screening				
Medicare Parts B & C	\$ 98,847	\$ 108,617	\$ 256,589	\$ 295,103
Commercial	106,002	99,352	280,451	261,521
Other	9,774	10,836	28,367	24,094
Total Screening	214,623	218,805	565,407	580,718
Precision Oncology				
Medicare Parts B & C	\$ 33,945	\$ —	\$ 114,973	\$ —
Commercial	37,402	—	137,212	—
International	16,243	—	56,227	—
Other	3,989	—	14,493	—
Total Precision Oncology	91,579	—	322,905	—
COVID-19 Testing	\$ 102,161	\$ —	\$ 136,740	\$ —
Total	\$ 408,363	\$ 218,805	\$ 1,025,052	\$ 580,718

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

Contract Balances

The timing of revenue recognition, billings and cash collections results in billed accounts receivable and deferred revenue on the condensed consolidated balance sheets. Generally, billing occurs subsequent to the release of a patient's test result to the ordering healthcare provider, resulting in an account receivable. However, the Company sometimes receives advance payment from a patient or a direct bill payer before a test result is completed, resulting in deferred revenue. The deferred revenue recorded is recognized as revenue at the point in time results are released to the patient's healthcare provider. Or, in the context of some of the Company's LSAs, the satisfaction of the performance obligation occurs when a specimen sample is not returned to the laboratory for processing before the end of the allotted testing window.

Deferred revenue balances are reported in other current liabilities in the Company's condensed consolidated balance sheets and were \$22.4 million and \$0.6 million as of September 30, 2020 and December 31, 2019, respectively. As of September 30, 2020, \$21.8 million of the Company's deferred revenue balance is a result of the billing terms pursuant to the existing COVID-19 LSAs with customers.

Revenue recognized for the three months ended September 30, 2020 and 2019, which was included in the deferred revenue balance at the beginning of each period was \$5,000 and \$0.2 million, respectively. Revenue recognized for the nine months ended September 30, 2020 and 2019, which was included in the deferred revenue balance at the beginning of each period was \$0.2 million and \$0.5 million, respectively.

Practical Expedients

The Company does not adjust the transaction price for the effects of a significant financing component, as at contract inception, the Company expects the collection cycle to be one year or less.

The Company expenses sales commissions when incurred because the amortization period would have been one year or less. These costs are recorded within sales and marketing expenses in the Company's condensed consolidated statements of operations.

The Company incurs certain other costs that are incurred regardless of whether a contract is obtained. Such costs are primarily related to legal services and patient communications (e.g. adherence reminder letters). These costs are expensed as incurred and recorded within general and administrative expenses in the Company's condensed consolidated statements of operations.

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(3) MARKETABLE SECURITIES

The following table sets forth the Company's cash, cash equivalents, restricted cash, and marketable securities at September 30, 2020 and December 31, 2019:

(In thousands)	September 30, 2020	December 31, 2019
Cash, cash equivalents, and restricted cash		
Cash and money market	\$ 456,701	\$ 146,932
Cash equivalents	349,977	30,322
Restricted cash (1)	291	274
Total cash, cash equivalents, and restricted cash	806,969	177,528
Marketable securities		
Available-for-sale debt securities	474,906	144,685
Equity securities	1,418	1,716
Total marketable securities	476,324	146,401
Total cash and cash equivalents, restricted cash and marketable securities	\$ 1,283,293	\$ 323,929

(1) Restricted cash is included in other long-term assets on the condensed consolidated balance sheets. There was no restricted cash at September 30, 2019.

Available-for-sale debt securities at September 30, 2020 consisted of the following:

(In thousands)	Amortized Cost	Gains in Accumulated Other Comprehensive Income (Loss)	Losses in Accumulated Other Comprehensive Income (Loss)	Estimated Fair Value
Cash equivalents				
U.S. government agency securities	\$ 349,975	\$ 2	\$ —	\$ 349,977
Total cash equivalents	349,975	2	—	349,977
Marketable securities				
Corporate bonds	191,651	970	—	192,621
U.S. government agency securities	257,102	60	—	257,162
Certificates of deposit	10,000	1	—	10,001
Asset backed securities	15,071	51	—	15,122
Total marketable securities	473,824	1,082	—	474,906
Total available-for-sale securities	\$ 823,799	\$ 1,084	\$ —	\$ 824,883

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Available-for-sale debt securities at December 31, 2019 consisted of the following:

(In thousands)	Amortized Cost	Gains in Accumulated Other Comprehensive Income (Loss)	Losses in Accumulated Other Comprehensive Income (Loss)	Estimated Fair Value
Cash equivalents				
U.S. government agency securities	\$ 30,320	\$ 2	\$ —	\$ 30,322
Total cash equivalents	30,320	2	—	30,322
Marketable securities				
U.S. government agency securities	140,745	10	(73)	140,682
Corporate bonds	4,017	—	(14)	4,003
Total marketable securities	144,762	10	(87)	144,685
Total available-for-sale securities	\$ 175,082	\$ 12	\$ (87)	\$ 175,007

The following table summarizes contractual underlying maturities of the Company's available-for-sale debt securities at September 30, 2020:

(In thousands)	Due one year or less		Due after one year through four years	
	Cost	Fair Value	Cost	Fair Value
Cash equivalents				
U.S. government agency securities	\$ 349,975	\$ 349,977	\$ —	\$ —
Total cash equivalents	349,975	349,977	—	—
Marketable securities				
U.S. government agency securities	249,943	249,949	7,159	7,213
Corporate bonds	148,903	149,409	42,748	43,212
Certificates of deposit	10,000	10,001	—	—
Asset backed securities	—	—	15,071	15,122
Total marketable securities	408,846	409,359	64,978	65,547
Total	\$ 758,821	\$ 759,336	\$ 64,978	\$ 65,547

The following table summarizes the gross unrealized losses and fair values of available-for-sale debt securities in an unrealized loss position as of September 30, 2020, 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 (1)
Cash equivalents						
U.S. government agency securities	\$ 49,996	\$ —	\$ —	\$ —	\$ 49,996	\$ —
Total cash equivalents	49,996	—	—	—	49,996	—
Marketable securities						
U.S. government agency securities	24,994	—	—	—	24,994	—
Total marketable securities	24,994	—	—	—	24,994	—
Total available-for-sale securities	\$ 74,990	\$ —	\$ —	\$ —	\$ 74,990	\$ —

(1) Available-for-sale debt securities in an unrealized loss position are insignificant as of September 30, 2020.

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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 September 30, 2020 and December 31, 2019 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 Company recorded a realized gain on available-for-sale debt securities of \$1,000 and \$3.1 million for the three months ended September 30, 2020 and 2019, respectively, net of insignificant realized losses. The Company recorded a realized gain on available-for-sale debt securities of \$0.1 million and \$3.3 million for the nine months ended September 30, 2020 and 2019, respectively, net of insignificant realized losses.

The Company recorded a gain of \$33,000 and a loss of \$0.3 million from its equity securities for the three and nine months ended September 30, 2020 as compared to no gain or loss for the three and nine months ended September 30, 2019.

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

(4) PROPERTY, PLANT AND EQUIPMENT

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

(In thousands)	Estimated Useful Life	September 30, 2020	December 31, 2019
Property, plant and equipment			
Land	n/a	\$ 4,466	\$ 4,466
Leasehold and building improvements	(1)	113,153	80,352
Land improvements	15 years	3,222	1,766
Buildings	30 - 40 years	200,141	112,815
Computer equipment and computer software	3 years	78,350	65,323
Laboratory equipment	3 - 10 years	136,462	104,008
Furniture and fixtures	3 - 10 years	23,950	14,539
Assets under construction	n/a	26,472	149,687
Property, plant and equipment, at cost		586,216	532,956
Accumulated depreciation		(129,761)	(77,631)
Property, plant and equipment, net		<u>\$ 456,455</u>	<u>\$ 455,325</u>

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

Depreciation expense for the three months ended September 30, 2020 and 2019 was \$19.5 million and \$8.4 million, respectively. Depreciation expense for the nine months ended September 30, 2020 and 2019 was \$52.9 million and \$21.8 million, respectively.

At September 30, 2020, the Company had \$26.5 million of assets under construction which consisted of \$9.7 million in laboratory equipment, \$8.4 million of building and leasehold improvements, \$7.9 million in capitalized costs related to software projects, and \$0.5 million related to furniture and fixtures. Depreciation will begin on these assets once they are placed into service. The Company expects to incur an additional \$2.0 million to complete the laboratory equipment, \$13.3 million to complete the building projects and leasehold improvements, \$3.6 million to complete the software projects, and minimal costs to complete the furniture and fixtures. These projects are expected to be completed throughout 2020 and 2021.

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(5) 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 September 30, 2020:

(In thousands)	Weighted Average Remaining Life (Years)	Cost	Accumulated Amortization	Net Balance at September 30, 2020
Finite-lived intangible assets				
Trade name	15.2	\$ 100,700	\$ (5,683)	\$ 95,017
Customer relationships	13.1	2,700	(359)	2,341
Patents	4.0	10,441	(5,089)	5,352
Acquired developed technology	9.2	814,171	(73,022)	741,149
Supply agreements	6.8	30,000	(3,538)	26,462
Internally developed technology	2.4	1,883	(750)	1,133
Total finite-lived intangible assets		959,895	(88,441)	871,454
Internally developed technology in process	n/a	206	—	206
Total intangible assets		\$ 960,101	\$ (88,441)	\$ 871,660

The following table summarizes the net-book-value and estimated remaining life of the Company's intangible assets as of December 31, 2019:

(In thousands)	Weighted Average Remaining Life (Years)	Cost	Accumulated Amortization	Net Balance at December 31, 2019
Finite-lived intangible assets				
Trade name	15.9	\$ 100,700	\$ (961)	\$ 99,739
Customer relationships	13.6	2,700	(224)	2,476
Patents	8.8	22,690	(5,974)	16,716
Acquired developed technology	9.9	806,371	(12,345)	794,026
Supply agreements	7.5	30,000	(571)	29,429
Internally developed technology	2.5	1,229	(336)	893
Total finite-lived intangible assets		963,690	(20,411)	943,279
In-process research and development	n/a	200,000	—	200,000
Internally developed technology in process	n/a	271	—	271
Total intangible assets		\$ 1,163,961	\$ (20,411)	\$ 1,143,550

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As of September 30, 2020, 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)	
2020	\$ 23,357
2021	93,322
2022	93,116
2023	92,812
2024	92,421
Thereafter	476,426
	<u>\$ 871,454</u>

The Company's acquired intangible assets are being amortized on a straight-line basis over the estimated useful life. The amortization expense recorded from these intangible assets is reported in amortization of acquired intangible assets on the condensed consolidated statements of operations.

During the third quarter of 2020, the Company began discussions with Biocartis regarding the termination of its agreements with Biocartis related to the development of an in vitro diagnostic ("IVD") version of the Oncotype DX Breast Recurrence Score test. As a result, and in connection with the preparation of the financial statements, the Company recorded a non-cash, pre-tax impairment loss of \$200.0 million related to the in-process research and development intangible asset that was initially recorded as part of the combination with Genomic Health. The impairment is recorded in intangible asset impairment charge in the condensed consolidated statement of operations for the three and nine months ended September 30, 2020. See Note 7 for additional information on Biocartis.

During the third quarter of 2020, the Company abandoned certain research and development assets acquired through an asset purchase agreement with Armune Biosciences, Inc. in 2017. These assets were expected to complement the Company's product pipeline and were expected to have alternative future uses at the time of acquisition; however, due to changes in strategic priorities and efforts during the third quarter of 2020, these assets are no longer expected to be utilized to advance the Company's product pipeline. As a result, and in connection with the preparation of the financial statements, the Company wrote-off the gross cost basis of the intangible asset of \$12.2 million and accumulated amortization of \$2.5 million as of September 30, 2020. This write-off resulted in a non-cash, pre-tax impairment loss of \$9.7 million, which is recorded in intangible asset impairment charge in the condensed consolidated statement of operations for the three and nine months ended September 30, 2020.

There were no impairment losses for the three and nine months ended September 30, 2019.

Goodwill

As a result of the acquisition of Paradigm Diagnostics, Inc. ("Paradigm") and Viomics, Inc. ("Viomics") in March 2020, the Company recognized goodwill of \$30.4 million, which includes an immaterial post-acquisition adjustment to goodwill in the second quarter of 2020. Refer to the Company's 2019 10-K for further discussion on goodwill recorded from previous business combinations.

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The Company evaluates goodwill for possible impairment in accordance with ASC 350 on an annual basis during the fourth quarter, or more frequently if events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Qualitative factors considered in this assessment include industry and market conditions, overall financial performance, and other relevant events and factors affecting the Company's business. Based on the qualitative assessment, if it is determined that the fair value of goodwill is more likely than not to be less than its carrying amount, the fair value of a reporting unit will be calculated and compared with its carrying amount and an impairment charge will be recognized for the amount that the carrying value exceeds the fair value. Due to the impact of COVID-19 on the Company's operations, the Company performed a qualitative assessment of goodwill to determine if an event indicating impairment was present. No such indicators were identified as of September 30, 2020. There were no impairment losses for the periods ended September 30, 2020 and September 30, 2019. During the nine months ended September 30, 2020, the Company recognized a measurement period adjustment to goodwill of \$4.0 million related to an increase in Genomic Health's pre-acquisition deferred tax liability due to finalization of certain income-tax related items.

The change in the carrying amount of goodwill for the periods ended September 30, 2020 and December 31, 2019 is as follows:

(In thousands)	
Balance, January 1, 2019	\$ 17,279
Genomic Health acquisition	1,185,918
Balance, December 31, 2019	1,203,197
Paradigm & Viomics acquisition	30,431
Genomic Health acquisition adjustment	4,044
Balance, September 30, 2020	\$ 1,237,672

(6) 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.

The following table presents the Company's fair value measurements as of September 30, 2020 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall.

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(In thousands)	Fair Value at September 30, 2020	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	\$ 456,701	\$ 456,701	\$ —	\$ —
U.S. government agency securities	349,977	—	349,977	—
Restricted cash	291	291	—	—
Marketable securities				
Corporate bonds	192,621	—	192,621	—
U.S. government agency securities	257,162	—	257,162	—
Certificates of deposit	10,001	—	10,001	—
Asset backed securities	15,122	—	15,122	—
Equity Securities	1,418	1,418	—	—
Liabilities				
Contingent consideration	(2,638)	—	—	(2,638)
Total	\$ 1,280,655	\$ 458,410	\$ 824,883	\$ (2,638)

The following table presents the Company's fair value measurements as of December 31, 2019 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, 2019	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	\$ 146,932	\$ 146,932	\$ —	\$ —
U.S. government agency securities	30,322	—	30,322	—
Restricted cash	274	274	—	—
Marketable securities				
U.S. government agency securities	140,682	—	140,682	—
Corporate bonds	4,003	—	4,003	—
Equity securities	1,716	1,716	—	—
Liabilities				
Contingent consideration	(2,879)	—	—	(2,879)
Total	\$ 321,050	\$ 148,922	\$ 175,007	\$ (2,879)

There have been no changes in valuation techniques or transfers between fair value measurement levels during the periods ended September 30, 2020 and December 31, 2019. 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 is classified as a Level 1 instrument. See Note 7 for additional information on Biocartis.

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Contingent Consideration

In connection with the Biomatrix Acquisition, a contingent earn-out liability was created to account for an additional \$20.0 million in contingent consideration that could be earned based upon certain revenue milestones being met. The following table provides a roll-forward of the fair values of the contingent consideration, which includes Level 3 measurements:

(In thousands)	Contingent consideration
Balance, January 1, 2020	\$ (2,879)
Changes in fair value	—
Gains (losses) recognized in earnings	—
Payments	241
Balance, September 30, 2020	\$ (2,638)

As of September 30, 2020, the fair value of the contingent earn-out liability is classified as a component of other long-term liabilities in the Company's condensed consolidated balance sheet.

This fair value measurement of contingent consideration related to the Biomatrix acquisition was categorized as a Level 3 liability, as the measurement amount is based primarily on significant inputs not observable in the market. The Company evaluates the fair value of expected contingent consideration and the corresponding liability each annual reporting period using the Monte Carlo Method, which is consistent with the initial measurement of the expected Biomatrix Acquisition earn-out liability. The Company estimates projections during the earn-out period utilizing various potential pay-out scenarios. Probabilities were applied to each potential scenario and the resulting values were discounted using a rate that considers weighted average cost of capital as well as a specific risk premium associated with the riskiness of the earn-out itself, the related projections, and the overall business.

Non-Marketable Equity Investment

The Company has non-marketable equity investments which are initially recorded at the estimated fair value based on observable transactions. The Company has concluded it is not a primary beneficiary with regards to these investments and does not have the ability to exercise significant influence over the investees and thus has not consolidated the investees pursuant to the requirements of ASC 810, Consolidation. The Company will continue to assess its investments and future commitments to the investees and to the extent its relationship with the investees change and whether such change may require consolidation of the investees in future periods. The Company remeasures the fair value only when an observable transaction occurs during the period that would suggest a change in the carrying value of the investment. As of September 30, 2020 and December 31, 2019, the Company had non-marketable equity investments of \$23.9 million and \$11.8 million, respectively, which are classified as a component of other long-term assets in the Company's condensed consolidated balance sheets. As of September 30, 2020, the balance primarily consists of the Company's preferred stock investments in 18,258,838 shares of Epic Sciences and 5,025,764 shares of Thrive Earlier Detection Corp. ("Thrive") of \$10.8 million and \$12.5 million, respectively. As of December 31, 2019, the balance consists of the Company's preferred stock investments in Epic Sciences and Thrive Earlier Detection Corp. ("Thrive") of \$10.8 million and \$1.0 million, respectively.

The Company purchased 4.0 million shares of Series B Preferred Stock of Thrive for \$10.0 million in July 2020. The Company previously held a \$1.0 million investment in the Series A Preferred Stock of Thrive, which does not have a readily determinable fair value and therefore, the Company elected the measurement alternative. The rights and obligations of the Series B Preferred Stock are generally the same as the Series A Preferred Stock previously held indicating that the transactions are identical or similar investments. As a result, the Company recorded an unrealized gain of \$1.5 million during the three months ended September 30, 2020 in investment income, net on the Company's condensed consolidated statement of operations to revalue the Company's initial investment to the value of the Series B Preferred Stock, which was the most recent observable transaction.

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There have been no other observable transactions during the three and nine months ended September 30, 2020 and 2019.

Fair Value of Long-Term Debt and Convertible Notes

The Company measures the fair value of its convertible notes and long-term debt for disclosure purposes. The following table summarizes the Company's outstanding convertible notes and long-term debt:

(In thousands)	September 30, 2020		December 31, 2019	
	Carrying Amount (1)	Fair Value	Carrying Amount (1)	Fair Value
2028 Convertible notes (2)	\$ 796,463	\$ 1,251,085	\$ —	\$ —
2027 Convertible notes (2)	506,294	881,631	483,909	843,741
2025 Convertible notes (2)	252,210	494,627	319,696	592,482
Construction loan (3)	23,962	23,962	24,866	24,866

- (1) The carrying amounts presented are net of debt discounts and debt issuance costs (see Note 12 and Note 15 of the condensed consolidated financial statements for further information).
- (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. A portion of the 2025 convertible notes were settled in 2020 resulting in a decrease in the liability.
- (3) The carrying amount of the construction loan approximates fair value due to the short-term nature 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 was due to payments made on the loan resulting in a decrease in the liability.

(7) 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 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.

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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 annual installments through 2024. The Company paid Mayo the first annual installment of \$1.3 million in the third quarter of 2020 and will make all subsequent annual payments in the first quarter of the year beginning in January 2021.

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 2037 (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 \$0.9 million and \$1.0 million for the three months ended September 30, 2020 and 2019, respectively. The Company incurred charges of \$2.8 million and \$3.6 million for the nine months ended September 30, 2020 and 2019, 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.

Epic Sciences

In June 2016, Genomic Health (now a wholly-owned subsidiary of the Company) entered into a collaboration agreement with Epic Sciences, which was superseded and replaced in March 2019 by a license agreement and laboratory services agreement with Epic Sciences, under which Genomic Health was granted exclusive distribution rights to commercialize Epic Sciences' AR-V7 Nucleus Detect test in the United States, which is marketed as Oncotype DX AR-V7 Nucleus Detect. The Company has primary responsibility, in accordance with applicable laws and regulations, for marketing and promoting the test, order fulfillment, billing and collections of receivables, claims appeals, customer support, and providing and maintaining order management systems for the test. Epic Sciences is responsible for performing all tests, performing studies including analytic and clinical validation studies, and seeking Medicare coverage and a Medicare payment rate from the CMS for the test. The license and laboratory service agreement has a term of ten years from June 2016, unless terminated earlier under certain circumstances. The Oncotype DX AR-V7 Nucleus Detect test became commercially available in February 2018. The Company recognizes revenues for the test performed under this arrangement and Epic Sciences receives a fee per test performed that represents the fair market value for the testing services they perform.

Biocartis N.V.

In September 2017, Genomic Health entered into an exclusive license and development agreement with Biocartis, a molecular diagnostics company based in Belgium, to develop and commercialize an IVD version of the Oncotype DX Breast Recurrence Score test on the Biocartis Idylla platform. Under the terms of the license and development agreement, the Company has an exclusive, worldwide, royalty-bearing license to develop and commercialize an IVD version of the Oncotype DX Breast Recurrence Score test on the Biocartis Idylla platform, and an option to expand the collaboration to include additional tests in oncology and urology. The Company has primary responsibility for developing, validating and obtaining regulatory authorizations and registrations for IVD Oncotype DX tests to be performed on the Idylla platform. The Company is also responsible for manufacturing and commercialization activities with respect to such tests.

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Pursuant to the license and development agreement, Genomic Health recorded a one-time upfront license and option fee of \$3.2 million. In December 2017, Genomic Health purchased 270,000 ordinary shares of Biocartis, a public company listed on the Euronext exchange, for a total cost of \$4.0 million. This investment was subject to a lock-up agreement that expired in December 2018. The investment has been recognized at fair value, which the Company estimated to be \$1.4 million and \$1.7 million as of September 30, 2020 and December 31, 2019, respectively, and is included in marketable securities on the Company's condensed consolidated balance sheets.

Under a November 2018 addendum to the license and development agreement, the Company exercised its option to expand the collaboration to include tests in urology and obtained a right of first refusal to add a test for the non-invasive detection of prostate cancer in a pre-biopsy setting.

Additional terms of the license and development agreement and the addendum include the Company's obligation to pay Biocartis (i) an aggregate of €2.5 million in cash upon achievement of certain milestones, (ii) €2.0 million for the expansion of the collaboration to include additional tests in oncology, and (iii) certain royalties based primarily on the future sales volumes of the Company's tests performed on the Idylla platform.

The Company is currently in discussions with Biocartis to terminate the agreements. The outcome of these discussions is not determinable at this time. Refer to Note 5 for further information regarding Biocartis.

(8) 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 Cologuard through a service fee, and provision of certain other sales and marketing services related to Cologuard. The Restated Promotion Agreement also includes additional fixed and performance-related fees, some of which retroactively go into effect on April 1, 2020. All payments to Pfizer are recorded in sales and marketing in the Company's condensed consolidated statements of operations. The Company incurred charges of \$15.8 million and \$15.8 million for promotion, sales and marketing services performed by Pfizer on behalf of the Company during the three months ended September 30, 2020 and 2019, respectively. The Company incurred charges of \$57.6 million and \$49.8 million for promotion, sales and marketing services performed by Pfizer on behalf of the Company during the nine months ended September 30, 2020 and 2019, respectively. Under the Original Promotion Agreement, the service fee was calculated based on incremental gross profits over specified baselines during the term. The Company incurred charges of \$16.0 million and \$54.5 million for this service fee during the three and nine months ended September 30, 2019. Under the Restated Promotion Agreement, the service fee was revised to a fee-for-service model, and includes certain fixed fees and performance-related bonuses. The Company incurred charges of \$18.0 million and \$37.5 million for the service fee during the three and nine months ended September 30, 2020. The Company will also pay Pfizer royalties for Cologuard related revenues over specified thresholds during the last year of the term of the Restated Promotion Agreement. The term of the Restated Promotion Agreement runs through December 31, 2022.

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(9) STOCKHOLDERS' EQUITY**Amendment to Certificate of Incorporation**

In July 2020, the Company filed a Certificate of Amendment (the "Certificate of Amendment") to its Sixth Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to increase the number of authorized shares of the Company's common stock from 200 million to 400 million shares. The Certificate of Amendment was approved by the Company's stockholders at the Company's 2020 annual meeting in July 2020.

Convertible Notes Settlement Stock Issuance

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 convertible notes. Refer to Note 15 for further discussion of this settlement transaction.

Genomic Health Combination Stock Issuance

In November 2019, the Company completed the combination with Genomic Health in a cash and stock transaction valued at \$2.5 billion. Of the \$2.5 billion purchase price, \$1.4 billion was settled through the issuance of 17.0 million shares of common stock. The Company incurred \$0.4 million in stock issuance costs as part of the transaction. Refer to Note 16 for further discussion of the consideration transferred as part of the combination with Genomic Health.

Paradigm and 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 valued at \$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 September 30, 2020, and the remainder was withheld and may become issuable as additional merger consideration on June 3, 2021 subject to the terms and conditions of the acquisition agreements.

Changes in Accumulated Other Comprehensive Income (Loss)

The amount recognized in accumulated other comprehensive income (loss) ("AOCI") for the nine months ended September 30, 2020 were as follows:

(In thousands)	Foreign Currency Translation Adjustments	Unrealized Gain (Loss) on Marketable Securities	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2019	\$ (25)	\$ (75)	\$ (100)
Other comprehensive income (loss) before reclassifications	—	1,159	1,159
Amounts reclassified from accumulated other comprehensive loss	25	—	25
Net current period change in accumulated other comprehensive loss	25	1,159	1,184
Balance at September 30, 2020	\$ —	\$ 1,084	\$ 1,084

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The amounts recognized in AOCI for the nine months ended September 30, 2019 were as follows:

(In thousands)	Foreign Currency Translation Adjustments	Unrealized Gain (Loss) on Marketable Securities	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2018	\$ (25)	\$ (1,397)	\$ (1,422)
Other comprehensive loss before reclassifications	—	815	815
Amounts reclassified from accumulated other comprehensive loss	—	616	616
Net current period change in accumulated other comprehensive loss, before tax	—	1,431	1,431
Income tax expense related to items of other comprehensive income	—	(341)	(341)
Balance at September 30, 2019	\$ (25)	\$ (307)	\$ (332)

Amounts reclassified from AOCI for the nine months ended September 30, 2020 and 2019 were as follows:

Details about AOCI Components (In thousands)	Affected Line Item in the Statements of Operations	Nine Months Ended September 30,	
		2020	2019
Change in value of available-for-sale investments			
Sales and maturities of available-for-sale investments	Investment income, net	\$ —	\$ 616
Foreign currency adjustment	General and administrative	25	—
Total reclassifications		\$ 25	\$ 616

(10) 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, the 2016 Inducement Award Plan and the 2000 Stock Option and Incentive 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 \$41.5 million and \$24.3 million in stock-based compensation expense during the three months ended September 30, 2020 and 2019, respectively. The Company recorded \$111.1 million and \$60.7 million in stock-based compensation expense during the nine months ended September 30, 2020 and 2019, respectively.

In February 2019, the Company issued performance-based equity awards to certain employees which vest upon the achievement of certain performance goals, including financial performance targets and operational milestones. Determining the appropriate amount to expense based on the anticipated achievement of the stated goals requires judgment, including forecasting future financial results. The estimate of the timing of the expense recognition is revised periodically based on the probability of achieving the goals and adjustments are made as appropriate. The cumulative impact of any revision is reflected in the period of the change. If the financial performance targets and operational milestones are not achieved, the award would not vest, so no compensation cost would be recognized and any previously recognized stock-based compensation expense would be reversed.

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In June 2020, the Company modified certain of the operational milestones within the outstanding performance-based equity awards, which were not deemed to have an impact on vesting and no incremental stock-based compensation expense was recorded for the three and nine months ended September 30, 2020. This modification impacted awards held by 36 employees.

In connection with the combination with Genomic Health, 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 and nine months ended September 30, 2020, the Company accelerated zero shares and 43,480 shares of previously unvested stock options, respectively, and 9,786 shares and 38,600 shares of previously unvested restricted stock units, respectively, and recognized the additional non-cash stock-based compensation expense of \$0.3 million and \$4.2 million, respectively, for the accelerated awards.

As a result of workforce reductions in April 2020 due to the COVID-19 pandemic, the Company accelerated the vesting of previously unvested stock options and restricted stock units for employees that were terminated. The Company accelerated 708 shares of previously unvested stock options and 33,123 shares of previously unvested restricted stock units, and recognized the additional non-cash stock-based compensation expense of \$1.8 million for the accelerated awards.

In connection with the termination in August 2020 of two former Genomic Health employees, the Company accelerated the vesting of 34,619 shares of previously unvested stock options and 6,836 shares of previously unvested restricted stock units as a result of the former employees experiencing a deemed “qualifying termination” under the terms of the merger agreement between the Company and Genomic Health. During the three months ended September 30, 2020, the Company recorded non-cash stock-based compensation of \$1.6 million for the accelerated awards. The previously unvested stock options and restricted stock units were converted awards held by the former employees prior to the combination with Genomic Health in November 2019.

In addition, the former employees held awards that were granted subsequent to the combination with Genomic Health that were modified as part of severance agreements with the Company to vest upon separation from service. The former employees will continue to provide consulting services to the Company for a fixed period, but those services were determined to be non-substantive, and therefore the unvested restricted stock units, excluding certain awards that were cancelled pursuant to the severance agreements, were fully expensed in the third quarter of 2020. 36,250 shares of previously unvested restricted stock units were expensed, and the Company recognized the additional non-cash stock-based compensation expense of \$2.4 million in the third quarter of 2020.

Determining Fair Value

Valuation and Recognition – The fair value of each service-based option award is estimated on the date of grant using the Black-Scholes option-pricing model. The fair value of service-based awards for each restricted stock unit award is determined on the date of grant using the closing stock price on that day. The estimated fair value of these awards is recognized to expense using the straight-line method over the vesting period. For awards that vest when a performance condition is achieved, the Company performs an evaluation of internal and external factors to determine the number of shares that are most likely to vest based on the probability of what performance conditions will be met. The Black-Scholes pricing model utilizes the following assumptions:

Expected Term – Expected life of an option award is the average length of time over which the Company expects employees will exercise their options, which is based on historical experience with similar grants. Expected life of a market measure-based award is based on the applicable performance period.

Expected Volatility - Expected volatility is based on the Company’s historical stock volatility data over the expected term of the awards.

Risk-Free Interest Rate - The Company bases the risk-free interest rate on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent expected term.

Forfeitures - The Company recognizes forfeitures as they occur.

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The fair value of each option is based on the assumptions in the following table:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Option Plan Shares				
Risk-free interest rates	(1)	(1)	0.11% - 1.47%	2.54% - 2.59%
Expected term (in years)	(1)	(1)	0.25 - 6.15	6.28
Expected volatility	(1)	(1)	44.19% - 77.51%	64.95% - 65.00%
Dividend yield	(1)	(1)	—%	—%
Weighted average fair value per share of options granted during the period	(1)	(1)	\$58.57	\$57.11
ESPP Shares				
Risk-free interest rates	(2)	(2)	0.12% - 0.2%	2.31% - 2.44%
Expected term (in years)	(2)	(2)	0.5 - 2	0.5 - 2
Expected volatility	(2)	(2)	63.7% - 89.0%	55.0% - 58.0%
Dividend yield	(2)	(2)	—%	—%
Weighted average fair value per share of stock purchase rights granted during the period	(2)	(2)	\$30.60	\$35.91

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

(2) The Company did not issue stock purchase rights under its 2010 Employee Stock Purchase Plan during the period indicated.

Stock Option, Restricted Stock, and Restricted Stock Unit Activity

A summary of stock option activity under the Stock Plans during the nine months ended September 30, 2020 is as follows:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term(Years)	Aggregate Intrinsic Value(1)
<i>(Aggregate intrinsic value in thousands)</i>				
Outstanding, January 1, 2020	2,700,293	\$ 34.01	6.7	
Granted	309,143	97.66		
Exercised	(509,335)	30.34		
Forfeited	(71,364)	82.76		
Outstanding, September 30, 2020	2,428,737	\$ 41.45	6.3	\$ 146,939
Exercisable, September 30, 2020	1,577,785	\$ 26.96	5.4	\$ 118,314

(1) The total intrinsic value of options exercised during the nine months ended September 30, 2020 and 2019 was \$29.0 million and \$41.7 million, respectively, determined as of the date of exercise.

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A summary of restricted stock and restricted stock unit activity under the Stock Plans during the nine months ended September 30, 2020 is as follows:

	Restricted Shares and RSUs	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2020	4,384,005	\$ 63.41
Granted	2,166,913	90.94
Released	(1,615,545)	48.97
Forfeited	(280,899)	80.67
Outstanding, September 30, 2020	4,654,474	\$ 80.10

As of September 30, 2020, there was \$285.2 million of 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 2.8 years.

(11) 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.

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.

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(12) 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.

As a condition to Fifth Third’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 September 30, 2020 and December 31, 2019, the outstanding balance was \$24.1 million and \$25.0 million, respectively, 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 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 September 30, 2020, 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.

By the end of 2019, the Company had earned and received payment of \$4.6 million from the City of Madison. As of September 30, 2020 and December 31, 2019, the Company has recorded a liability of \$ 0.3 million and \$2.7 million, respectively, in other current liabilities on the Company’s condensed consolidated balance sheets, reflecting when the expected benefit of the financial benefits amortization will reduce future operating expenses.

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(13) 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)	Nine Months Ended September 30, 2020	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 12,827	\$ 3,744
Operating cash flows from finance leases	125	—
Finance cash flows from finance leases	620	—
Non-cash investing and financing activities:		
Right-of-use assets obtained in exchange for new operating lease liabilities (1)	13,662	20,147
Right-of-use assets obtained in exchange for new finance lease liabilities	17,420	—

(1) For the nine months ended September 30, 2019, this includes right-of-use assets obtained from the initial adoption of ASC 842 of approximately \$17.9 million.

As of September 30, 2020 and December 31, 2019, the Company's right-of-use assets from operating leases are \$129.8 million and \$126.4 million, respectively, which are reported in operating lease right-of-use assets in the Company's condensed consolidated balance sheets. As of September 30, 2020, the Company has outstanding operating lease obligations of \$134.7 million, of which \$10.7 million is reported in operating lease liabilities, current portion and \$124.0 million is reported in operating lease liabilities, less current portion in the Company's condensed consolidated balance sheets. As of December 31, 2019, the Company had outstanding operating lease obligations of \$126.6 million, of which \$7.9 million is reported in operating lease liabilities, current portion and \$118.7 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. The Company's weighted average discount rate and weighted average lease term remaining on operating lease liabilities is approximately 6.83% and 8.95 years, respectively.

As of September 30, 2020 and December 31, 2019, the Company's right-of-use assets from finance leases are \$16.9 million and \$0.3 million, respectively, which are reported in other long-term assets, net in the Company's condensed consolidated balance sheets. As of September 30, 2020, the Company has outstanding finance lease obligations of \$16.9 million, of which \$4.0 million is reported in other current liabilities and \$12.9 million is reported in other long-term liabilities in the Company's condensed consolidated balance sheets. As of December 31, 2019, the Company had outstanding finance lease obligations of \$0.2 million, of which \$32,000 is reported in other current liabilities and \$0.2 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's weighted average discount rate and weighted average lease term remaining on finance lease liabilities is approximately 5.87% and 3.86 years, respectively.

Legal Matters

The Company is currently responding to civil investigative demands initiated by the United States Department of Justice ("DOJ") concerning (1) Genomic Health's compliance with the Medicare Date of Service billing regulations and (2) allegations that the Company offered or gave gift cards to patients in exchange for returning the Cologuard screening test, in violation of the Federal Anti-Kickback Statute and False Claims Act. The Company has

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been cooperating with these inquires and has produced documents in response thereto. Adverse outcomes from these investigations 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 and adversely affect the Company's business, financial condition and results of operation.

The DOJ's investigations are still in process and the scope and outcome of the investigations is not determinable at this time. Refer to the Company's 2019 Form 10-K for additional information on the Company's fair value determination of the pre-acquisition loss contingency related to the Genomic Health investigation. There can be no assurance that any settlement, resolution, or other outcome of these matters during any subsequent reporting period will not have a material adverse effect on the Company's results of operations or cash flows for that period or on the Company's financial position.

(14) 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 September 30, 2020, the Company has earned all \$9.0 million of the refundable tax credits and has received payment of \$5.9 million from the WEDC. The unpaid portion is \$3.1 million, of which \$1.6 million is reported in prepaid expenses and other current assets and \$1.5 million is reported in other long-term assets, reflecting when collection of the refundable tax credits is expected to occur. As of September 30, 2020, the Company also has recorded a \$0.5 million liability in other current liabilities, which reflects when the expected benefit of the tax credit amortization will reduce future operating expenses.

During the three and nine months ended September 30, 2020, the Company amortized \$0.6 million and \$1.7 million, respectively, of the tax credits earned as a reduction of operating expenses. During the three and nine months ended September 30, 2019, the Company amortized \$0.6 million and \$1.8 million, respectively, of the tax credits earned as a reduction of operating expenses.

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(15) CONVERTIBLE NOTES

Convertible note obligations included in the condensed consolidated balance sheets consisted of the following:

(In thousands)	Coupon Interest Rate	Effective Interest Rate	Fair Value of Liability Component at Issuance (1)	September 30, 2020	December 31, 2019
2028 Convertible notes	0.375%	5.2%	\$ 790,608	\$ 1,150,000	\$ —
2027 Convertible notes	0.375%	6.3%	472,501	747,500	747,500
2025 Convertible notes	1.000%	6.0%	227,103	315,049	415,049
Total Convertible notes				2,212,549	1,162,549
Less: Debt discount (2)				(628,820)	(342,463)
Less: Debt issuance costs (3)				(28,762)	(16,481)
Net convertible debt				\$ 1,554,967	\$ 803,605

(1) As each of the convertible instruments may be settled in cash upon conversion, for accounting purposes, they were separated into a liability component and an equity component. The amount allocated to the equity component is the difference between the principal value of the instrument and the fair value of the liability component at issuance. The resulting debt discount is being amortized to interest expense at the respective effective interest rate over the contractual term of the debt. A portion of the 2025 Convertible Notes have been extinguished or converted. The fair value of the liability component at issuance reflected above represents the liability value at issuance for the applicable portion of the 2025 Notes which remain outstanding at September 30, 2020. The fair value of the liability component of the 2025 Notes at issuance was \$654.8 million with the equity component being \$267.9 million.

(2) The unamortized discount consists of the following:

(In thousands)	September 30, 2020	December 31, 2019
2028 Convertible notes	\$ 337,968	\$ —
2027 Convertible notes	232,038	253,340
2025 Convertible notes	58,814	89,123
Total unamortized discount	\$ 628,820	\$ 342,463

(3) Debt issuance costs consists of the following:

(In thousands)	September 30, 2020	December 31, 2019
2028 Convertible notes	\$ 15,569	\$ —
2027 Convertible notes	9,168	10,251
2025 Convertible notes	4,025	6,230
Total debt issuance costs	\$ 28,762	\$ 16,481

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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 will be 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 \$375.0 million was allocated to the liability component, \$300.8 million was allocated to the equity component, and \$0.7 million was used to pay off interest accrued on the 2025 Notes. The consideration transferred was allocated to the liability and equity components of the 2025 Notes using the equivalent rate that reflected the borrowing rate for a similar non-convertible debt instrument immediately prior to settlement. The transaction resulted in a loss on settlement of convertible notes of \$10.6 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 liability component and (ii) the sum of the carrying value of the debt component and any unamortized debt issuance costs at the time of repurchase.

In February 2020, the Company issued and sold \$1,150.0 million 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 \$1,125.6 million, after deducting underwriting discounts and commissions and the offering expenses payable by the Company.

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 \$85.5 million was allocated to the liability component, \$64.2 million, net of a tax impact of \$0.3 million, was allocated to the equity component, and \$0.1 million was used to pay off interest accrued on the 2025 Notes. The consideration transferred was allocated to the liability and equity components of the 2025 Notes using the equivalent rate that reflected the borrowing rate for a similar non-convertible debt instrument immediately prior to settlement. The transaction resulted in a loss on settlement of convertible notes of \$8.0 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 liability component and (ii) the sum of the carrying value of the debt component and any unamortized debt issuance costs at the time of repurchase.

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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. 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. 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.

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 conversion rate is subject to adjustment upon the occurrence of certain specified events 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 our common stock of \$101.95 on September 30, 2020, the if-converted values on our 2025 Notes exceed the principal amount by \$110.8 million and the 2027 Notes and 2028 Notes do not exceed the principal amount.

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; equal in right of payment to all of the Company's future liabilities that are not so subordinated, unsecured indebtedness; (ii) are effectively junior to all of our 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 (iii) are structurally subordinated to all indebtedness and other liabilities of the Company's subsidiaries.

While the Notes are currently classified on the Company's condensed consolidated balance sheets at September 30, 2020 as long-term, the future convertibility and resulting balance sheet classification of this liability will be monitored at each quarterly reporting date and will be analyzed dependent upon market prices of the Company's common stock during the prescribed measurement periods. In the event that the holders of the Notes have the election to convert the Notes at any time during the prescribed measurement period, the Notes would then be considered a current obligation and classified as such.

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The Company allocates total transaction costs of the Notes to the liability and equity components based on their relative values. Transaction costs attributable to the liability component are amortized to interest expense over the term of the Notes, and transaction costs attributable to the equity component are netted with the equity component in stockholders' equity. The following table summarizes the original transaction costs at the time of issuance for each set of Notes and the respective allocation to the liability and equity components:

(In thousands)	January 2025 Notes	June 2025 Notes	2027 Notes	2028 Notes
Transaction costs allocated to:				
Liability component	\$ 13,569	\$ 5,052	\$ 11,395	\$ 16,811
Equity component	5,340	2,311	6,632	7,642
Total transaction costs	<u>\$ 18,909</u>	<u>\$ 7,363</u>	<u>\$ 18,027</u>	<u>\$ 24,453</u>

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.

Interest expense includes the following:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Debt issuance costs amortization	\$ 1,123	\$ 658	\$ 3,084	\$ 1,989
Debt discount amortization	19,461	10,322	52,138	28,789
Loss on settlement of convertible notes	—	—	7,954	10,558
Coupon interest expense	2,567	1,739	7,065	5,585
Total interest expense on convertible notes	<u>23,151</u>	<u>12,719</u>	<u>70,241</u>	<u>46,921</u>
Other interest expense	431	490	1,406	990
Total interest expense	<u>\$ 23,582</u>	<u>\$ 13,209</u>	<u>\$ 71,647</u>	<u>\$ 47,911</u>

The remaining period over which the unamortized debt discount will be recognized as non-cash interest expense is 7.42, 6.46, and 4.30 years for the 2028 Notes, 2027 Notes, and 2025 Notes, respectively.

(16) BUSINESS COMBINATIONS

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 are 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 September 30, 2020, 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 September 30, 2020. The purchase price was allocated to the underlying assets acquired and liabilities assumed based upon their estimated fair values at the date of acquisition as follows:

(In thousands)	
Net operating assets	\$ 5,373
Goodwill	30,431
Developed technology	7,800
Net operating liabilities	(3,203)
Total purchase price	<u>\$ 40,401</u>

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.

The partial year results from the operations of Paradigm and Viomics are included in the Company's condensed consolidated financial statements and not disclosed separately due to immateriality. Pro forma disclosures have not been included due to immateriality.

Genomic Health, Inc.

On November 8, 2019, the Company acquired all of the outstanding capital stock of Genomic Health. Genomic Health, headquartered in Redwood City, California, provides genomic-based diagnostic tests that address both the overtreatment and optimal treatment of early and late stage cancer.

The Company entered into this combination to create a leading global cancer diagnostics company and provide a robust platform for continued growth. This combination provides the Company with a commercial presence in more than 90 countries in which the combined company expects to continue to increase adoption of current tests, and to bring new innovative cancer tests to patients around the world.

Refer to the Company's 2019 10-K for detailed disclosures on the combination, including the fair value of the consideration transferred, purchase price allocation, and goodwill and intangible assets identified in the transaction. During the period ended September 30, 2020, there were no material changes to the purchase price allocation.

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

(17) 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.

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
United States	\$ 392,120	\$ 218,805	\$ 968,825	\$ 580,718
Outside of United States	16,243	—	56,227	—
Total revenues	\$ 408,363	\$ 218,805	\$ 1,025,052	\$ 580,718

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

(18) INCOME TAXES

The Company recorded an income tax benefit of \$4.5 million and an expense of \$0.7 million for the three months ended September 30, 2020 and 2019, respectively. The Company recorded an income tax benefit of \$7.1 million and \$0.2 million for the nine months ended September 30, 2020 and 2019, respectively. The Company's income tax benefit recorded during the three and nine months ended September 30, 2020, is primarily related to future limitations on and expiration of certain Federal and State deferred tax assets. As a result of these limitations, the recording of a valuation allowance resulted in a deferred tax liability of approximately \$21.5 million remaining as of September 30, 2020, which is included in other long-term liabilities on the Company's condensed consolidated balance sheet. The Company's income tax benefit recorded during the nine months ended September 30, 2019 was primarily related to the intraperiod tax allocation rules that required the Company to allocate the provision for income taxes between continuing operations and other categories of earnings. 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 \$14.4 million and \$10.2 million of unrecognized tax benefits at September 30, 2020 and December 31, 2019, respectively. The Company does not anticipate a material change to its unrecognized tax benefits over the next 12 months that would affect its effective tax rate. Unrecognized tax benefits may change during the next 12 months for items that arise in the ordinary course of business.

Accrued interest and penalties related to unrecognized tax benefits are recognized as part of the Company's income tax provision in its condensed consolidated statements of operations. The Company is subject to U.S. federal income tax examinations for the tax years 2001 through 2020, state income tax examinations for the tax years 2003 through 2020, and for the years 2014 through 2020 in foreign jurisdictions.

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

(19) SUBSEQUENT EVENTS

In October 2020, the Company and Pfizer entered into an Amended and Restated Cologuard Promotion Agreement (the “Restated Agreement”), which modifies, and amends and restates in its entirety, the Promotion Agreement effective August 2018. The term of the Restated Agreement runs until December 31, 2022. The Restated Agreement extends the relationship between the Company and Pfizer and restructures the manner in which the Company compensates Pfizer for promotion of Cologuard and provision of certain other sales and marketing services related to Cologuard. The Company agreed to pay Pfizer specified amounts for each instance Pfizer promotes Cologuard to a healthcare provider that is eligible to prescribe Cologuard, which includes a one-time lump sum payment for the promotion of Cologuard between April 1, 2020 and September 30, 2020. The Company also agreed to pay Pfizer certain bonuses during 2020 and 2021, certain quarterly fees in 2020 and 2021, and a one-time fee in connection with Pfizer securing certain media and advertising for Cologuard for 2022. During the last year of the term of the Restated Agreement, the Company agreed to pay Pfizer a royalty based on Cologuard revenues over a specified threshold. See Note 8 for further discussion on the Promotion Agreement with Pfizer.

On October 26, 2020, the Company acquired all of the outstanding capital stock of Base Genomics Limited, headquartered in Cambridge, England, for \$410.0 million in cash, net of cash received and certain other adjustments. This acquisition was funded with cash on hand and is expected to enhance the Company’s efforts in multi-cancer and colorectal cancer screening, as well as other cancers across the continuum.

On October 26, 2020, the Company entered into a definitive agreement and plan of merger (the “Thrive Merger Agreement”) with Thrive Earlier Detection Corporation (“Thrive”), which contemplates that, among other things, Thrive will be merged with and into one of the Company’s wholly owned subsidiaries, with the Company’s previously existing subsidiary surviving. Thrive 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. Under the terms of the Thrive Merger Agreement, Thrive will receive total consideration of \$2.2 billion, of which \$1.7 billion would be payable at closing, comprised of 35% in cash and 65% in the Company’s common stock. An additional \$450.0 million would be payable in cash based upon the achievement of certain milestones related to the development and commercialization of a blood-based, multi-cancer screening test. The Thrive merger was approved by the Company’s board of directors and the board of directors and stockholders of Thrive. The Company currently expects the Thrive merger to close during the first quarter of 2021, subject to customary closing conditions and regulatory approvals.

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, 2019, which has been filed with the SEC (the “2019 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, objectives and the pending acquisition of Thrive Earlier Detection Corporation (“Thrive”) are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results, anticipated results of our sales, marketing and patient adherence efforts, expectations concerning payer reimbursement, the anticipated results of our product development efforts, the anticipated benefits of the pending acquisition of Thrive, including estimated synergies and other financial impacts, and the expected timing of completion of the transaction. 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 the demand for our 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 success of our efforts to facilitate patient access to Cologuard via telehealth; 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 the adoption, modification or repeal of any law, rule, order, interpretation or policy relating to the healthcare system, including without limitation as a result of any judicial, executive or legislative action; the effects of changes in pricing, coverage and reimbursement for our products and services, including without limitation as a result of the Protecting Access to Medicare Act of 2014; recommendations, guidelines and quality metrics issued by various organizations such as the U.S. Preventive Services Task Force, the American Society of Clinical Oncology, the American Cancer Society, and the National Committee for Quality Assurance 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, such as through our Restated Promotion Agreement with Pfizer, Inc., and acquisitions; our success establishing and maintaining collaborative, licensing and supplier arrangements; our ability, and the ability of Thrive and Base Genomics Limited (“Base”), to 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 (including the pending acquisition of Thrive and recent acquisition of Base) cannot 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’ (including Thrive’s and Base’s) operations will be greater than expected and the possibility of disruptions to our business during integration efforts and strain on management time and resources; the outcome of any litigation, government investigations, enforcement actions or other legal proceedings; the ability of the

Company and Thrive to receive the required regulatory approvals for the pending merger and to satisfy the conditions to the closing of the transaction on a timely basis or at all; the occurrence of events that may give rise to a right of one or both of the Company and Thrive to terminate the merger agreement; possible negative effects of the announcement or the consummation of the pending acquisition of Thrive or recent acquisition of Base on the market price of our common stock and/or on our and/or Thrive's or Base's respective businesses, financial conditions, results of operations and financial performance; significant transaction costs and/or unknown liabilities; risks associated with contracts containing consent and/or other provisions that may be triggered by the pending acquisition of Thrive or the recent acquisition of Base; risks associated with potential transaction-related litigation; the ability of Thrive, Base and the combined company to retain and hire key personnel; and the other risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of the 2019 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 for other types of cancer, with the goal of bringing new innovative cancer tests to patients throughout the world.

Our Cologuard Test

Colorectal cancer is the second leading cause of cancer deaths in the United States ("U.S.") and the leading cause of cancer deaths in the U.S. among non-smokers. In 2020 in the U.S. there are projected 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, Cologuard became the first and only FDA-approved sDNA non-invasive colorectal cancer screening test. Cologuard is now indicated for average risk adults 45 years of age and older.

Our original premarket approval submission to the FDA for Cologuard included the results of our pivotal DeeP-C clinical trial that had over 10,000 patients enrolled at 90 sites in the U.S. and Canada. The results of our DeeP-C clinical trial for Cologuard were published in the New England Journal of Medicine in April 2014. The peer-reviewed study, "Multi-target Stool DNA Testing for Colorectal-Cancer Screening," highlighted the performance of Cologuard in the trial population:

- Cancer Sensitivity: 92%
- Stage I and II Cancer Sensitivity: 94%
- High-Grade Dysplasia Sensitivity: 69%
- Specificity: 87%

Our Oncotype DX 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.

We believe our Oncotype DX tests provide information that has the following benefits:

- *Improved Quality of Treatment Decisions.* We believe our approach to genomic-based cancer analysis improves the quality of cancer treatment decisions by providing an individualized analysis of each patient's tumor that is correlated to clinical outcome, rather than solely using subjective, anatomic and qualitative factors to determine treatments. Our Oncotype DX tests for breast cancer, Ductal Carcinoma in Situ ("DCIS"), prostate cancer, and colon cancer have been analytically and clinically validated in multiple published studies. The Recurrence Score® results from our tests have been demonstrated to classify patients into recurrence risk categories different than classifications based primarily on clinical and pathologic features. Additionally, multiple decision impact studies conducted worldwide consistently show that the Recurrence Score result changes treatment decisions in more than 30% of patients. As a result, we believe our tests enable patients and healthcare providers to make more informed decisions about the risks and benefits of various treatments, and consequently design an individualized treatment plan.
- *Improved Health Economics of Cancer Care.* We believe that improving the quality of treatment decisions can result in significant economic benefits. The results of a number of clinical studies have demonstrated that by using the Oncotype DX Breast Recurrence Score® test, physicians and patients can better evaluate treatment options, such as whether a patient will or will not benefit from chemotherapy. Patients are benefited when (1) those who aren't likely to benefit from chemotherapy avoid it and the associated chemotoxicities and (2) those who are likely to benefit from chemotherapy receive it resulting in reduced incidence of distant recurrences. These better clinical outcomes increase survival rates and also save the patient as well as the healthcare system significant costs.

International Business Background and Products

Prior to our combination with Genomic Health, we did not have international revenue. We now commercialize our Oncotype DX tests internationally through employees in Canada, Japan and six European countries, as well as through exclusive distribution agreements. We have provided our Oncotype DX tests in more than 90 countries outside of the United States. We do not offer Cologuard or COVID-19 testing outside of the U.S.

Inclusion of our products in guidelines and quality measures will be critical to our international success. The Oncotype DX breast cancer test is recognized in international guidelines issued by the St. Gallen International Breast Cancer Expert Panel and European Society for Medical Oncology and has been included in certain guidelines and recommendations in England, Germany and Japan. We have obtained coverage for our invasive breast cancer test outside of the U.S., including coverage for certain patients in Canada, France, Spain, Germany, Italy, Ireland, Israel, Saudi Arabia, Switzerland, and the United Kingdom. We expect that broadening coverage and reimbursement for our Oncotype DX tests outside of the United States will take years.

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. These development efforts may lead to a variety of possible new products, including risk assessment, screening and prevention, early disease diagnosis, adjuvant and/or neoadjuvant disease treatment, metastatic disease treatment selection and patient monitoring.

In October 2020 we announced the introduction of the Oncotype MAP™ Pan-Cancer Tissue test ("Oncotype MAP" test). The Oncotype MAP test is a rapid, comprehensive tumor profiling panel that aids therapy selection for patients with advanced, metastatic, refractory, or recurrent cancer. The Oncotype MAP test utilizes next generation sequencing and immunohistochemistry to provide in-depth insights into genomic alterations in hundreds of cancer-related genes. The Oncotype MAP test report supports clinical decision making by showing actionable biomarkers associated with more than 100 evidence-based therapies, over 45 combination therapies, and more than 650 active clinical trial associations. The identification of these biomarkers helps to inform treatment options for a breadth of solid tumor types.

Through our collaboration with Mayo Foundation for Medical Education and Research, we have successfully performed validation studies on multiple types of cancer using tissue, blood and other samples. In September 2020, Mayo agreed to make available certain personnel to provide us product development and research and development assistance through January 2025. We are currently focusing our research and development efforts on building a pipeline of potential future products and services with a focus on improving Cologuard's performance characteristics and on developing blood or other fluid-based ("liquid biopsy") tests. We expect to advance liquid biopsy through biomarker discovery and validation in tissue, blood, or other fluids.

We are pursuing the following opportunities:

- *Colon Cancer Screening.* We are seeking opportunities to improve upon Cologuard'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 and hemoglobin. To establish the performance of the novel multi-target stool DNA test in November 2019, we launched the BLUE-C study, a multi-center, prospective study. We expect to enroll more than 10,000 patients 40 years of age and older in the BLUE-C study. The timing of any such enhancements to Cologuard 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 September 2020, we reported that together with Mayo we have identified methylation markers with a 97% average accuracy in identifying cancers in tissue and blood. We also presented results from an internal study using these markers on blood samples that demonstrated 86% sensitivity at 95% specificity when looking at six different cancers.
- *Hepatocellular Carcinoma ("HCC") Test Development.* We are currently seeking to develop 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 develop a patient-friendly test that performs better than the current standard of care. In November 2019, we released the results of a 443-patient study which demonstrated 80% sensitivity 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.
- *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.

Coronavirus ("COVID-19") Pandemic

The spread of COVID-19 has affected many segments of the global economy, including the cancer screening and diagnostics industry. The COVID-19 outbreak, which the World Health Organization has classified as a pandemic, has prompted governments and regulatory bodies throughout the world to enact broad precautionary measures, including "stay at home" orders, restrictions on the performance of "non-essential" services, public gatherings and travel. Health systems, including in key markets where we operate, have been, or may be, overwhelmed with high volumes of patients suffering from COVID-19. The territories in which we market, sell, distribute and perform our tests are attempting 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. Even in the absence of legal restrictions, businesses and individuals may voluntarily continue to limit in-person interactions and practice social distancing, and such behaviors may continue beyond the formal end of the pandemic. 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 pandemic and related precautionary measures began to materially disrupt our business in March 2020 and may continue to disrupt our business for an unknown period of time. As a result, we anticipate significant impact to our 2020 operating results, including our revenues, margins, and cash utilization, among other measures.

Beginning in March 2020, we undertook temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring most employees to work remotely; suspending field-based, face-to-face interactions by our sales force; requiring on-site employees to undergo COVID-19 testing, wear personal protective equipment (including face masks or shields) and maintain social distancing; pausing all non-essential travel worldwide for our employees; and limiting employee attendance at industry events and in-person work-related meetings, to the extent those events and meetings are continuing. Our commercial partner for Cologuard, Pfizer, Inc. (“Pfizer”), took similar precautions, including suspending face-to-face interactions between sales representatives and healthcare providers.

We expect to adjust our precautionary measures at our various locations based on local recovery levels and applicable governmental regulations. For example, a portion of the Company’s and Pfizer’s sales force has recommenced field-based interactions, although access to healthcare providers remains limited and the resumption of normal activities is expected to be gradual. Our business could be negatively affected if we take excessive, ineffective or inadequate precautions.

Due to social distancing, stay-at-home orders, and other actions taken in response to COVID-19, there has been a significant and widespread decline in standard wellness visits and preventive services. That decline negatively impacted Cologuard test orders during the second quarter of 2020 in our Screening business, notwithstanding the availability of alternative ordering channels such as telehealth. During the third quarter, orders have recovered to pre-pandemic levels.

The Precision Oncology business started to see weakening underlying conditions in April 2020 because of COVID-19, more notably in the U.S. prostate business and in certain international geographies. 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.

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 the extent to which behavioral changes resulting from the pandemic continue even after it ends.

COVID-19 Testing Business

In late March 2020, we began providing COVID-19 testing. The U.S. Food and Drug Administration (FDA) has granted us Emergency Use Authorization to test for SARS-CoV-2, the virus that causes COVID-19, in upper respiratory samples. We have partnered with various customers, including the State of Wisconsin Department of Health, 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.

2020 Priorities

As a result of COVID-19 and its impact to our business, we have re-prioritized our goals for 2020 with a focus on serving patients who continue to need the healthcare services we provide while aligning our cost structure with the anticipated lower sales volumes and revenues. Our top priorities for 2020 are (1) get people tested, (2) take care of our customers, and (3) preserve financial strength.

Get People Tested

Business continuity plans are in place at all of our sites to help sustain operations and ensure continuity of services for patients during this unprecedented time. Despite the COVID-19 pandemic, many people still need to be screened for colorectal cancer, and treated for breast, colon, and prostate cancers. Our lab facilities presently remain operational so that we can continue to process results of our Cologuard, Oncotype DX and COVID-19 tests.

Take Care of our Customers

Due to social distancing, stay-at-home orders, and other actions taken in response to COVID-19, there has been a significant and widespread decline in standard wellness visits and preventive services. We have taken 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 sales team that is not engaged in face-to-face interactions will serve healthcare providers via telephone and online technologies until it is safe to return to the field and practices allow representatives back in their offices.

Preserve Financial Strength

In order to minimize the adverse impacts to our business and operations anticipated during 2020 due to the COVID-19 pandemic, beginning in April 2020, we initiated proactive measures to achieve cost savings. Actions we took included a temporary reduction of base pay for our executive officers and other employees, a reduction in the annual retainer payable to our board of directors, and a reduction of quarterly sales commissions. We implemented a workforce reduction, involuntary furloughs, work schedule reductions, as well as a voluntary furlough program. Additionally, we reduced investments in marketing and other promotional activities, paused certain clinical trial activities, reduced travel and professional services, and delayed or terminated certain capital projects. We also saw a reduction in certain volume based cost of goods sold expenses consistent with the reduction in revenue. These actions have contributed to significant cost savings in 2020 during the nine months ended September 30, 2020.

Recent Events

On October 26, 2020, we entered into a definitive agreement and plan of merger (“Thrive Merger Agreement”) with Thrive, which we currently expect to be completed in the first quarter of 2021. On October 26, 2020, we acquired all of the outstanding stock of Base (“Base Merger Agreement”). Refer to Note 19 in our condensed consolidated financial statements included in this Quarterly Report for additional information.

Results of Operations

We have generated significant losses since inception and, as of September 30, 2020, we had an accumulated deficit of approximately \$1.5 billion. We expect to continue to incur losses for the near future, and it is possible we may never achieve profitability. As mentioned in further detail above, the COVID-19 outbreak has had an adverse impact on our operations beginning in March 2020. While we have seen recovery in our Screening and Precision Oncology businesses, the impact of the pandemic in the fourth quarter of 2020 and after is uncertain and subject to factors beyond our control.

Revenue. Our revenue is primarily generated by our laboratory testing services, from our Cologuard, Oncotype DX and COVID-19 tests. For the three months ended September 30, 2020 and 2019, we generated Screening revenue of \$214.6 million and \$218.8 million, respectively. For the nine months ended September 30, 2020 and 2019, we generated Screening revenue of \$565.4 million and \$580.7 million, respectively. Screening includes laboratory service revenue from Cologuard and revenue from Biomatrix products. For the three months ended September 30, 2020, we generated Precision Oncology revenue of \$91.6 million. For the nine months ended September 30, 2020, we generated Precision Oncology revenue of \$322.9 million. Precision Oncology includes laboratory service revenue from global Oncotype DX and Paradigm products. For the three and nine months ended September 30, 2020, we also generated \$102.2 million and \$136.7 million, respectively, in revenue from our COVID-19 testing.

For the three and nine months ended September 30, 2020, our Screening and Precision Oncology testing service revenue was adversely impacted by the effects of the COVID-19 outbreak. In response to the pandemic, we are conducting COVID-19 testing, which has served as additional revenue outside our normal Screening and Precision Oncology testing services.

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 gross margin 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 \$95.1 million for the three months ended September 30, 2020 from \$52.3 million for the three months ended September 30, 2019. Cost of sales increased to \$254.6 million for the nine months ended September 30, 2020 from \$146.3 million for the nine months ended September 30, 2019. The increase in cost of sales is primarily due to costs incurred on our Precision Oncology tests due to the completion of the combination with Genomic Health in November 2019 and costs incurred from our COVID testing.

Amounts in millions	Three Months Ended September 30,		
	2020	2019	Change
Production costs	\$ 51.4	\$ 36.5	\$ 14.9
Personnel expenses	26.8	9.4	17.4
Facility and support services	13.3	4.9	8.4
Stock-based compensation	3.5	1.4	2.1
Other cost of sales expenses	0.1	0.1	—
Total cost of sales expense	\$ 95.1	\$ 52.3	\$ 42.8

Amounts in millions	Nine Months Ended September 30,		
	2020	2019	Change
Production costs	\$ 134.3	\$ 103.4	\$ 30.9
Personnel expenses	72.5	25.7	46.8
Facility and support services	38.2	13.2	25.0
Stock-based compensation	9.3	3.9	5.4
Other cost of sales expenses	0.3	0.1	0.2
Total cost of sales expense	\$ 254.6	\$ 146.3	\$ 108.3

Research and development expenses. Research and development expenses decreased to \$31.5 million for the three months ended September 30, 2020 compared to \$34.7 million for the three months ended September 30, 2019. Research and development expenses increased to \$107.7 million for the nine months ended September 30, 2020 compared to \$96.5 million for the nine months ended September 30, 2019. The decrease during the three months ended September 30, 2020 was primarily due to a reduction of certain direct research and development costs due to the cost saving measures and the timing of certain expenditures as a result of the COVID-19 pandemic. The increase during the nine months ended September 30, 2020 was primarily due to an increase in personnel related costs as a result of the combination with Genomic Health in November 2019, which was partially offset by a reduction in of certain direct research and development costs as discussed above.

Amounts in millions	Three Months Ended September 30,		
	2020	2019	Change
Personnel expenses	\$ 13.1	\$ 7.9	\$ 5.2
Direct research and development	7.3	16.4	(9.1)
Stock-based compensation	5.0	6.9	(1.9)
Facility and support services	5.0	1.2	3.8
Professional fees	0.6	1.8	(1.2)
Other research and development	0.5	0.5	—
Total research and development expenses	\$ 31.5	\$ 34.7	\$ (3.2)

Amounts in millions	Nine Months Ended September 30,		
	2020	2019	Change
Personnel expenses	\$ 45.2	\$ 23.7	\$ 21.5
Direct research and development	32.4	51.3	(18.9)
Stock-based compensation	14.6	12.9	1.7
Facility and support services	11.1	3.3	7.8
Professional fees	2.3	3.9	(1.6)
Other research and development	2.1	1.4	0.7
Total research and development expenses	\$ 107.7	\$ 96.5	\$ 11.2

General and administrative expenses. General and administrative expenses increased to \$115.6 million for the three months ended September 30, 2020 compared to \$80.5 million for the three months ended September 30, 2019. General and administrative expenses increased to \$336.3 million for the nine months ended September 30, 2020 compared to \$208.1 million for the nine months ended September 30, 2019. The increase in general and administrative expenses was primarily related to the operations of Genomic Health being included in our results after the completion of the combination in November 2019, and an overall increase in headcount, information technology and customer care center costs to support the growth of the Company.

Amounts in millions	Three Months Ended September 30,		
	2020	2019	Change
Personnel expenses	\$ 53.7	\$ 29.2	\$ 24.5
Professional and legal fees	15.9	20.1	(4.2)
Stock-based compensation	21.5	11.1	10.4
Facility and support services	13.4	16.1	(2.7)
Other general and administrative	11.1	4.0	7.1
Total general and administrative expenses	\$ 115.6	\$ 80.5	\$ 35.1

Amounts in millions	Nine Months Ended September 30,		
	2020	2019	Change
Personnel expenses	\$ 159.3	\$ 85.9	\$ 73.4
Professional and legal fees	52.9	39.4	13.5
Stock-based compensation	54.8	29.6	25.2
Facility and support services	42.4	42.0	0.4
Other general and administrative	26.9	11.2	15.7
Total general and administrative expenses	\$ 336.3	\$ 208.1	\$ 128.2

Sales and marketing expenses. Sales and marketing expenses increased to \$136.5 million for the three months ended September 30, 2020 compared to \$86.2 million for the three months ended September 30, 2019. Sales and marketing expenses increased to \$423.1 million for the nine months ended September 30, 2020 compared to \$265.3 million for the nine months ended September 30, 2019. The increase in sales and marketing expenses was a result of additional sales and marketing personnel, including the Precision Oncology team added following the completion of the Genomic Health combination in November 2019, which was partially offset by a reduction in advertising and marketing spend as a result of the COVID-19 pandemic.

Amounts in millions	Three Months Ended September 30,		
	2020	2019	Change
Personnel expenses	\$ 67.4	\$ 37.7	\$ 29.7
Direct marketing costs and professional fees	26.9	23.0	3.9
Professional and legal fees	19.5	19.6	(0.1)
Facility and support services	10.5	0.8	9.7
Stock-based compensation	11.5	4.9	6.6
Other sales and marketing expenses	0.7	0.2	0.5
Total sales and marketing expenses	\$ 136.5	\$ 86.2	\$ 50.3

Amounts in millions	Nine Months Ended September 30,		
	2020	2019	Change
Personnel expenses	\$ 209.0	\$ 111.0	\$ 98.0
Direct marketing costs and professional fees	90.0	68.9	21.1
Professional and legal fees	56.9	68.5	(11.6)
Facility and support services	33.4	2.4	31.0
Stock-based compensation	32.4	14.3	18.1
Other sales and marketing expenses	1.4	0.2	1.2
Total sales and marketing expenses	\$ 423.1	\$ 265.3	\$ 157.8

Amortization of acquired intangible assets. Amortization of acquired intangible assets increased to \$23.4 million for the three months ended September 30, 2020 compared to \$0.7 million for the three months ended September 30, 2019. Amortization of acquired intangible assets increased to \$70.2 million for the nine months ended September 30, 2020 compared to \$2.3 million for the nine months ended September 30, 2019. The increase in amortization of acquired intangible assets was primarily due to the Genomic Health combination.

Intangible asset impairment charge. Intangible asset impairment charge was \$209.7 million for the three and nine months ended September 30, 2020 compared to zero for the three and nine months ended September 30, 2019. The impairment recorded during the nine months ended September 30, 2020 primarily relates to the impairment of the in-process research and development intangible asset acquired as part of the combination with Genomic Health.

Other operating income. Other operating income increased to \$23.7 million for the nine months ended September 30, 2020 compared to zero for the nine months ended September 30, 2019. The income generated during the nine months ended September 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 decreased to \$2.5 million for the three months ended September 30, 2020 compared to \$9.1 million for the three months ended September 30, 2019. Investment income, net decreased to \$5.5 million for the nine months ended September 30, 2020 compared to \$23.4 million for the nine months ended September 30, 2019. The decrease in investment income, net was due to a decrease in realized gains generated from the sale of marketable securities and a decrease in the average rate of return on investments due to an decrease in market interest rates and a lower average balance in marketable securities for the nine months ended September 30, 2020 when compared to the same period in 2019.

Interest expense. Interest expense increased to \$23.6 million for the three months ended September 30, 2020 compared to \$13.2 million for the three months ended September 30, 2019. Interest expense increased to \$71.6 million for the nine months ended September 30, 2020 compared to \$47.9 million for the nine months ended September 30, 2019. The increase is primarily due to the issuance of additional convertible notes in February 2020, which was partially offset by lower interest rates on the convertible notes issued in February 2020. Interest expense recorded from our outstanding convertible notes totaled \$23.2 million and \$12.7 million during the three months ended September 30, 2020 and 2019, respectively. Of the interest expense recorded on outstanding convertible notes for the three months ended September 30, 2020 and 2019, \$20.6 million and \$11.0 million of interest expense relates to amortization of debt discount and debt issuance costs, respectively. Interest expense recorded from our outstanding convertible notes totaled \$62.3 million and \$36.4 million during the nine months ended September 30, 2020 and 2019, respectively. Of the interest expense recorded on outstanding convertible notes for the nine months ended September 30, 2020 and 2019, \$55.2 million and \$30.8 million of interest expense relates to amortization of debt discount and debt issuance costs, respectively. The remaining interest expense recorded on outstanding convertible notes relates to the stated interest that is paid out in cash. In addition to the interest expense recorded on outstanding convertible notes, an additional \$8.0 million and \$10.6 million was recorded during the nine months ended September 30, 2020 and 2019, respectively, as a result of the settlement of convertible notes. The convertible notes are further described in Note 15 of our condensed consolidated financial statements included in this Quarterly Report. The remaining interest expense for the three and nine months ended September 30, 2020 and 2019, relates to the stated interest on our construction loan.

Income tax benefit (expense). Income tax benefit increased to \$4.5 million for the three months ended September 30, 2020 compared to an expense of \$0.7 million for the three months ended September 30, 2019. Income tax benefit increased to \$7.1 million for the nine months ended September 30, 2020 compared to \$0.2 million for the nine months ended September 30, 2019. This increase in income tax benefit is primarily due to future limitations on and expiration of certain Federal and State deferred tax assets.

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 the Cologuard, and since the completion of our Genomic Health combination, of Oncotype DX tests. As of September 30, 2020, we had approximately \$806.7 million in unrestricted cash and cash equivalents and approximately \$476.3 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 provided by operating activities was \$25.1 million for the nine months ended September 30, 2020 compared to cash use of \$86.4 million for the nine months ended September 30, 2019. The increase in cash provided by operating activities for the nine months ended September 30, 2020 was primarily due to the increase in revenue and reduction of discretionary operating expenses due to cost saving measures as a result of the COVID-19 pandemic.

Net cash used in investing activities was \$395.4 million for the nine months ended September 30, 2020 compared to cash provided of \$713.7 million for the nine months ended September 30, 2019. The increase in cash used in investing activities for the nine months ended September 30, 2020 compared to the same period in 2019 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 \$65.3 million for the nine months ended September 30, 2020 compared to \$131.5 million for the nine months ended September 30, 2019. Cash use consisted primarily of purchases of property and equipment of \$47.8 million and \$131.0 million for the nine months ended September 30, 2020 and 2019, respectively, investments in privately held companies of \$10.6 million, and an acquisition of \$6.7 million. There were also minimal purchases of intangible assets during the nine months ended September 30, 2020 and 2019.

Net cash provided by financing activities was \$999.8 million for the nine months ended September 30, 2020 compared to \$246.6 million for the nine months ended September 30, 2019. During the nine months ended September 30, 2020, we received net cash of \$1,125.5 million from the 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 Convertible Notes with an original maturity date of January 15, 2025 (the “2025 Notes”). The cash provided by financing activities for the nine months ended September 30, 2019 was primarily the result of proceeds of \$729.5 million from our issuance of Convertible Notes with a maturity date of March 15, 2027 (the “2027 Notes”, and, collectively with the 2025 Notes and 2028 Notes, the “Notes”), and we used \$493.4 million of cash to settle a portion of the 2025 Notes. In addition, during the nine months ended September 30, 2020 we received proceeds of \$15.4 million from the exercise of stock options and \$9.8 million from our employee stock purchase plan.

As described above, on October 26, 2020, we entered into the Base Merger Agreement, under which we acquired Base in a cash transaction valued at approximately \$410.0 million.

As described above, on October 26, 2020, we entered into the Thrive Merger Agreement, under which we agreed to acquire Thrive in a cash and stock transaction valued at approximately \$2.2 billion, of which \$1.7 billion would be payable at closing. We currently expect the merger will be completed in the first quarter of 2021, subject to customary closing conditions and regulatory approvals. We anticipate that cash of approximately \$0.6 billion will be required to pay the aggregate cash portion of the merger consideration.

We expect that cash and cash equivalents and marketable securities on hand at September 30, 2020 will be sufficient to fund the cash portion of the purchase price to be paid in connection with the Thrive and Base acquisitions as well as 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 Cologuard and Oncotype DX 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, we cannot assure that our business will ever generate sufficient cash flow from operations to become profitable.

The spread of COVID-19 and measures to prevent further spread, have significantly disrupted our business, and may continue to disrupt our business for an unknown period of time. The full impact of the outbreak is uncertain at this time and continues to evolve globally. We do not yet know the extent to which COVID-19 will negatively impact our financial results or liquidity. The outbreak has disrupted our operations, as well as the operations and behaviors of healthcare providers, patients and suppliers. Depending on how healthcare providers, patients and suppliers are adversely impacted by the pandemic, as well as the overall duration and severity of the pandemic and changes in behavior that continue even after the pandemic, our liquidity could be materially and adversely affected. Management continues to monitor and assess the evolving developments with respect to COVID-19.

A table reflecting certain of our specified contractual obligations as of December 31, 2019 was provided in the Management’s Discussion and Analysis of Financial Condition and Results of Operation of our 2019 Form 10-K. During the nine months ended September 30, 2020, we issued \$1,150.0 million in aggregate principal amount of 0.375% Convertible Notes that will mature on March 1, 2028. The holders of the Notes may convert prior to September 1, 2027 only under certain circumstances and may convert at any time after September 1, 2027. The 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. Of the cash received upon issuance of the 2028 Notes, approximately \$150.1 million was used to repay a portion of the outstanding principal balance and accrued interest of the 2025 Notes held by certain Noteholders. Upon repayment of such portion of the outstanding principal balance

of the 2025 Notes, there was \$315.0 million in aggregate principal balance remaining under the 2025 Notes. See Note 15 of the condensed consolidated financial statements included in this Quarterly Report for further details. With the exception of this item, there were no material changes outside the ordinary course of our business in our specified contractual obligations during the nine months ended September 30, 2020.

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 United States ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, tax positions and stock-based compensation. 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.

Our significant accounting policies are more fully described in Note 1 of our financial statements included in our 2019 Form 10-K, as well as our Management's Discussion and Analysis of Financial Condition and Results of Operations on our 2019 Form 10-K. There have not been any significant changes to our critical accounting policies and estimates during the nine months ended September 30, 2020.

Revenue Recognition. Revenues are recognized when control of the promised services are transferred to the patient's 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 constrained amount that we expect to ultimately collect. We determine the amount we expect to ultimately collect on a per-payer or per-agreement basis, 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 who assumes the downstream patient billing. 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 relieved upon the release of the applicable patient's test result to the ordering healthcare provider, the date a non-conforming specimen is received, 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 cycle for areas of opportunity as we believe adequate operations support our ability 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 contractual allowance is adjusted. Finally, should we later determine the judgments underlying estimated collections change, our financial results could be negatively impacted in future quarters.

Convertible Notes. We account for convertible debt instruments that may be settled in cash or equity upon conversion by separating the liability and equity components of the instruments in a manner that reflects our nonconvertible debt borrowing rate. In February 2020 we issued the 2028 Notes of \$1,150.0 million in aggregate principal amount of 0.375% Convertible Notes with a maturity date of March 1, 2028. As part of that issuance, we settled approximately \$100.0 million in outstanding 2025 Notes. We determined the carrying amount of the liability component of the 2028 Notes by using assumptions that market participants would use in pricing a debt instrument, including market interest rates, credit standing, yield curves and volatilities. Determining the fair value of the debt component requires the use of accounting estimates and assumptions. These estimates and assumptions are judgmental in nature and could have a significant impact on the determination of the debt component, and the associated non-cash interest expense.

For the February 2020 offering, we allocated \$346.6 million, net of tax, to the equity component of the convertible debt instrument. That equity component is treated as a discount on the liability component of the Notes, which is amortized over the eight-year term of the 2028 Notes using the effective interest rate method. In addition, debt issuance costs related to the 2028 Notes was \$24.4 million. We allocated the costs to the liability and equity components of the 2028 Notes based on their relative values. The debt issuance costs allocated to the liability component are being amortized over the life of the 2028 Notes as additional non-cash interest expense. The transaction costs allocated to the equity component are netted with the equity component of the convertible debt instrument in stockholders' equity.

Business Combinations. Business Combinations are accounted for under the acquisition method in accordance with 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.

In March 2020, we recognized goodwill of \$30.4 million from the acquisitions of Paradigm and Viomics. We evaluate goodwill impairment on an annual basis or more frequently should an event or change in circumstance occur that indicates that the carrying amount is in excess of the fair value. Refer to Note 5 and Note 16 of the condensed consolidated financial statements included in this Quarterly Report for further discussion of the goodwill recorded.

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.

During the third quarter, we recorded an impairment loss of \$200.0 million related to the in-process research and development intangible asset acquired as part of the business combination with Genomic Health and an impairment loss of \$9.7 million relating to the abandonment of certain research and development efforts using intangible assets acquired as part of an asset purchase agreement with Armune Biosciences, Inc. The determination to record these impairment charges was made in connection with the preparation of the financial statements as of September 30, 2020. Refer to Note 5 of the condensed consolidated financial statements included in this Quarterly Report for further discussion on the impairment charges recorded.

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 September 30, 2020, 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 September 30, 2020 and December 31, 2019 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 growing percentage 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.

Prior to 2019, the functional currency for each of our international subsidiaries was its local currency. For 2019 our international subsidiaries use the U.S. dollar as the functional currency, resulting in us not being subject to gains and losses from foreign currency translation of the subsidiary financial statements. In September 2017, Genomic Health (now a wholly owned subsidiary) started entering 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 September 30, 2020, we had open foreign currency forward contracts with notional amounts of \$18.2 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 September 30, 2020, 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 November 2019, the Company acquired all of the outstanding capital stock of Genomic Health (see Note 16 to the accompanying consolidated financial statements for additional information). As of September 30, 2020, management is in the process of evaluating and integrating the internal controls of Genomic Health into the Company’s existing operations. Other than the controls enhanced or implemented to integrate the Genomic Health business, there have been no changes in the Company’s internal controls over financial reporting during the quarter ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, the Company’s internal controls 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.

We are currently responding to civil investigative demands initiated by the United States Department of Justice (“DOJ”) concerning (1) Genomic Health’s compliance with the Medicare Date of Service billing regulations and (2) allegations that we offered or gave gift cards to patients in exchange for returning the Cologuard screening test, in violation of the Federal Anti-Kickback Statute and False Claims Act. We have been cooperating with these inquiries and have produced documents in response thereto. Adverse outcomes from these investigations could include our being required to pay treble damages, incur civil and criminal penalties, paying attorney’s 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 and adversely affect our business, financial condition and results of operations.

In connection with our 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. The complaint asserts individual and class action claims, including: (i) a violation of 8 Del. C. § 203 by Genomic Health's former directors; (ii) conversion by Genomic Health, Exact and Spring Acquisition Corp.; (iii) breach of fiduciary duty by Genomic Health's former directors; (iv) breach of fiduciary duty by a purported controlling group of former Genomic Health stockholders comprised of funds managed by former Genomic Health directors, Julian Baker and Felix Baker; and (v) aiding and abetting breach of fiduciary duty against Exact, Spring Acquisition and Goldman Sachs & Co. LLC, Genomic Health's financial advisor in the combination. The complaint seeks, among other things, declaratory relief, unspecified monetary damages and attorneys' fees and costs. All defendants intend to move to dismiss the complaint.

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 2019 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 2019 Form 10-K and in subsequently filed Quarterly Reports on Form 10-Q.

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

The COVID-19 outbreak, which the World Health Organization has classified as a pandemic, together with related precautionary measures, began to materially disrupt our business in March 2020 and may continue to disrupt our business for an unknown period of time. The territories in which we market, sell, distribute and perform our tests are attempting 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. Even in areas where “stay-at-home” restrictions have been lifted and the number of cases of COVID-19 has declined, many individuals remain cautious about resuming activities such as preventive-care medical visits. Medical practices continue to be cautious about allowing individuals, such as sales representatives, into their offices. Many individuals continue to work from home rather than from an office setting. 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, we anticipate significant impact to at least our 2020 operating results, including our revenues, margins, and cash utilization, among other measures.

Beginning in March 2020, we undertook temporary precautionary measures intended to help minimize the risk of the virus to our employees, including requiring most employees to work remotely; suspending field-based, face-to-face interactions by our sales force; requiring on-site employees to undergo COVID-19 testing, wear personal protective equipment (including face masks or shields) and maintain social distancing; pausing all non-essential travel worldwide for our employees; and limiting employee attendance at industry events and in-person work-related meetings, to the extent those events and meetings are continuing. Our commercial partner for Cologuard, Pfizer, Inc. (“Pfizer”), took similar precautions, including suspending face-to-face interactions between sales representatives and healthcare providers.

We expect to adjust our precautionary measures at our various locations based on local recovery levels and applicable governmental regulations. For example, a portion of the Company’s and Pfizer’s sales force has recommenced field-based interactions, although access to healthcare providers remains limited and the resumption of normal activities is expected to be gradual. Our business could be negatively affected if we take excessive, ineffective or inadequate precautions.

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 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; while we amended and restated our promotion agreement with Pfizer to, among other things, address changes to the operational landscape resulting from the COVID-19 pandemic, our expectations regarding the duration, severity and effects of the pandemic may prove inaccurate, and we may not realize the expected benefits from this 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;
- Illnesses, quarantines, financial hardships, restrictions on travel, commerce and shipping, or other consequences of the pandemic, may disrupt our supply chain or other 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;

- We have taken, and may take additional, cost cutting measures, which may hinder our efforts to commercialize our products or delay the development of future products and services. We might not realize all of the cost savings we expect to achieve as a result of those efforts;
- We and our partners have postponed or cancelled clinical studies, which may delay or prevent our launch of future products and services;
- Our workforce, much of which has been asked to work remotely in an effort to reduce the spread of COVID-19, may be infected by the virus or otherwise distracted;
- A combination of factors, including infection from the virus, supply shortfalls, and inability to obtain or maintain equipment, could adversely affect our lab capacity and our ability to meet the demand for our testing services. In March of 2020 we began offering a COVID-19 test and by devoting lab capacity and supplies to that test, we may experience capacity limitations and supply shortfalls that adversely affect our ability to provide Cologuard and other tests that may generate more revenue and higher profits; 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 market 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.

Additionally, the anticipated economic consequences of the COVID-19 pandemic have adversely impacted financial markets, resulting in high share price volatility, reduced market liquidity, and substantial declines in the market prices of the securities of many publicly traded companies. Volatile or declining markets for equities could adversely affect our ability to raise capital when needed through the sale of shares of common stock or other equity or equity-linked securities. If these market conditions persist when and if we need to raise capital, and if we are able to sell shares of our common stock under then prevailing market conditions, we might have to accept lower prices for our shares and issue a larger number of shares than might have been the case under better market conditions, resulting in significant dilution of the interests of our stockholders.

We currently offer COVID-19 testing, but there can be no assurance that we will continue to be able to successfully offer, perform or generate revenues from the test.

In late March 2020, we began providing COVID-19 testing. The U.S. Food and Drug Administration (FDA) has granted us Emergency Use Authorization to test for SARS-CoV-2, the virus that causes COVID-19, in upper respiratory samples.

While we have entered into a limited number of contracts to provide COVID-19 testing and expect to pursue additional contracts, there can be no assurance that our efforts to offer and perform COVID-19 testing will be successful. The success of our test, our ability to continue to generate revenues from COVID-19 testing, and our ability to generate profits from COVID-19 testing will depend on a variety of factors, including:

- the level of demand for COVID-19 testing, the price we are able to charge for performing the test, and the length of time for which that demand persists;
- the availability of COVID-19 testing, from other laboratories;
- acceptance of our COVID-19 testing in the medical community;
- the emergence of other forms of COVID-19 testing (including antigen and antibody screening tests) and other sample collection methods, which healthcare providers and patients may prefer to our test;
- the period of time for which the FDA will permit us to offer COVID-19 testing under an Emergency Use Authorization;
- our ability to maintain regulatory approvals to perform and market COVID-19 testing and to respond to any changes in regulatory requirements;
- the potential for supply disruptions and our reliance on certain single-source suppliers;
- the potential for disruption in the delivery of patient samples to our laboratories;

- the capacity of our laboratories to satisfy both COVID-19 testing and other testing demands;
- the extent to which we choose to allocate limited laboratory capacity, supplies and other resources to areas of our business other than COVID-19 testing;
- the complexity of billing for, and collecting revenue for, our test;
- healthcare provider and patient compliance with instructions for performing the nasal swab and providing samples to our laboratories;
- our ability to maintain laboratory operations during the COVID-19 pandemic and to perform the test accurately and punctually; and
- the ease of use of our ordering and reporting process.

Additionally, we have previously only offered cancer screening and diagnostic tests. The addition of COVID-19 testing may divert resources and distract management's attention from other projects that may be more profitable or strategic. If we are unable to successfully provide COVID-19 testing while continuing to operate our existing Screening and Precision Oncology business, our results of operations, financial position and reputation may suffer.

Our business is subject to complex and evolving laws, as well as customer and patient expectations, regarding data privacy, protection and security.

The interpretation and application of consumer, health related and data protection laws in the U.S., Europe and elsewhere are often uncertain, contradictory and in flux. In order to mitigate concerns about overseas data transfers and to comply with provisions of the GDPR and its predecessor regulations, we self-certified with the Department of Commerce for compliance with the U.S.-E.U. Privacy Shield. However, on July 16, 2020, the Court of Justice of the European Union rendered its judgment in *Data Protection Commissioner v. Facebook Ireland*, invalidating the U.S.-E.U. Privacy Shield program. Although we expect to implement other measures to ensure compliance with the GDPR, the changing legal landscape could cause us to incur substantial costs or change our operations and compliance procedures, all of which may adversely affect our business.

If we fail to comply with the GDPR and other applicable data privacy, protection and security laws, or if we fail to satisfy customer or patient concerns regarding data handling, we could be subject to government enforcement actions, private litigation, civil or criminal penalties, reduced orders and adverse publicity.

Our failure to successfully complete or integrate acquisitions, including our recently announced acquisition of Thrive, in the expected timeframes, or to realize all or any part of the anticipated benefits of such acquisitions, may adversely affect our results of operations..

We undertake acquisition activities from time to time. In November 2019, we completed the acquisition of Genomic Health, Inc., and in March 2020, we completed the acquisitions of Paradigm Diagnostics, Inc. and Viomics, Inc. On October 27, 2020, we announced our entry into the Thrive Merger Agreement and our acquisition of Base. Certain risks may exist as a result of these and other acquisition activities, including, among others, that:

- a failure to complete the merger with Thrive, including due to the inability to receive the required regulatory approvals, the occurrence of events that may give rise to the right of one or both of us and Thrive to terminate the Thrive Merger Agreement, a ruling or judgment by a government authority enjoining or prohibiting the Thrive merger, or the failure of us or Thrive to satisfy another closing condition outside of our control, could negatively impact our stock price and our future business and financial results;
- we will incur substantial expenses, and may encounter potential unknown liabilities and unforeseen increased expenses, delays or unfavorable conditions, in connection with the closing of the Thrive merger and other business acquisitions, including our acquisition of Base, whether or not such acquisitions are completed, and the subsequent integration, reducing our cash available for operations and other uses;
- the pendency of the Thrive merger or other acquisitions could adversely affect our business and operations, including by diverting significant focus of management and other resources and limiting our ability to execute certain business strategies;
- we may be unable to successfully integrate the acquired businesses into our business;

- we may lose key employees;
- we may encounter potential unknown liabilities and unforeseen risks associated with contracts containing consent and/or other provisions that may be triggered by the acquisitions;
- we may be unable to realize the anticipated benefits of the acquisitions or do so within the anticipated timeframe;
- our future results will suffer if we do not effectively manage our expanded operations; and
- the market price of our common stock may decline as a result of the acquisitions.

In the future, we may enter into transactions to acquire other businesses, products, services or technologies. Because we have only made a limited number of acquisitions to date, our ability to do so successfully is unproven. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by investors, healthcare providers, patients and others. In addition to the risks outlined above, we may decide to incur debt in connection with an acquisition or issue our common stock or other securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

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

In January 2020, we entered into an amendment to a services and license agreement with Mayo Foundation for Medical Education and Research (“Mayo”) relating to medical officer services provided by certain Mayo employees. As part of the agreement, in July 2020 we issued Mayo 4,984 shares of restricted stock.

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.
- At the time of the purchase, Mayo was an accredited investor, as defined in Rule 501(a) of the Securities Act.
- Mayo has had access to information regarding Exact and is knowledgeable about us and our business affairs.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On October 23, 2020, we notified The Nasdaq Stock Market (“Nasdaq”) of an inadvertent noncompliance with Nasdaq Listing Rule 5605(c) (“Rule 5605(c)”), which prohibits members of a listed company’s audit committee from receiving, directly or indirectly, consulting fees of any amount. During the time period from July 25, 2019, to October 22, 2020, Pierre Jacquet, a member of our board of directors, served as a member of our Audit and Finance Committee. Mr. Jacquet is Vice Chairman, Global Healthcare Managing Director at L.E.K. Consulting, a global management consulting firm that we have engaged from time to time to perform strategic consulting services for the

Company. We made payments to L.E.K. Consulting of \$359,231 during the period in which Mr. Jacquet served on our Audit and Finance Committee in 2019 and \$506,234 during the period in which Mr. Jacquet served on our Audit and Finance Committee in 2020. Mr. Jacquet did not provide the consulting services to the Company and did not receive any direct compensation related thereto. Once it was determined that the payments to L.E.K. Consulting were deemed indirect consulting fees to Mr. Jacquet under Rule 5605(c) by virtue of its requirement that members of a listed company's audit committee meet the criteria for independence set forth in Rule 10A-3(b)(1) under the Securities Exchange Act of 1934 (the "Exchange Act"), we promptly corrected the non-compliance. Daniel Levangie, who our board of directors has determined meets the criteria for independence required by Rule 5605(c), succeeded Mr. Jacquet as a member of the Audit and Finance Committee on October 22, 2020.

The notification to Nasdaq was made in accordance with Nasdaq Rule 5625, which requires a company with common securities listed on Nasdaq to report any noncompliance of Nasdaq's Rule 5600 Series. This report shall not constitute an admission that the inadvertent noncompliance reported herein is material.

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	Fourth Amended and Restated By-Laws of the Registrant		8-K (Exhibit 3.1)	1/31/2020	001-35092
10.1	Second Amended and Restated License Agreement, effective January 31, 2020, by and between Mayo Foundation for Medical Education and Research and the Registrant *	X			
10.2	Amended and Restated Cologuard Promotion Agreement by and between the Registrant and Pfizer, Inc.		8-K (Exhibit 10.1)	10/7/2020	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 September 30, 2020 filed on October 27, 2020, 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 September 30, 2020, filed with the Securities and Exchange Commission on October 27, 2020, is formatted in Inline Extensible Business Reporting Language (“iXBRL”)	X			

* Confidential portions of this exhibit, indicated by asterisks, have been omitted.

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: October 27, 2020

By: /s/ Kevin T. Conroy
Kevin T. Conroy
President and Chief Executive Officer
(Principal Executive Officer)

Date: October 27, 2020

By: /s/ Jeffrey T. Elliott
Jeffrey T. Elliott
Chief Financial Officer
(Principal Financial and Accounting Officer)

**MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH
SECOND AMENDED AND RESTATED LICENSE AGREEMENT**

This Second Amended and Restated License Agreement (this “**Agreement**”), effective as of January 31, 2020 (the “**Effective Date**”), is entered into by and between Mayo Foundation for Medical Education and Research, a Minnesota charitable corporation, located at the address set forth in Section 11.05 (“**Mayo**”), and Exact Sciences Development Company, LLC, a Delaware limited liability company, located at the address set forth in Section 11.05 (“**ESDC**”), each a “Party”, and collectively, “**Parties**”.

WHEREAS, Exact Sciences Corporation, a Delaware for-profit corporation located at the address set forth in Section 11.05 and sole equityholder in ESDC (“**Exact**”) and Mayo entered into that certain License Agreement effective June 12, 2009, as amended by that (i) Amendment No. 1 effective as of January 1, 2010, (ii) Amendment No. 2 effective as of 17 February 2011, (iii) Amendment No. 3 effective as of March 26, 2010, (iv) Amendment No. 4 effective as of May 15, 2012 and (v) Letter Agreement effective as of April 1, 2014, (such agreement, together with the foregoing amendments and letter agreement, collectively referred to as, the “**Original Agreement**”);

WHEREAS, Exact and Mayo entered into that certain Amended and Restated License Agreement effective January 31, 2015, to amend and restate the Original Agreement in its entirety, which agreement was amended pursuant to that certain (i) First Amendment to Amended and Restated License Agreement effective as of January 11, 2016, and (ii) Second Amendment to Amended and Restated License Agreement effective October 1, 2017 (the “**Second Amendment**”);

WHEREAS, pursuant to the Second Amendment, Mayo consented to the assignment of the agreement, as then amended, from Exact to ESDC, and ESDC agreed to assume and perform all covenants stipulations, agreements and obligations of Exact under the agreement, as then amended;

WHEREAS, ESDC and Mayo entered into that certain Third Amendment to Amended and Restated License Agreement effective as of January 1, 2019 (such amended and restated agreement, together with the foregoing First Amendment, Second Amendment and Third Amendment, collectively referred to as, the “**Prior Agreement**”);

WHEREAS, ESDC and Mayo are desirous of amending and restating the Prior Agreement in its entirety and creating a single second amended and restated agreement on the terms set forth below;

WHEREAS, Mayo desires to make its intellectual property rights available for the development and commercialization of products, methods and processes for public use and benefit;

WHEREAS, ESDC represents itself as being knowledgeable in developing and commercializing tests for the detection of Gastrointestinal cancer; and

WHEREAS, Mayo is willing to grant and ESDC is willing to accept an exclusive license under such rights for the purpose of developing such diagnostic tests.

NOW THEREFORE, in consideration of the foregoing and the terms and conditions set forth below, the Parties hereby agree as follows:

Article 1.00 — Definitions

For purposes of this Agreement, the terms defined in this Article will have the meaning specified and will be applicable both to the singular and plural forms:

1.01 For Mayo, “**Affiliate**”: any corporation or other entity within the same “controlled group of corporations” as Mayo or its parent Mayo Clinic. For purposes of this definition, the term “controlled group of corporations” will have the same definition as Section 1563 of the Internal Revenue Code as of 10 November 1998, but will include corporations or other entities which, if not a stock corporation, more than 50% of the board of directors or other governing body of such corporation or other entity is controlled by a corporation within the controlled group of corporations of Mayo or Mayo Clinic. Mayo’s Affiliates include, but are not limited to: Mayo Clinic; Mayo Collaborative Services, LLC; Mayo Clinic Hospital—Rochester; Mayo Clinic Rochester; Mayo Clinic Florida; Mayo Clinic Arizona; and its Mayo Health System entities. Mayo will provide ESDC with a list of current Affiliates within thirty (30) days after the Effective Date and thereafter, by January 31 of each year.

For ESDC, “**Affiliate**”: any corporation or other entity that controls, is controlled by, or is under common control with, ESDC, including Exact. For purposes of this definition, “control” means ownership of: (a) at least 50% of the outstanding voting securities of such entity; or (b) at least 50% of the decision-making authority of such entity.

1.02 “**Change of Control**”: a merger, acquisition, consolidation or other transaction or series or related transactions following which the holders of ESDC’s outstanding voting securities prior to such transaction hold less than 50% of the outstanding voting securities of the acquiring or surviving corporation or a sale, license or transfer of all or substantially all of ESDC’s assets to which this Agreement relates to a third party that is not an Affiliate of ESDC.

1.03 “**Cologuard**”: non-invasive colon cancer screening *in-vitro* diagnostic test kit developed by Exact and approved by the U.S. Food and Drug Administration on August 11, 2014, including any Update, Improvement or Replacement of Cologuard.

1.04 “**Cologuard 2.0**”: any non-invasive colon cancer screening *in-vitro* diagnostic test kit that Exact or its Affiliates may develop, but explicitly excluding Cologuard (and, for the avoidance of doubt, any Update, Improvement or Replacement of Cologuard).

1.05 “Confidential Information”: any information or material disclosed by one Party (or any Affiliate of a Party), the disclosing party, to the other (or any Affiliate of the other), the receiving party, identified in writing as confidential at the time of disclosure or, if first disclosed orally, identified as confidential and confirmed in writing, within forty-five (45) days. Confidential Information expressly includes Know How and data and inventions generated in connection with the Sponsored Research Agreement, activities pursuant to Section 2.06, and employing materials or data transferred from ESDC or Exact to Mayo. Confidential Information does not include any information or material that the receiving party evidences is: (a) already known to the receiving party at the time of disclosure (other than from the disclosing party); (b) publicly known other than through acts or omissions of the receiving party; (c) disclosed to the receiving party by a third party who was not and is not under any obligation of confidentiality; or (d) independently developed by employees of the receiving party without knowledge of or access to the Confidential Information.

1.06 “Gastrointestinal”: any organ that exfoliates cells into the lumen of the gastrointestinal tract (*i.e.*, (a) primary GI organs: esophagus, stomach, pancreas, small intestine, liver, bile duct, colon and rectum; (b) airway: pharynx, larynx, trachea, bronchi and lungs; and (c) head and neck: nasal passages, mouth and throat).

1.07 “FDA”: the United States Food and Drug Administration or any successor agency.

1.08 “Field”: any screening, surveillance or diagnostic test or tool intended for use in connection with (a) any cancer, precancer, or disease or condition which predisposes an individual to cancer, or (b) a project included in an annual statement of work under the Sponsored Research Agreement.

1.09 “Know-How”:

(a) unpublished research and development information, materials, technical data, unpatented inventions, know-how and supportive information of Dr. Ahlquist, Dr. Kisiel and any laboratory or research team operated in connection with the Original Agreement, the Prior Agreement or this Agreement by Dr. Ahlquist or Dr. Kisiel or his successor) or their respective laboratories as of the Original Agreement Effective Date, the Prior Agreement Effective Date and as of the Effective Date (such team or laboratory, including Dr. Ahlquist and Dr. Kisiel, the “**Collaborating Team**”) to the extent it is necessary for the development or manufacture of a Licensed Product. As of the Effective Date, such Know-How includes the Mayo File numbers set forth on Exhibit A, to the extent it is necessary for the development or manufacture of a Licensed Product.

(b) research and development information, technical data, unpatented inventions, know-how and supportive information developed by the Collaborating Team pursuant to Section 2.06 to the extent it is necessary for the development or manufacture of a Licensed Product; and

(c) research and development information, technical data, unpatented inventions, know-how and supportive information developed by Mayo as a result of Mayo’s activities under

the Sponsored Research Agreement to the extent it is necessary for the development or manufacture of a Licensed Product.

1.10 “Licensed Product”: any product or process: (a) described by a pending claim of the Patent Rights, which claim has not lapsed, become abandoned, or been pending for more than ten years; (b) infringing a Valid Claim of the Patent Rights, or that would infringe but for the exception in 35 U.S.C. §271(e)(1), or similar exception in the United States or other countries; (c) the manufacture, use, sale, offer for sale, or importation of which incorporates or uses markers identified by Mayo; or (d) the development of which utilized the material and substantial contribution of Know-How.

1.11 “Materials”:

(a) Mayo Materials are biological specimens of human origin, including tissues, blood, plasma, urine, stool and derivatives thereof used by Mayo pursuant to work by the Collaborating Team within the Field pursuant to Section 2.06 or provided by Mayo (including by Dr. Ahlquist or Dr. Kisiel) to ESDC or Exact for use within the Field.

(b) ESDC Materials include any material provided by ESDC or Exact to Mayo pursuant to Section 2.06.

1.12 “Net Sales”: the amount invoiced by ESDC or Sublicensee for the transfer of a Licensed Product to a third party less documented: (a) sales, excise or use taxes shown on the face of the invoice, excluding value-added tax; (b) credits for defective or returned Licensed Products actually given; (c) regular trade and discount allowances given; and (d) write-offs and write-downs of uncollected invoices. Leasing, lending, consigning or any other activity by means of which a third party acquires the right to possess or use a Licensed Product is a transfer for the purpose of determining Net Sales. Net Sales on Licensed Products transferred as part of a non-cash exchange or other than to third parties shall be calculated at the then-current customary sales price invoiced to third parties or fair market value if there are no current invoices to third parties. For the avoidance of doubt, the Parties agree that Exact Sciences Laboratories, LLC (“ESL”) shall be deemed a “third party” for purposes of this “Net Sales” definition. Net Sales accrues with the delivery of an invoice for a Licensed Product associated with a reportable patient result.

For purposes of this definition of “Net Sales” and the calculation of milestone fees under Section 3.02 and Earned Royalties under Section 3.03, the phrase “amount invoiced by ESDC or Sublicensee for the transfer of a Licensed Product to a third party” shall be deemed to mean:

(a) with respect to Cologuard, the amount invoiced by ESDC or Sublicensee to a laboratory, including ESL, for the transfer of Cologuard to such laboratory as an *in-vitro* diagnostic test kit and shall not include any amounts invoiced (including amounts invoiced by ESL) to or received from a patient or payor for the performance of Cologuard as a test service; provided, however, that in the event Cologuard is transferred by ESDC to ESL as an *in-vitro* diagnostic kit, the amount invoiced by ESDC to ESL for such transfer, for purposes of determining “Net Sales” with respect to such transfer, shall be deemed to be the greater of (i) the

amount actually invoiced by ESDC to ESL per reportable patient result, and (ii) [***] percent ([***]%) of the List Price of Cologuard as a test service per reportable patient result; “List Price” is the price publicly identified by ESDC or ESL as the “list price” for Cologuard as a test services on a website at the beginning of each quarter;

(b) with respect to Cologuard 2.0, \$[***] per test service resulting in revenues (construed according to GAAP) to a laboratory, including ESL (an “**Exact Lab**”);

(c) with respect to a Licensed Product, including a pan-cancer Licensed Product, other than Cologuard or Cologuard 2.0;

(i) to the extent such Licensed Product is marketed by ESDC or Sublicensee as an in-vitro diagnostic test kit (“IVD”), [***] PERCENT ([***]%) of the gross amount received by ESDC or the Exact Lab from a patient or payor for the performance of such test service; or

(ii) to the extent such Licensed Product is marketed by ESDC or Sublicensee as a lab-developed test service (“LDT”) and not as an IVD, the gross amount received by ESDC or Sublicensee (which may include ESL) from a patient or payor for the performance of such LDT;

The classification of a Licensed Product as an LDT or an IVD shall be determined on a jurisdiction by jurisdiction basis. By way of example, if a product is marketed as an IVD in China but as an LDT in the US, ESDC would pay the applicable IVD rates with respect to Net Sales in China and the applicable LDT rates with respect to Net Sales in the U.S. Nothing in this Agreement will be construed to limit ESDC’s discretion with respect to the development of a Licensed Product, including with respect to the determination to market a Licensed Product as an IVD or an LDT in any jurisdiction.

The Parties agree that Net Sales shall not include for any purpose hereunder, and no Earned Royalties or milestones shall be payable hereunder relating to, any amounts received by ESDC or Sublicensee as a result of transfers to, or uses by, Mayo or Mayo Affiliates. In addition, Net Sales shall not include for any purpose hereunder, and no Earned Royalties or milestones shall be payable hereunder relating to, amounts received by ESDC or Sublicensee with respect to Licensed Products, or transfers of Licensed Products, that are used or made in connection with orders made by Mayo, a Mayo Affiliate or any physician, healthcare provider or other party associated with Mayo or a Mayo Affiliate. Notwithstanding the foregoing, however, transfers by ESDC of Licensed Products to Mayo Collaborative Services, LLC shall be considered transfers for purposes of determining Net Sales and for calculating Earned Royalties in those instances in which such Licensed Product is used as a test for a patient and ordered by a third party other than Mayo, a Mayo Affiliate or any physician or other party associated with Mayo or a Mayo Affiliate.

1.13 “Original Agreement Effective Date”: June 12, 2009.

1.14 “Patent Rights”:

(a) U.S. patents and applications listed in Exhibit B hereto, together with divisionals, continuations, and continuations-in-part (but only for subject matter supported pursuant to 35 U.S.C. §112 by the foregoing) therefrom, patents issuing thereon, re-examinations and re-issues thereof, as well as extensions and supplementary protection certificates and any foreign counterpart of any of the foregoing;

(b) Any patent applications filed as a result of the Collaborating Team's activities pursuant to Section 2.06, together with divisionals, continuations, and continuations-in-part (but only for subject matter supported pursuant to 35 U.S.C. §112 by the foregoing) therefrom, patents issuing thereon, re-examinations and re-issues thereof, as well as extensions and supplementary protection certificates and any foreign counterpart of any of the foregoing;

(c) Any patent applications filed with Mayo inventors as a result of activities performed by Mayo under the work plans that are part of the Sponsored Research Agreement, together with divisionals, continuations, and continuations-in-part (but only for subject matter supported pursuant to 35 U.S.C. §112 by the foregoing) therefrom, patents issuing thereon, re-examinations and re-issues thereof, as well as extensions and supplementary protection certificates and any foreign counterpart of any of the foregoing; and

(d) Any patent applications filed disclosing or describing data generated using ESDC Materials or reagents provided by ESDC or Exact to Mayo.

As part of Mayo's semi-annual update to Exhibit B pursuant to Section 2.07, Mayo shall add a patent or patent application, along with the patent or application number, title, and filing date, to Exhibit B if either: (i) it is a patent or patent application defined by any of Section 1.14(b), (c) or (d); or (ii) Mayo provides written confirmation that the patent or patent application is within Patent Rights.

1.15 "PMA": FDA Premarket Approval Application.

1.16 "Prior Agreement Effective Date": January 31, 2015.

1.17 "Sponsored Research Agreement": that agreement dated effective as of June 11, 2009, by and between Mayo, with Dr. Ahlquist as principal investigator, and Exact. Effective October 1, 2017, Exact assigned such agreement to ESDC. The Sponsored Research Agreement was amended by that certain Amendment #1 effective January 1, 2019, by and among Mayo and ESDC and acknowledged by Dr. Kisiel as investigator in place of Dr. Ahlquist. The Sponsored Research Agreement outlines the research to be funded by ESDC and performed at Mayo, as agreed upon by such parties in accordance with the Original Agreement. The Sponsored Research Agreement is also the mechanism whereby Mayo bills ESDC on a monthly or quarterly basis, as needed, for support of research expenses for mutually agreed upon protocols/budgets for ESDC-Mayo collaborations.

1.18 "Sublicensee": any third party or any Affiliate to whom ESDC or Exact has conveyed rights or the forbearance of suit under the Patent Rights, Know-How and Materials.

1.19 “Term”: begins on the Original Agreement Effective Date and ends, subject to Article 10, upon the expiration date of the last to expire of the Patent Rights, unless the Know-How or Materials are still in use in a manner generating Net Sales, in which case upon the earlier of five (5) years following the expiration date of the last to expire of the Patent Rights or the date upon which ESDC or Exact, as applicable, ceases such use of the Know-How or Materials.

1.20 “Territory”: worldwide.

1.21 “Update, Improvement or Replacement”: an assay that modifies an existing FDA-approved assay and is FDA compliant without the requirement of a *de novo* PMA.

1.22 “Valid Claim”: a claim of an unexpired, issued or granted Patent Right, excluding any claims that have been held invalid or unenforceable, or are patentably indistinct from claims that have been held invalid or unenforceable.

Article 2.00 — Grant of Rights

2.01 GRANT. Subject to the terms and conditions of this Agreement, Mayo grants to ESDC: (a) an exclusive license with the right to sublicense, within the Field and Territory, under the Patent Rights to make, have made, use, offer for sale, sell, and import Licensed Products; and (b) a nonexclusive license with the right to sublicense, within the Field and Territory, to use the Know-How to develop, make, have made, use, offer for sale, sell, and import Licensed Products.

2.02 RESERVATION OF RIGHTS. All rights herein are subject to (a) the rights and obligations to and requirements of the U.S. government, if any have arisen or may arise, regarding the Patent Rights, including as set forth in 35 U.S.C. §§200 *et al.*, 37 C.F.R. Part 401 *et al.* (“**Bayh-Dole Act**”); and (b) Mayo’s and its Affiliates’ reserved, irrevocable right to practice and have practiced the Patent Rights in connection with Mayo’s and its Affiliates’ educational, research and non-commercial, and non-competitive with ESDC, clinical programs (for the avoidance of doubt, Mayo will not practice the Patent Rights to develop or offer to third parties products or services that are competitive to any product or service offered or sold by ESDC or its Affiliates). ESDC agrees to comply with the provisions of the Bayh-Dole Act, to the extent such act applies and a waiver has not been obtained, including promptly providing Mayo with information requested to enable Mayo to meet its compliance requirements and substantially manufacturing Licensed Product in the U.S.

2.03 NO OTHER RIGHTS GRANTED. This Agreement does not grant any right, title or interest in or to any tangible or intangible property right of Mayo or its Affiliates, including any improvements thereon, or to any Patent Rights or Know-How and Materials outside the Field or Territory that is not expressly stated in Section 2.01 or 2.07. All such rights, titles and interests are expressly reserved by Mayo, and ESDC agrees that in no event will this Agreement be construed as a sale, an assignment, or an implied license by Mayo or its Affiliates to ESDC of any such tangible or intangible property rights. This Agreement does not grant any right, title or interest in or to any tangible or intangible property right of ESDC or its Affiliates, including rights in jointly owned intellectual property, unless expressly recited herein.

2.04 SUBLICENSES. Any sublicense by ESDC shall be to a Sublicensee that agrees in writing to be bound by substantially the same terms and conditions as ESDC herein, and with the financial terms and conditions at least as favorable to Mayo as set forth in this Agreement, or such sublicense shall be null and void. Sublicenses granted hereunder shall not be transferable, including by further sublicensing, delegatable or assignable without the prior written approval of Mayo. ESDC will provide Mayo with a copy of each sublicense agreement promptly after execution. ESDC is responsible for the performance of all Sublicensees as if such performance were carried out by ESDC itself, including the payment of any royalties or other payments provided for hereunder triggered by Sublicensee, regardless of whether the terms of any sublicense require that Sublicensee pay such amounts (such as in a fully paid-up license), or that such amounts be paid by the Sublicensee directly to Mayo. Each sublicense agreement shall name Mayo as a third party beneficiary and, unless Mayo has provided written consent, all rights of Sublicensees shall terminate when ESDC's rights terminate. The parties acknowledge that ESDC has sublicensed to Exact rights under this Agreement and that Exact may desire to further sublicense the rights granted under said sublicense. Mayo hereby consents to one tier of sublicense from Exact, provided that any such sublicense meets all other requirements under this Section 2.04.

2.05 USE OF MATERIALS.

- (a) Mayo Materials.
 - (i) Use of the Mayo Materials by Mayo or ESDC shall be subject to the prior approvals of Mayo's Institutional Review Board and the Mayo Clinic Research Biospecimen Subcommittee.
 - (ii) Mayo Materials are owned by Mayo and any transfer of such Mayo Materials to ESDC under the terms of this Agreement shall not affect Mayo's ownership interest therein. Mayo shall clearly mark and identify all Mayo Materials transferred to ESDC. All Mayo Materials will be maintained by ESDC so that such Mayo Materials are readily identifiable. The transfer of Mayo Materials to ESDC gives ESDC no rights in such Mayo Materials other than those specifically set forth in this Agreement. ESDC agrees to use the Mayo Materials solely for research purposes and shall not transfer, deliver or otherwise release such Materials to a third party without the express prior written consent of Mayo. Upon expiration of a project and at the instructions of Mayo, ESDC shall either return to Mayo or destroy all unused Mayo Materials.
 - (iii) ESDC agrees to use the Mayo Materials in accordance with the rights granted to ESDC under this Agreement. All research conducted by ESDC using the Mayo Materials shall be conducted in accordance with all applicable state and federal laws regarding such research.
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- (iv) Nothing in this Agreement provides ESDC the right to transfer nucleic acids or any other material extracted from Mayo Materials to any third-party.
- (b) ESDC Materials.
- (i) Mayo agrees to use the ESDC Materials solely for purposes pursuant to Section 2.06. Upon expiration of a project and at the instructions of ESDC, Mayo shall either return to ESDC or destroy all unused ESDC Materials.
 - (ii) All research conducted by Mayo using the ESDC Materials shall be conducted in accordance with all applicable state and federal laws regarding such research.
 - (iii) Mayo shall not transfer, deliver or otherwise release ESDC Materials to a third party without the express prior written consent of ESDC.
 - (iv) Mayo shall treat the ESDC Materials and related information as Confidential Information under Article 8.

2.06 COMMITMENT TO CONFER.

(a) Mayo will collaborate with ESDC on the development of Licensed Products, including sharing Know-How and providing access to Mayo Materials and laboratory equipment, conducting scientific studies, providing biostatistical support, and making submissions for peer-reviewed publications (Mayo files #2009-169, #2012-130, and #2020-207).

(b) Between the Prior Agreement Effective Date and January 1, 2019, Dr. Ahlquist was obligated to, and did, consult on, collaborate with, and oversee Exact and ESDC on product development efforts, as a special advisor to the Exact board of directors and senior management. Between the Prior Agreement Effective Date and the Effective Date, Dr. Kisiel was obligated to, and did, consult on, collaborate with, and oversee ESDC on product development efforts, as a special advisor to the Exact board of directors and senior management. Beginning on the Effective Date and continuing through February 1, 2025, and for so long as Dr. Kisiel is an employee of Mayo (the “**Commitment to Confer Period**”), Dr. Kisiel will consult on, collaborate with, and oversee ESDC on product development efforts, as a special advisor to the Exact board of directors and senior management on behalf of ESDC. ESDC will confer with Dr. Kisiel in person in Rochester, MN, Madison, WI or as mutually agreed, or by telephone. All travel expenses incurred by Dr. Kisiel in this role as advisor shall be paid by ESDC. Dr. Kisiel will contribute up to 50% of his time to services for ESDC, with the remainder of his time allocated to clinical practice. Mayo shall be solely responsible for compensating Dr. Kisiel, provided, however, that in consideration of the services provided under this Section 2.06(b), ESDC shall pay Mayo the amounts set forth in Section 3.05. If for any reason Dr. Kisiel becomes unavailable to direct the performance of the work under this Agreement, Mayo shall notify ESDC and the Parties will work together to identify a mutually acceptable successor to provide

the advisory services formerly provided by Dr. Kisiel, as well as mutually acceptable compensation to replace that described in Section 3.05 for Dr. Kisiel, with the intent to keep Dr. Kisiel's research team and projects intact; provided, however, if the Parties fail to agree on a mutually acceptable successor within a reasonable period of time, ESDC may, upon written notice to Mayo, terminate the Commitment to Confer Period and the Parties' obligations under this Section 2.06(b) as well as ESDC's payment obligations under Section 3.05 (for the avoidance of doubt, any such terminations shall not have the effect of terminating ESDC's other rights under this Agreement, including its license rights).

(c) Notwithstanding ESDC's rights to sublicense pursuant to Section 2.01, ESDC shall not have the right to sublicense any obligation of Dr. Kisiel to confer. In addition, in the event of a Change of Control, Mayo may, within thirty (30) days of the effective date of such Change of Control, terminate the Parties' obligations under Section 2.06(b), which shall automatically result in the termination of ESDC's payment obligations under Section 3.05 (for the avoidance of doubt, any such terminations shall not have the effect of terminating ESDC's other rights under this Agreement, including its license rights).

2.07 LICENSE GRANT FOR NEW MARKERS.

(a) Mayo grants to ESDC a perpetual exclusive license within the Field with the right to sublicense, make, have made, use, offer for sale, sell, and import Licensed Products that incorporate, use, or derive from any markers identified by any member of the Collaborating Team from the Effective Date through the expiration or earlier termination of the Commitment to Confer Period, whether such markers are patented or unpatented. Mayo represents and warrants that all such markers that have been identified as of the Effective Date, along with any associated patent or patent application number, title, and filing date, are listed on Exhibit B hereto, and Mayo agrees that it shall update Exhibit B from time to time to include all new markers within the Field, along with any associated patent or patent application number, title, and filing date. Exhibit B shall be updated on a semi-annual basis.

(b) Notwithstanding anything to the contrary in this Section 2.07, Mayo and its Affiliates reserve the right to use (without a right to license or otherwise authorize any other parties) in connection with their educational, research and clinical programs, including use by Mayo Collaborative Services for both Mayo and non-Mayo patients, any such marker in connection with any disease or condition, provided that:

- (i) such marker was previously identified as relating to the same cancer, precancer, disease or condition for which any member of the Collaborating Team subsequently identified the markers for ESDC:

(A) by a third party and published in a patent or patent application, peer-reviewed scientific journal, other widely-circulated scientific publication, or distributed in print at a national scientific conference, provided Mayo shall notify ESDC in writing of any such previous public identification of such markers prior to Mayo or its Affiliates exercising the right to use those markers, or

(B) by Mayo outside of and without assistance of any member of the Collaborating Team and disclosed to Mayo Clinic Ventures, provided that Mayo shall notify ESDC in writing of any such previous identification within ninety (90) days of receipt of the disclosure from the Collaborating Team; or

(ii) each of the following is true:

(A) at least one (1) year has elapsed since such marker was identified to ESDC in writing as provided in Section 2.07(a) above; and

(B) the use of such marker in connection with such cancer, precancer, disease or condition is not covered by a claim within a pending application of the Patent Rights; and

(C) such marker is not under Active Development in connection with such cancer, precancer, disease or condition by or on behalf of ESDC; or

(iii) each of the following is true:

(A) at least four (4) years have elapsed since such marker was identified to ESDC in writing as provided in Section 2.07(a) above; and

(B) the use of such marker in connection with such cancer, precancer, disease or condition is not covered by a Valid Claim; and

(C) such marker is not under Active Development in connection with such cancer, precancer, disease or condition by or on behalf of ESDC.

(a) Additionally, to exercise the rights provided in Section 2.07(b), Mayo must provide (i) written notice to ESDC of Mayo's interest in exercising its rights under this Section 2.07(b), including an identification and explanation of the specific markers of interest to Mayo, and (ii) ESDC with the opportunity to confirm, within sixty (60) days, that either Section 2.07(b)(i) or Section 2.07(b)(ii) in fact applies, and ESDC either has confirmed that either Section 2.07(b)(i) or Section 2.07(b)(ii) in fact applies, or has failed to respond within sixty (60) days.

(b) In the event a marker is either (i) under Active Development and not covered by a Valid Claim but is covered by a pending claim that has been pending for more than seven (7) years from the filing date from which such claim takes priority, or (ii) not under Active Development but is covered by a Valid Claim, then, upon request by Mayo, the Parties will discuss in good faith ESDC granting Mayo the right to use such markers, unless ESDC has exclusively sublicensed such markers to a third party that is not an Affiliate of ESDC. In negotiating the terms, conditions and pricing for any such grant, the parties would consider, among other factors, (i) ESDC's and Mayo's relative investments in such markers to date, (ii) the market conditions at such time, (iii) Mayo's proposed use for such markers, and (iv) the mutually expressed intent of the parties to see such markers utilized for the benefit of patients.

(c) “Active Development” shall mean the ongoing expenditure of reasonable resources (including under the Sponsored Research Agreement) toward the commercialization of a Licensed Product in one or more of the following activities: marker validation, assay development, preparation or performance of clinical studies, data analysis, test manufacturing, preparation for or pursuit of regulatory approvals or payor coverage, preparing or offering to sell. For purposes of clarification, any of the foregoing activities for a Licensed Product constitutes Active Development of all markers remaining under Active Development for all Licensed Product for the same cancer, precancer, disease or condition. The Parties acknowledge that (i) a marker may be under Active Development for multiple Licensed Products (including Licensed Products for the same cancer, precancer, disease or condition), (ii) a marker would be considered to remain under Active Development during reasonable pauses between development activities, provided that such pause lasts no longer than six months and ESDC maintains the good faith intention to continue development of such marker for a Licensed Product, (iii) discontinuation of Active Development with respect to a marker for one Licensed Product does not constitute discontinuation of Active Development with respect to a marker for any other Licensed Product, and (iv) activities performed by a diagnostic reference laboratory that is not an Affiliate of ESDC under a sublicense do not constitute Active Development.

Article 3.00 — Consideration and Royalties

3.01 PAYMENTS TO MAYO.

(a) The Parties agree and acknowledge that payments were made under the Original Agreement and Prior Agreement and that no payments, including royalty payments, or other consideration are now owing under either of the foregoing agreements.

(b) As additional consideration for the services provided under Section 2.06(b), ESDC shall make five (5) annual payments to Mayo of ONE MILLION TWO HUNDRED FIFTY THOUSAND DOLLARS (\$1,250,000) each, commencing on September 18, 2020 (with the second annual payment due on January 31, 2021, the third annual payment due on January 31, 2022, the fourth annual payment due on January 31, 2023 and the fifth annual payment due on January 31, 2024); provided, however, that ESDC’s obligation to make the payments set forth in this Section 3.01(b) shall terminate upon ESDC’s termination of the Parties’ obligations under Section 2.06(b) pursuant to ESDC’s termination rights thereunder; and provided, further, however, that the payments set forth in this Section 3.01(b) shall accelerate and become due and payable in full within thirty (30) days following the effective date of Mayo’s termination of the Parties’ obligations under Section 2.06(b) pursuant to Mayo’s termination rights under Section 2.06(c) resulting from a Change of Control. Within MAYO, this additional consideration will be allocated to file #2020-207.

3.02 MILESTONE FEES. ESDC will pay the following nonrefundable and non-creditable milestone fees to Mayo:

(a) TWO HUNDRED THOUSAND DOLLARS (\$200,000) cash payment, paid in two annual installments of ONE HUNDRED THOUSAND DOLLARS (\$100,000) each, over a

two (2) year period, upon each Licensed Product launched after the Effective Date reaching FIVE MILLION DOLLARS (\$5,000,000) in cumulative Net Sales;

(b) SEVEN HUNDRED FIFTY THOUSAND DOLLARS (\$750,000) cash payment, paid in two annual installments of THREE HUNDRED SEVENTY-FIVE THOUSAND DOLLARS (\$375,000) each, over a two (2) year period, upon each Licensed Product launched after the Effective Date reaching TWENTY MILLION DOLLARS (\$20,000,000) in cumulative Net Sales;

(c) TWO MILLION DOLLARS (\$2,000,000) cash payment, paid in two annual installments of ONE MILLION DOLLARS (\$1,000,000) each, over a two (2) year period, upon each Licensed Product launched after the Effective Date reaching FIFTY MILLION DOLLARS (\$50,000,000) in cumulative Net Sales.

(d) For the avoidance of doubt, the Parties acknowledge and agree that Cologuard was launched *prior to* the Effective Date.

(e) In no event shall ESDC be required to pay milestone fees to Mayo with respect to each individual Licensed Product, including a pan-cancer Licensed Product, more than one time under Sections 3.02(a), 3.02(b), and 3.02(c).

3.03 EARNED ROYALTIES. ESDC will make nonrefundable and noncreditable earned royalty payments to Mayo of a percentage of Net Sales of Licensed Products (“**Earned Royalties**”). The Earned Royalties are payable as described in Section 4.01. Licensed Products transferred to Mayo or its Affiliates are not considered transfers for purposes of determining Net Sales or for calculating Earned Royalties.

The Earned Royalties shall be paid as follows:

(a) [***] percent ([***]%) of the Net Sales of Cologuard;

(b) Subject to the royalty-stacking limitations described in clauses (i) and (ii) below, for Licensed Products that are commercially launched after Cologuard: (A) [***] percent ([***]%) of the Net Sales of such products to the extent marketed by ESDC or Sublicensee as IVDs, and (B) [***] percent ([***]%) of Net Sales of such products to the extent marketed by ESDC or Sublicensee as LDTs and not as IVDs.

(i) Notwithstanding the foregoing, the Earned Royalty percentages set forth in this subsection shall increase to (i) [***] percent ([***]%) of the Net Sales of such Licensed Product to the extent marketed by ESDC or Sublicensee as an IVD, and (ii) [***] percent ([***]%) of the Net Sales of such Licensed Product to the extent marketed by ESDC or Sublicensee as a LDT and not as an IVD, in each case, if, and only if, an Additional Contribution is made to the Licensed Product. An “Additional Contribution” shall mean a material and substantial contribution of research and development effort resulting in (i) Know-How that actually is

used in and specifically incorporated into a Licensed Product or (ii) a Valid Claim of the Patent Rights that a Licensed Product would infringe, which such contribution (x) is made by a Mayo employee who is not a member of the Collaborating Team (“Additional Collaborator”), (y) has received ESDC’s prior written authorization, and (z) is performed pursuant to this Agreement and the Sponsored Research Agreement. For the avoidance of doubt, merely contributing samples, or assisting in or facilitating the collection of samples, would not be considered a “a material and substantial contribution of research development effort”. Exhibit C sets forth (i) all Additional Collaborator contributions that ESDC has authorized as of the Effective Date, (ii) all Additional Collaborators authorized to perform each authorized contribution and (iii) whether each authorized contribution has been completed.

- (ii) In the event that ESDC or Sublicensee is required or agrees to pay a royalty to one or more third parties unaffiliated with ESDC (including Mayo Affiliates) for rights under or to any intellectual property relating to a Licensed Product commercially launched after Cologuard, and if the total percentage of such royalty obligation, when added to the Earned Royalty percentage otherwise payable to Mayo under Section 3.03(b), exceeds [***] percent ([***]%) of Net Sales, then ESDC shall be entitled to reduce the Earned Royalty percentage payable to Mayo under Section 3.03(b) for such Licensed Product by an amount equal to the amount of such excess multiplied by a fraction, the numerator of which is the Earned Royalty percentage otherwise payable by ESDC to Mayo under Section 3.03(b) and the denominator of which is the total percentage royalty otherwise payable by ESDC or Sublicensee to Mayo and such third parties with regard to such Licensed Product; provided, however, in no event shall any Earned Royalty percentage under Section 3.03(b) be reduced by operation of this Section 3.03(b)(iii) to less than [***] percent ([***]%). For example, if the Earned Royalty percentage otherwise payable to Mayo under Section 3.03(b) for a given Licensed Product launched after Cologuard were [***] percent ([***]%), and if ESDC or Sublicensee agreed to pay one third-party licensor [***] percent ([***]%) and another third-party licensor [***] percent ([***]%) with regard to intellectual property for the same Licensed Product, the Earned Royalty percentage payable to Mayo under Section 3.03(b) would be reduced by [***] percent ([***]%) to three and [***] percent ([***]%) $[(\text{[***]}\% - \text{[***]}\%) \times (\text{[***]}\% / \text{[***]}\%) = \text{[***]}\%]$.

(c) In no event shall ESDC be required to pay Earned Royalties to Mayo with respect to a given Licensed Product under more than one of Sections 3.03(a) and 3.03(b) (subject to reduction under Section 3.03(b)(iii)). For example, in the event that a Licensed Product could be construed to include two or more separate Licensed Products that otherwise would be subject to Earned Royalty payments under Section 3.03(b), the Earned Royalty would be calculated only

pursuant to Section 3.03(b) (subject to reduction under Section 3.03(b)(iii) and would not be calculated as two (or more) times an Earned Royalty under Section 3.03(b). If more than one Earned Royalty rate would otherwise be applicable for a given Licensed Product, only the higher Earned Royalty rate would be paid.

3.04 [Intentionally deleted]

3.05 COMPENSATION TO MAYO FOR KISIEL KNOW-HOW. During the Commitment to Confer Period, ESDC will reimburse Mayo for up to fifty percent (50%) of Dr. Kisiel's salary and benefits (the "**Reimbursement Amount**"). As of the Effective Date, Mayo projects that the Reimbursement Amount for year 2020 will be approximately [***] (\$[***]). The actual Reimbursement Amount shall be subject to reasonable standard programmed adjustments in salary and benefits and shall be determined based on the portion of time that Dr. Kisiel contributed to services for ESDC during the applicable quarter. For example, if in a particular quarter, Dr. Kisiel contributed forty-five percent (45%) of his time to services for ESDC and fifty-five percent (55%) of his time to clinical practice, ESDC would reimburse Mayo for forty-five percent (45%) of Dr. Kisiel's salary and benefits. On a quarterly basis Mayo will deliver to ESDC an invoice setting forth (i) Dr. Kisiel's then current salary and benefits, (ii) the portion of Dr. Kisiel's time contributed to services to ESDC during the applicable quarter and (iii) the Reimbursement Amount for the applicable quarter. Such invoices shall be paid by ESDC within thirty (30) days of receipt. The financial information in this Section 3.05 is Mayo's Confidential Information. This amount will be proportionately adjusted each year based on any increase in that year's rate of salary and benefits for Dr. Kisiel as compared to the prior year.

3.06 TAXES. ESDC is responsible for all taxes, duties, import deposits, assessments, and other governmental charges, however designated, which are now or hereafter imposed by any authority on ESDC: (a) by reason of the performance by Mayo of its obligations under this Agreement, or the payment of any amounts by ESDC to Mayo under this Agreement; (b) based on the Patent Rights; or (c) related to use, sale or import of the Licensed Product. Any withholding taxes which ESDC is required by law to withhold on remittance of the royalty payments shall be deducted from the royalty paid and ESDC shall promptly furnish Mayo with original copies of all official receipts for such taxes. ESDC will obtain, or assist Mayo in obtaining, any tax reduction (including avoidance of double taxation), tax refund or tax exemption available to Mayo by treaty or otherwise. Notwithstanding the foregoing, Mayo shall be responsible for paying and withholding all employment related taxes with respect to the services of members of the Collaborating Team.

3.07 U.S. CURRENCY. All payments to Mayo under this Agreement will be made by draft drawn on a U.S. bank, and payable in U.S. dollars. In the event that conversion from foreign currency is required in calculating a payment under this Agreement, the exchange rate used shall be the Interbank rate quoted by Citibank at the end of the last business day of the month in which the payment accrued. Unless otherwise specified herein, all references to currency, monetary values and dollars set forth herein shall mean United States (U.S.) dollars.

3.08 OVERDUE PAYMENTS. If overdue, the payments due under this Agreement shall bear interest until paid at a per annum rate two percent (2%) above the prime rate in effect at Citibank

on the due date and Mayo shall be entitled to recover, in addition to all other remedies, reasonable attorneys' fees and costs related to the administration or enforcement of this Agreement, including collection of payments, following such failure to pay. The acceptance of any payment, including of such interest, shall not foreclose Mayo from exercising any other right or seeking any other remedy that it may have as a consequence of the failure of ESDC to make any payment when due.

Article 4.00 — Accounting and Reports

4.01 REPORTS AND PAYMENT. ESDC will deliver to Mayo on or before the following dates: 1 February, 1 May, 1 August, and 1 November, a written report setting forth a full accounting showing how any Earned Royalties due to Mayo for the preceding quarter have been calculated as provided in this Agreement, including an accounting of total Net Sales with a reporting of any applicable foreign exchange rates, deductions, allowances, and charges. If no Licensed Product transfers have occurred and no other amounts are due to Mayo, ESDC will submit a report so stating. Each such report will be accompanied by the payment of all amounts due for such quarter.

4.02 ACCOUNTING. ESDC will keep complete, continuous, true, and accurate books of accounts and records sufficient to support and verify diligence and the calculation of Net Sales, all royalties and any other amount believed due and payable to Mayo under this Agreement. Such books and records will be kept at ESDC's principal place of business for at least three years after the end of the year to which they pertain, and will be open at all reasonable times for inspection by a representative of Mayo for verification of royalty statements or compliance with other aspects of this Agreement. The Mayo representative will treat as confidential all relevant matters and will be a person or firm reasonably acceptable to ESDC. In the event such audit reveals an underpayment by ESDC, ESDC will within thirty (30) days pay the royalty due in excess of the royalty actually paid. In the event the audit reveals an underpayment by ESDC of more than five percent (5%) of the amount due, ESDC will pay interest on the royalty due in excess of the royalty actually paid at a per annum rate two per cent (2%) above the prime rate in effect at Citibank on the date notice of the deficiency is provided to ESDC, and ESDC will pay all of Mayo's costs in conducting the audit.

Article 5.00 — Diligence

5.01 DEVELOPMENT PLAN. ESDC will make commercially reasonable efforts to bring Licensed Products to market.

5.02 DEVELOPMENT REPORTS AND INQUIRIES. ESDC will provide Mayo with annual reports that set forth: (a) Licensed Products under Active Development, (b) the Mayo-identified markers under Active Development for each Licensed Product, (c) the efforts constituting Active Development during the preceding annual period, and (d) an updated development plan for the next annual period. In addition, upon request by Mayo that includes a substantive explanation of the rationale or basis for Mayo's request for an update on those specific markers, ESDC will make commercially reasonable efforts to provide an update as to the status of specific markers of interest. All reports and updates provided under this Section 5.02

are ESDC's Confidential Information and may not be shared with any Mayo personnel outside the department of Business Development, or any third parties, and specifically may not be provided in any manner to any commercial labs of Mayo or its Affiliates. Notwithstanding the above, the department of Business Development may share with the department of Laboratory Medicine and Pathology and Mayo Collaborative Services the list of markers under Active Development for a given cancer, precancer, disease or condition.

5.03 THIRD PARTY COLLABORATIONS REGARDING ANCILLARY PRODUCTS. To the extent that ESDC or its Affiliates do not have currently available resources to develop and bring to market a commercially viable new product that is (a) identified by the Parties pursuant to their work under this Agreement, (b) covered by a jointly owned Patent Right and (c) not competitive with any existing or planned product of ESDC or its Affiliates (an "**Ancillary Product**"), the Parties agree to use their good faith, commercially reasonable efforts to explore entering into an agreement with a third party pursuant to which such third party would undertake such development or marketing activities and would provide the Parties with royalties, milestone payments, or such other consideration upon which the Parties may agree between themselves and with such third party. The Parties will schedule a meeting or phone conference to discuss this topic at least once per year.

Article 6.00 — Intellectual Property Management

6.01 CONTROL.

(a) ESDC shall diligently prosecute and maintain the United States and foreign patents and patent applications covering Patent Rights as it deems appropriate, at ESDC's expense, using counsel of its choice and after due consultation with Mayo. ESDC shall provide Mayo with copies of all relevant documentation so that Mayo may be informed and apprised of the continuing prosecution and Mayo agrees to keep this documentation confidential. ESDC shall also notify Mayo of its intention to not apply for patent protection for any invention with a Mayo inventor or to abandon the prosecution of any patent within the Patent Rights thirty (30) days prior to any applicable deadlines affecting such application or abandonment. Following such written notification and discussion between the Parties, Mayo shall be entitled to take over prosecution of such patent, at its own expense, of those patents within the Patent Rights that ESDC has elected not to pursue and, for Mayo owned patents and patent applications, ESDC shall then have no further rights to any patent that issues under such prosecution. For jointly owned patents and patent applications, ESDC shall retain its ownership rights.

(b) The Parties shall take commercially reasonable steps to ensure that the Know-How and Materials remain confidential in accordance with Article 8.

6.02 PATENT TERM EXTENSION. ESDC shall consult with Mayo in selecting the patent within the Patent Rights covering each Licensed Product for term extension or supplementary protection certificate in accordance with the applicable laws of any country; provided, however that ESDC may decide, in its sole discretion, not to select any such patent for term extension or supplementary protection. Each Party agrees to execute any documents and to take any additional actions as the other Party may reasonably request in connection therewith.

6.03 PATENT MARKING. To the extent commercially feasible, ESDC will mark all Licensed Products that are manufactured or sold under this Agreement with the number of each issued patent within the Patent Rights that covers such Licensed Product. Any such marking will be in conformance with the patent laws and other laws of the country of manufacture or sale.

6.04 ENFORCEMENT. ESDC shall promptly inform Mayo in writing of any alleged or threatened infringement of any of the Patent Rights or Know-How and Materials and provide Mayo with any available evidence of such infringement.

(a) First Right. ESDC shall have the first right, but not the obligation, to enforce the Patent Rights so long as Mayo is kept fully informed and given the right and opportunity to advise and comment. Mayo shall reasonably cooperate in any such action at ESDC's expense but shall not be required to join such action unless: (i) it has agreed to do so in writing prior to commencement thereof, or (ii) ESDC determines that Mayo is a necessary party in the action. ESDC shall pay to Mayo twenty-five percent (25%) of any recovery or damages, net of all reasonable costs and expenses associated with each suit or settlement.

(b) Non-Election to Enforce. If ESDC elects not to enforce the Patent Rights, it shall so notify Mayo in writing within ninety (90) days of receiving notice that an infringement may exist, and Mayo may, in its sole judgment and without any obligation, enforce, settle, and defend the Patent Rights and keep for its own account any recovery and damages. ESDC shall reasonably cooperate in any such actions if requested to do so by Mayo, at Mayo's expense.

6.05 DEFENSE. ESDC will have the first right, but not the obligation, to take any measures deemed appropriate by ESDC in consultation with Mayo, regarding challenges to the Patent Rights, Know-How or Materials brought (including interferences in the U.S. Patent and Trademark Office and oppositions in foreign jurisdictions) and defense of the Patent Rights, Know-How or Materials required (including declaratory judgment actions). Mayo shall reasonably cooperate in any such measures if requested to do so by ESDC at ESDC's expense, but shall not be required to join any action unless: (a) it has agreed to do so in writing prior to commencement thereof; or (b) the court determines that Mayo is a necessary party in the action. ESDC shall be entitled to retain any related recovery, provided that all costs of Mayo related to such action have been fully paid by ESDC. If ESDC elects not to defend the Patent Rights, it shall so notify Mayo in writing within ninety (90) days of receiving notice that a challenge has been made, and Mayo may, in its sole judgment and without any obligation, enforce, settle, and defend the Patent Rights and keep for its own account any related recovery. ESDC shall reasonably cooperate in any such actions if requested to do so by Mayo, at Mayo's expense.

6.06 THIRD PARTY LITIGATION. In the event a third party institutes a suit against ESDC for patent infringement involving a Licensed Product, ESDC will so inform Mayo within fifteen (15) business days and keep Mayo regularly informed of the proceedings.

Article 7.00 — Use of Name

7.01 USE OF NAME AND LOGO. Neither Party will use for publicity, promotion, or otherwise, any logo, name, trade name, service mark, or trademark of the other party or its

Affiliates (in the case of Mayo, including the terms “Mayo®,” “Mayo Clinic®,” and the triple shield Mayo logo, or any simulation, abbreviation, or adaptation of the same and in the case of ESDC, including the terms “Exact Sciences” and “Cologuard”), or the name of any of the other Party’s employees or agents, without the other Party’s prior, written, express consent. Each Party may withhold such consent in its absolute discretion. With regard to the use of Mayo’s name, all requests for approval pursuant to this Section must be submitted to the Mayo Clinic Public Affairs Business Relations Group, at the following e-mail address: BusinessRelations@Mayo.edu at least five (5) business days prior to the date on which a response is needed. Notwithstanding the foregoing, any member of the Collaborating Team may use ESDC’s corporate name and any trademarked name relating to a product developed under this Agreement in any non-commercial academic publications, educational settings, professional engagements, or in a conflict-of-interest disclosure.

Article 8.00 — Confidentiality

8.01 TREATMENT OF CONFIDENTIAL INFORMATION. Except as provided for in Section 8.02, neither Party (nor any Affiliate of either Party) will disclose, use or otherwise make available the other’s Confidential Information during the Term or for three years thereafter and will use the same degree of care it employs to protect its own confidential information.

8.02 RIGHT TO DISCLOSE.

(a) To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement, a Party (or any of its Affiliates) may use or disclose Confidential Information to its Sublicensees, consultants, and outside contractors on the condition that each such entity agrees to obligations of confidentiality and non-use at least as stringent as those herein.

(b) If a Party (or any of its Affiliates) is required by law, regulation or court order to disclose any of the Confidential Information of the other Party (or any of its Affiliates), it will have the right to do so, provided it: (i) promptly notifies the disclosing party; and (ii) reasonably assists the disclosing party in efforts to obtain a protective order or other remedy of disclosing party’s election and at disclosing party’s expense.

8.03 CONFIDENTIALITY OF AGREEMENTS. Except as otherwise required by law, the specific terms and conditions of this Agreement shall be Confidential Information but the existence and Field of this Agreement will not be Confidential Information and the Parties may state that ESDC is licensed under the Patent Rights. Notwithstanding the foregoing, a Party may disclose the contents of this Agreement to its actual or prospective sublicensees, investors, professional advisors, and as required by law or the rules of any applicable securities exchange.

8.04 PUBLICATION. To enable the receiving Party to secure adequate intellectual property protection that would be affected by a public disclosure, Mayo and ESDC will submit any manuscript or material for any proposed academic publication, meeting, conference, or talk (“**Public Disclosure**”) of research underlying Patent Rights to the other Party at least thirty (30) days before transmission of any manuscript or material to a third party (or at least thirty (30)

days before Public Disclosure where no manuscript or material exists), and the receiving Party shall have the right to review and comment upon the Public Disclosure in order to protect confidential information. Upon the receiving Party's request, publication will be delayed up to sixty (60) additional days. Notwithstanding the above, the Public Disclosure shall not include ESDC Confidential Information without prior approval by ESDC.

Article 9.00 — Warranties, Representations, Disclaimers and Indemnification

9.01 REPRESENTATIONS AND WARRANTIES OF ESDC. ESDC warrants and represents to Mayo that:

(a) together with its Affiliates, it is experienced in the development, production, quality control, service, manufacture, marketing, and sales of products similar to the subject matter of the Patent Rights, and that it will commit itself to a thorough, vigorous, and diligent program of developing and marketing Licensed Products;

(b) it has independently evaluated the Patent Rights, Know-How, Materials and Confidential Information, if any, their applicability or utility in ESDC's activities, is entering into this Agreement on the basis of its own evaluation and not in reliance of any representation by Mayo, and assumes all risk and liability in connection with such determination;

(c) the execution and delivery of this Agreement has been duly authorized and no further approval, corporate or otherwise, is required in order to execute this Agreement;

(d) it shall comply and require its Sublicensees to comply with all applicable international, national, and state laws, ordinances and regulations in its performance under this Agreement; and

(e) its rights and obligations under this Agreement do not conflict with any contractual obligation or court or administrative order by which it is bound.

9.02 REPRESENTATIONS AND WARRANTIES OF MAYO. Mayo warrants and represents to ESDC that:

(a) it is the owner of the Patent Rights and has full power and authority to grant the licenses which are provided for in this Agreement;

(b) the execution and delivery of this Agreement has been duly authorized and no further approval, corporate or otherwise, is required in order to execute this Agreement;

(c) to the best of its internal counsel's knowledge, its rights and obligations under this Agreement do not conflict with any contractual obligation or court or administrative order by which it is bound;

(d) no claim, suit or action has been made or initiated alleging that the Patent Rights are invalid or that the practice of the Patent Rights will infringe the rights of any third party; and

(e) to the best of its internal counsel's knowledge the Patent Rights are valid and subsisting.

9.03 DISCLAIMERS.

(A) EXCEPT AS EXPRESSLY SET FORTH HEREIN, NEITHER PARTY HAS MADE ANY PROMISES, COVENANTS, GUARANTEES, REPRESENTATIONS OR WARRANTIES OF ANY NATURE, DIRECTLY OR INDIRECTLY, EXPRESS, STATUTORY OR IMPLIED, INCLUDING MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE, SUITABILITY, DURABILITY, CONDITION, QUALITY, OR ANY OTHER CHARACTERISTIC OF THE LICENSED PRODUCT, KNOW-HOW, MATERIALS OR PATENT RIGHTS.

(B) KNOW-HOW, MATERIALS, CONFIDENTIAL INFORMATION AND PATENT RIGHTS ARE PROVIDED "AS IS," "WITH ALL FAULTS," AND "WITH ALL DEFECTS," AND ESDC EXPRESSLY WAIVES ALL RIGHTS TO MAKE ANY CLAIM WHATSOEVER AGAINST Mayo FOR MISREPRESENTATION OR FOR BREACH OF PROMISE, GUARANTEE, REPRESENTATION OR WARRANTY OF ANY KIND RELATING TO THE LICENSED PRODUCTS, KNOW-HOW, MATERIALS, CONFIDENTIAL INFORMATION OR PATENT RIGHTS, EXCEPT AS EXPRESSLY SET FORTH HEREIN. Mayo EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES ARISING FROM ANY COURSE OF DEALING, USAGE, OR TRADE PRACTICE, WITH RESPECT TO: THE SCOPE, VALIDITY OR ENFORCEABILITY OF THE PATENT RIGHTS, KNOW-HOW, OR MATERIALS; THAT ANY PATENT WILL ISSUE BASED UPON ANY PENDING PATENT APPLICATION; OR THAT THE MANUFACTURE, USE, SALE, OFFER FOR SALE OR IMPORTATION OF THE LICENSED PRODUCTS WILL NOT INFRINGE OTHER INTELLECTUAL PROPERTY RIGHTS. NOTHING IN THIS AGREEMENT WILL BE CONSTRUED AS AN OBLIGATION FOR Mayo TO BRING, PROSECUTE OR DEFEND ACTIONS REGARDING THE PATENT RIGHTS, KNOW-HOW OR MATERIALS.

(C) ESDC AGREES THAT Mayo AND ITS AFFILIATES WILL NOT BE LIABLE FOR ANY LOSS OR DAMAGE CAUSED BY OR ARISING OUT OF ANY RIGHTS GRANTED OR PERFORMANCE MADE UNDER THIS AGREEMENT, WHETHER TO OR BY ESDC, A SUBLICENSEE OR A THIRD PARTY. IN NO EVENT WILL MAYO'S LIABILITY OF ANY KIND INCLUDE ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE LOSSES OR DAMAGES, EVEN IF Mayo HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, OR EXCEED THE TOTAL AMOUNT OF ROYALTIES WHICH HAVE ACTUALLY BEEN PAID TO Mayo BY ESDC AS OF THE DATE OF FILING AN ACTION AGAINST Mayo WHICH RESULTS IN THE SETTLEMENT OR AWARD OF DAMAGES TO ESDC.

9.04 INDEMNIFICATION AND INSURANCE.

(a) ESDC will defend, indemnify, and hold harmless Mayo, Mayo's Affiliates and their respective trustees, officers, agents, independent contractors and employees ("Mayo

Indemnitees”) from any and all claims, actions, demands, judgments, losses, costs, expenses, damages and liabilities (including attorneys’ fees, court costs and other expenses of litigation), regardless of the legal theory asserted, arising out of or connected with: (a) the practice or exercise of any rights granted hereunder by or on behalf of ESDC or any Sublicensee; (b) research, development, design, manufacture, distribution, use, sale, importation, exportation or other disposition of Licensed Products; and (c) any act or omission of ESDC or any Sublicensee hereunder, including the negligence or willful misconduct thereof Mayo and Mayo Affiliates shall have no obligation to indemnify ESDC hereunder. Notwithstanding the foregoing, the indemnity obligations of ESDC shall not apply with respect to any claims, actions, demands, judgments, losses, costs, expenses, damages and liabilities which arise (1) due to a breach of this Agreement by Mayo or the gross negligence or willful misconduct of Mayo or its agents or employees or (2) solely among Mayo Indemnitees.

(b) The Parties agree that this indemnity should be construed and applied in favor of maximum indemnification of Mayo Indemnitees.

(c) Commencing on the date of first commercial sale of a Licensed Product by ESDC, ESDC will continuously carry claim-based liability insurance, including products liability and contractual liability, in an amount and for a time period sufficient to cover the liability assumed by ESDC hereunder during the Term and after, such amount being at least THREE MILLION DOLLARS (\$3,000,000). In addition, such policy will name Mayo and its Affiliates as additional-named insureds. In such case, ESDC will self-insure or obtain, at its cost, an extended reporting endorsement upon termination of this Agreement sufficient to cover the liability assumed by ESDC hereunder for as long as the appropriate statute of limitations. The minimum limits of any insurance coverage required herein shall not limit ESDC’s liability.

9.05 PROHIBITION AGAINST INCONSISTENT STATEMENTS. ESDC shall not make any statements, representations or warranties, or accept any liabilities or responsibilities whatsoever which are inconsistent with any disclaimer or limitation included in this section or any other provision of this Agreement. ESDC shall not settle any matter that will incur liability for Mayo or require Mayo to make any admission of liability without Mayo’s prior written consent.

Article 10.00 — Term and Termination

10.01 TERM. This Agreement will expire at the end of the Term.

10.02 TERMINATION FOR BREACH. If ESDC commits a material breach of this Agreement, including the failure to make any required royalty or fee payments hereunder, Mayo will notify ESDC in writing of such breach and ESDC will have thirty (30) days after such notice to cure such breach to Mayo’s satisfaction. If ESDC fails to cure such breach, Mayo may, at its sole option, terminate this Agreement in whole or in part by sending ESDC written notice of termination.

10.03 TERMINATION FOR SUIT. Mayo does not license entities that bring suit against Mayo or its Affiliates and as such, Mayo may immediately terminate this Agreement if ESDC or

any Sublicensee directly or indirectly brings any action or proceeding against Mayo or its Affiliates, except for an uncured material breach of this Agreement by Mayo.

10.04 TERMINATION BY ESDC. Subject to the terms of the Sponsored Research Agreement, ESDC may without cause terminate this Agreement at any time following payment and delivery of the compensation provided for in Section 3.01, upon written notice to Mayo.

10.05 INSOLVENCY OF ESDC. This Agreement terminates immediately without an obligation of notice of termination to ESDC in the event ESDC ceases conducting business in the normal course, becomes insolvent or bankrupt, makes a general assignment for the benefit of creditors, admits in writing its inability to pay its debts as they are due, permits the appointment of a receiver for its business or assets, or avails itself of or becomes subject to any proceeding under any statute of any governing authority relating to insolvency or the protection of rights of creditors.

10.06 SURVIVAL. The termination or expiration of this Agreement does not relieve either Party of its rights and obligations that have previously accrued. After the Term, all rights granted immediately revert to Mayo. All Confidential Information of the other Party shall be returned or destruction certified, at the disclosing party's election. Rights and obligations that by their nature prescribe continuing rights and obligations shall survive the termination or expiration of this Agreement including Sections 4.02, 9.04, or 10.05 and Articles 7, 8 or 11. ESDC and its Sublicensees shall provide an accounting for and pay, within thirty (30) days of termination or expiration, all amounts due hereunder. Upon any termination of this Agreement, the licenses granted hereunder shall cease. Upon expiration of this Agreement, the licenses granted hereunder shall become fully paid up.

Article 11.00 — General Provisions

11.01 ASSIGNMENT AND TRANSFER. Each Party is strictly prohibited from assigning, delegating or otherwise transferring any of its obligations or rights under this Agreement without the other Party's prior, express and written consent, which shall not be unreasonably withheld. Any assignment, delegation or transfer in contravention hereof is null and void. Notwithstanding the foregoing, ESDC may assign this Agreement to an Affiliate and either Party may assign this Agreement, in whole or in part, without approval in connection with a sale, merger or other transaction which involves the transfer of all or substantially all of the assets of a Party used in connection with any business of such Party that relates to this Agreement. Any assignment shall not in any manner relieve the assignor from liability for the performance of this Agreement by its assignee and shall not otherwise affect the terms or conditions under this Agreement. The assignor shall provide prompt notice to the other Party upon making such assignment.

11.02 WAIVER. No part of this Agreement may be waived except by the further written agreement of the Party granting such waiver. Forbearance in any form from demanding the performance of a duty owed under this Agreement is not a waiver of that duty. Until complete performance of a duty owed under this Agreement is accomplished, the Party to which that duty is owed may invoke any remedy under this Agreement or under law, despite its past forbearance in demanding performance of that duty.

11.03 GOVERNING LAW AND JURISDICTION. This Agreement is made and performed in Minnesota. The terms and conditions of this Agreement, as well as all disputes arising under or relating to this Agreement, shall be governed by Minnesota law, specifically excluding its choice-of-law principles, except that the interpretation, validity and enforceability of the Patent Rights will be governed by the patent laws of the country in which the patent application is pending or issued. This is not an agreement for the sale of goods and as such Article 2 of the Uniform Commercial Code as enacted in Minnesota does not apply.

11.04 HEADINGS. The headings of articles and sections used in this document are for convenience of reference only.

11.05 NOTICES. Any notice required to be given under this Agreement is properly provided if in writing and sent to the Party at its address or email below, or as otherwise designated by the Party in accordance with this provision, and duly given or made: (a) on the date delivered in person; (b) on the date transmitted by email or facsimile, if confirmation is received or no email delivery is received; (c) three (3) days after deposit in the mail if sent by certified U.S. mail postage prepaid, return receipt requested; and (d) one (1) day after deposit with a nationally recognized overnight carrier service with charges prepaid.

For Mayo:

Mayo Foundation for Medical Education and Research
Mayo Clinic Ventures -BB4
200 First Street SW
Rochester, Minnesota 55905-0001
Attn: Ventures Operations
Phone: (507) 293-3900
Email: intellectualproperty@mayo.edu
Fed Tax ID: 41-1506440

For ESDC:

Exact Sciences Development Company, LLC
501 Charmany Drive,
Madison, WI 53719
Attn: Jacob Orville
Email: jorville@exactsciences.com

with a copy to

Exact Sciences Corporation

5505 Endeavor Lane
Madison, WI 53719
Attn: D. Scott Coward; James Herriott
Email: scoward@exactsciences.com; jherriott@exactsciences.com

11.06 LIMITATION OF RIGHTS CREATED. This Agreement is personal to the Parties and shall be binding on and inure to the sole benefit of the Parties and their permitted successors and assigns and shall not be construed as conferring any rights to any third party. Specifically, no interests are intended to be created for any customer, patient, research subjects, or other persons (or their relatives, heirs, dependents, or personal representatives) by or upon whom the Licensed Products may be used.

11.07 INDEPENDENT CONTRACTORS. ESDC and any Sublicensee is an independent contractor not an agent, employee, partner, joint venturer or servant of Mayo and has no right to obligate or bind Mayo in any manner.

11.08 ENTIRE AGREEMENT. This Agreement states the entire agreement and understanding between the Parties about the licenses granted hereunder, the collaboration pursuant to Section 2.06 and the amounts payable for the foregoing. All past and contemporaneous discussions, writings, agreements, proposals, promises, covenants, warranties, representations, guarantees, correspondence, and understandings with respect to such services and collaboration, whether oral or written, formal or informal, are entirely superseded by this Agreement, with the exception of the Sponsored Research Agreement and Statements of Work thereunder. For the avoidance of doubt, nothing herein is intended to modify or supersede the terms of any agreement, current as of the Effective Date, between ESDC or its Affiliates, on the one hand, and Mayo or its Affiliates, on the other hand, governing any license granted, or materials or services provided, pursuant to any agreement other than the Original Agreement or the Prior Agreement, including but not limited to materials transfer, clinical trials, or consulting services, which remain in full force and effect.

11.09 SEVERABILITY. If any terms or conditions of this Agreement are or become in conflict with the laws, regulations or court order of any jurisdiction or any governmental entity having jurisdiction over the Parties or this Agreement, those terms and conditions shall be deemed automatically deleted in such jurisdiction only, and the remaining terms and conditions of this Agreement shall remain in full force and effect. If such a deletion is not so allowed in a given jurisdiction or if such a deletion leaves terms and conditions thereby made clearly illogical or inappropriate in effect, the Parties agree to substitute new terms and conditions as similar in effect to the present terms of this Agreement as may be allowed under the applicable laws, regulations or court order of such jurisdiction. The Parties desire the terms and conditions herein to be valid and enforced to the maximum extent not prohibited by law, regulation or court order in a given jurisdiction.

11.10 CHANGES TO AGREEMENT. No terms or conditions of this Agreement may be changed except in writing, through another document signed by both Parties, and expressly referencing this Agreement.

11.11 CONSTRUCTION. Each Party acknowledges that it was provided an opportunity to seek advice of counsel and as such this Agreement shall not be construed for or against either Party. Unless the context of this Agreement otherwise clearly requires, (a) references to the plural include the singular, and references to the singular include the plural, (b) references to any

gender include the other genders, (c) the words “include,” “includes” and “including” do not limit the preceding terms or words and shall be deemed to be followed by the words “without limitation,” (d) the term “or” is not exclusive, (e) the terms “hereof,” “herein,” “hereunder,” “hereto” and similar terms in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement, (f) the terms “day” and “days” mean and refer to calendar day(s), (g) the terms “quarter” and “quarter” mean and refer to calendar quarter(s) and (h) the terms “year” and “years” mean and refer to calendar year(s). Unless otherwise set forth herein, references in this Agreement to (i) any document, instrument or agreement (including this Agreement) (A) includes and incorporates all exhibits, schedules and other attachments thereto, (B) includes all documents, instruments or agreements issued or executed in replacement thereof and (C) means such document, instrument or agreement, or replacement or predecessor thereto, as amended, modified or supplemented from time to time in accordance with its terms and in effect at any given time, and (ii) a particular law means such law as amended, modified, supplemented or succeeded, from time to time and in effect at any given time. All Article, Section, Exhibit and Schedule references herein are to Articles, Sections, Exhibits and Schedules of this Agreement, unless otherwise specified. This Agreement shall not be construed as if prepared by one of the Parties, but rather according to its fair meaning as a whole, as if all Parties had prepared it.

11.12 REGISTRATION OF LICENSES. ESDC will register and give required notice concerning this Agreement, at its expense, in each country in the Territory where an obligation under law exists to so register or give notice.

11.13 EXPORT CONTROL. Mayo is subject to U.S. laws and regulations controlling the export of technical data, computer software, laboratory prototypes, and other commodities that may require a license from the applicable agency of the United States government or may require written assurances by ESDC that it will not export data or commodities to certain foreign countries without prior approval of such agency. Mayo neither represents that a license is required, nor that, if required, it will be issued; provided, however that Mayo will act in good faith and take commercially reasonable efforts to cause any such agency of the United States government to issue such license.

[Signature page follows.]

The Parties execute this Agreement in one or more counterparts, each of which shall be deemed an original but all of which taken together constitute one and the same instrument, as of the Effective Date.

MAYO FOUNDATION FOR MEDICAL
EDUCATION AND RESEARCH

/s/ Andrew J. Danielsen
Andrew J. Danielsen
Chair, Business Development

EXACT SCIENCES DEVELOPMENT COMPANY, LLC

/s/ Kevin T. Conroy
Name: Kevin T. Conroy
Title: President and Chief Executive Officer

CERTAIN INFORMATION (INDICATED BY ASTERISKS) HAS BEEN OMITTED FROM THIS DOCUMENT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

Exhibit A

KNOW-HOW

[***]

CERTAIN INFORMATION (INDICATED BY ASTERISKS) HAS BEEN OMITTED FROM THIS DOCUMENT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

EXHIBIT 10.1

Exhibit B

MARKERS AND PATENT RIGHTS

[***]

CERTAIN INFORMATION (INDICATED BY ASTERISKS) HAS BEEN OMITTED FROM THIS DOCUMENT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

EXHIBIT 10.1

Exhibit C

AUTHORIZED CONTRIBUTIONS BY ADDITIONAL COLLABORATORS

[***]

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: October 27, 2020

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: October 27, 2020

By: /s/ Jeffrey T. Elliott

Jeffrey T. Elliott
Chief Financial 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 September 30, 2020 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.

/s/ Kevin T. Conroy

Kevin T. Conroy
President and Chief Executive Officer

October 27, 2020

/s/ Jeffrey T. Elliott

Jeffrey T. Elliott
Chief Financial Officer

October 27, 2020