Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021
OR

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

For the transition period from to

Commission file number 001-36156

VERACYTE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-5455398**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

6000 Shoreline Court, Suite 300
South San Francisco, California 94080
(Address of principal executive offices, zip code)

(650) 243-6300
(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, par value, $0.001 per share	VCYT	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 x No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x 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	x	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

As of November 3, 2021, there were 71,043,062 shares of common stock, par value $0.001 per share, outstanding.

VERACYTE, INC.
INDEX

PART I. — FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements-(Unaudited)

VERACYTE, INC.
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share and per share amounts)

	September 30, 2021	December 31, 2020 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 164,029	$ 349,364
Accounts receivable	40,309	18,461
Supplies	9,824	4,657
Prepaid expenses and other current assets	15,146	3,197
Total current assets	229,308	375,679
Property and equipment, net	14,868	8,990
Right-of-use assets, operating lease	16,001	7,843
Intangible assets, net	209,521	59,924
Goodwill	714,273	2,725
Restricted cash	749	603
Other assets	1,636	1,399
Total assets	$ 1,186,356	$ 457,163
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 11,201	$ 3,116
Accrued liabilities	29,044	11,705
Current portion of deferred revenue	3,440	371
Current portion of acquisition-related contingent consideration	2,646	—
Current portion of operating lease liability	3,465	1,589
Current portion of other liabilities	241	—
Total current liabilities	50,037	16,781
Long-term debt	1,075	810
Deferred revenue, net of current portion	552	829
Deferred tax liability	6,234	—
Acquisition-related contingent consideration, net of current portion	5,251	7,594
Operating lease liability, net of current portion	14,236	9,917
Other liabilities	1,891	—
Total liabilities	79,276	35,931
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, 0 shares issued and outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value; 125,000,000 shares authorized, 71,032,336 and 58,200,526 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	71	58
Additional paid-in capital	1,461,778	702,768
Accumulated deficit	(346,629)	(281,594)
Accumulated other comprehensive loss	(8,140)	—
Total stockholders' equity	1,107,080	421,232
Total liabilities and stockholders' equity	$ 1,186,356	$ 457,163

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

VERACYTE, INC.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Testing revenue	$ 50,897	$ 28,270	$ 134,768	$ 70,473
Product revenue	2,959	2,027	8,706	7,149
Biopharmaceutical and other revenue	6,514	824	8,704	5,325
Total revenue	60,370	31,121	152,178	82,947
Operating expenses:				
Cost of testing revenue	16,073	9,118	42,494	26,157
Cost of product revenue	1,491	1,048	4,304	3,539
Cost of biopharmaceutical and other revenue	4,079	204	4,720	572
Research and development	8,006	4,042	19,591	12,618
Selling and marketing	21,670	10,955	57,628	39,240
General and administrative	20,749	8,546	82,504	24,316
Intangible asset amortization	4,983	1,274	10,507	3,822
Total operating expenses	77,051	35,187	221,748	110,264
Loss from operations	(16,681)	(4,066)	(69,570)	(27,317)
Other income (loss), net	1,202	(58)	(762)	452
Loss before income tax benefit	(15,479)	(4,124)	(70,332)	(26,865)
Income tax benefit	(1,350)	—	(5,297)	—
Net loss	$ (14,129)	$ (4,124)	$ (65,035)	$ (26,865)
Net loss per common share, basic and diluted	$ (0.20)	$ (0.08)	$ (0.97)	$ (0.52)
Shares used to compute net loss per common share, basic and diluted	69,743,733	54,858,052	66,820,654	51,632,750

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

VERACYTE, INC.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	$ (14,129)	$ (4,124)	$ (65,035)	$ (26,865)
Other comprehensive loss:				
Change in currency translation adjustments	(8,140)	—	(8,140)	—
Net comprehensive loss	$ (22,269)	$ (4,124)	$ (73,175)	$ (26,865)

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

VERACYTE, INC.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2021	67,472	$ 67	$ 1,303,610	$ (332,500)	$ —	$ 971,177
Issuance of common stock for acquisition	3,347	3	147,086	—	—	147,089
Issuance of common stock on exercise of stock options and vesting of restricted stock units	181	1	2,843	—	—	2,844
Issuance of common stock under employee stock purchase plan (ESPP)	32	—	1,195	—	—	1,195
Tax portion of vested restricted stock units	—	—	(824)	—	—	(824)
Stock-based compensation expense (employee)	—	—	7,359	—	—	7,359
Stock-based compensation expense (non-employee)	—	—	15	—	—	15
Stock-based compensation expense (ESPP)	—	—	494	—	—	494
Net loss	—	—	—	(14,129)	—	(14,129)
Comprehensive loss	—	—	—	—	(8,140)	(8,140)
Balance at September 30, 2021	71,032	$ 71	$ 1,461,778	$ (346,629)	$ (8,140)	$ 1,107,080
Balance at December 31, 2020	58,201	$ 58	$ 702,768	$ (281,594)	$ —	$ 421,232
Sale of common stock in a public offering, net of offering costs of $38,677	8,547	9	593,812	—	—	593,821
Issuance of common stock for acquisition	3,347	3	147,086	—	—	$ 147,089
Issuance of common stock upon exercise of stock options and vesting of restricted stock units	856	1	8,279	—	—	8,280
Issuance of common stock under employee stock purchase plan (ESPP)	81	—	2,353	—	—	2,353
Tax portion of vested restricted stock units	—	—	(8,307)	—	—	(8,307)
Stock-based compensation expense (employee)	—	—	14,687	—	—	14,687
Stock-based compensation expense (non-employee)	—	—	45	—	—	45
Stock-based compensation expense (ESPP)	—	—	1,055	—	—	1,055
Net loss	—	—	—	(65,035)	—	(65,035)
Comprehensive loss	—	—	—	—	(8,140)	(8,140)
Balance at September 30, 2021	71,032	$ 71	$ 1,461,778	$ (346,629)	$ (8,140)	$ 1,107,080

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

VERACYTE, INC.
Condensed Consolidated Statements of Stockholders' Equity (Continued)
(Unaudited)
(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at June 30, 2020	50,446	$ 50	$ 495,523	$ (269,426)	$ 226,147
Sale of common stock in a public offering, net of offering costs of $13,169	6,900	7	193,824	—	193,831
Issuance of common stock on exercise of stock options and vesting of restricted stock units	427	1	3,328	—	3,329
Issuance of common stock under ESPP	41	—	935	—	935
Tax portion of vested restricted stock units	—	—	(483)	—	(483)
Stock-based compensation expense (employee)	—	—	3,032	—	3,032
Stock-based compensation expense (non-employee)	—	—	15	—	15
Stock-based compensation expense (ESPP)	—	—	43	—	43
Net loss and comprehensive loss	—	—	—	(4,124)	(4,124)
Balance at September 30, 2020	57,814	$ 58	$ 696,217	$ (273,550)	$ 422,725
Balance at December 31, 2019	49,625	$ 50	$ 486,090	$ (246,685)	$ 239,455
Sale of common stock in a public offering, net of offering costs of $13,169	6,900	7	193,824	—	193,831
Issuance of common stock upon exercise of stock options and vesting of restricted stock units	1,187	1	8,073	—	8,074
Issuance of common stock under ESPP	102	—	2,037	—	2,037
Tax portion of vested restricted stock units	—	—	(3,161)	—	(3,161)
Stock-based compensation expense (employee)	—	—	8,591	—	8,591
Stock-based compensation expense (non-employee)	—	—	35	—	35
Stock-based compensation expense (ESPP)	—	—	728	—	728
Net loss and comprehensive loss	—	—	—	(26,865)	(26,865)
Balance at September 30, 2020	57,814	$ 58	$ 696,217	$ (273,550)	$ 422,725

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

VERACYTE, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2021	**2020**
Operating activities		
Net loss	$ (65,035)	$ (26,865)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	13,189	5,919
Stock-based compensation	15,787	9,354
Benefit from income taxes	(5,297)	—
Interest on end-of-term debt obligation	161	162
Write-down of excess supplies	—	1,088
Noncash lease expense	1,566	714
Revaluation of acquisition-related contingent consideration	303	332
Effect of foreign currency on operations	1,601	(17)
Changes in operating assets and liabilities:		
Accounts receivable	(6,285)	1,742
Supplies	4	1,262
Prepaid expenses and other current assets	(1,905)	(923)
Other assets	353	134
Operating lease liability	(1,710)	(1,040)
Accounts payable	3,872	(534)
Accrued liabilities and deferred revenue	3,329	(3,300)
Net cash used in operating activities	(40,067)	(11,972)
Investing activities		
Acquisition of Decipher Biosciences, net of cash acquired	(574,411)	—
Acquisition of HalioDx, net of cash acquired	(163,645)	—
Proceeds from sale of equity securities	3,000	—
Purchase of equity securities	—	(1,000)
Purchases of property and equipment	(4,535)	(1,949)
Net cash used in investing activities	(739,591)	(2,949)
Financing activities		
Proceeds from the issuance of common stock in a public offering, net of issuance costs	593,821	193,831
Payment of long-term debt	—	(100)
Payment of taxes on vested restricted stock units	(8,307)	(3,161)
Proceeds from the exercise of common stock options and employee stock purchases	10,633	10,114
Net cash provided by financing activities	596,147	200,684
(Decrease) increase in cash, cash equivalents and restricted cash	(183,511)	185,763
Effect of foreign currency on cash, cash equivalents and restricted cash	(1,678)	—
Net (decrease) increase in cash, cash equivalents and restricted cash	(185,189)	185,763
Cash, cash equivalents and restricted cash at beginning of period	349,967	159,920
Cash, cash equivalents and restricted cash at end of period	$ 164,778	$ 345,683
Supplementary cash flow information:		
Purchases of property and equipment included in accounts payable and accrued liability	$ 31	$ 355
Interest paid on debt	$ 9	$ 3
Issuance of common stock for acquisition of HalioDx	$ 147,089	$ —

Cash, Cash Equivalents and Restricted Cash:

	September 30, 2021	**December 31, 2020**
Cash and cash equivalents	$ 164,029	$ 349,364
Restricted cash	749	603
Total cash, cash equivalents and restricted cash	$ 164,778	$ 349,967

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

VERACYTE, INC.
Notes to Financial Statements
(unaudited)

1. Organization, Description of Business and Summary of Significant Accounting Policies

Veracyte, Inc., or Veracyte, or the Company, is a global diagnostics company that improves patient care by answering important clinical questions to inform diagnosis and treatment decisions throughout the patient journey in cancer and other diseases. The Company's growing menu of tests leverage advances in genomic science and machine learning technology to change care for patients, enabling them to avoid unnecessary and potentially harmful procedures and interventions, and accelerate time to more appropriate treatment. In addition to making its tests available in the United States through its central laboratories, the Company believes its exclusive access to the nCounter Analysis System, a best-in-class diagnostics platform, positions the company to deliver its tests to patients worldwide through laboratories and hospitals that can perform them locally. In August 2021, Veracyte acquired HalioDx SAS, giving Veracyte the ability to manufacture its own in vitro diagnostic tests for use on the nCounter, while also deepening Veracyte's scientific capabilities into immuno-oncology and expanding its presence into eight of the ten most common cancers by incidence in the United States that impact patients globally.

Veracyte was incorporated in the state of Delaware on August 15, 2006, as Calderome, Inc. Calderome operated as an incubator until early 2008. On March 4, 2008, the Company changed its name to Veracyte, Inc. The Company's headquarters are in South San Francisco, California, and it also has operations in San Diego, California; Austin, Texas; Richmond, Virginia; Vancouver, Canada; and Marseille, France. It performs diagnostic testing in its Clinical Laboratory Improvement Amendments of 1988, or CLIA, certified laboratories in South San Francisco, San Diego, Austin, Richmond and Marseille.

Veracyte's foundational approach for its tests, or classifiers, begins with determining what clinical questions need to be answered in order to inform what happens next for the patient. The Company deploys rigorous science and technology to develop and validate its tests and collects extensive clinical utility data to demonstrate the tests' ability to influence care. This approach has enabled the Company to obtain Medicare reimbursement for its genomic classifiers in each of its clinical indications. The Company positions its tests to integrate seamlessly into the way physicians currently evaluate patients, to facilitate adoption.

Veracyte currently offers genomic tests, which it believes are changing patient care in lung cancer (Percepta); prostate and bladder urologic cancers (Decipher); thyroid cancer (Afirma); breast cancer (Prosigna); and interstitial lung diseases, or ILD, including idiopathic pulmonary fibrosis, or IPF (Envisia). The Company's genomic classifiers in each of these indications are covered by Medicare. Additionally, through its acquisition of HalioDx, the Company also offers a clinically validated immuno-oncology test in colon cancer (Immunoscore).

The Company performs its genomic tests for thyroid cancer, lung cancer and IPF in its CLIA-certified laboratory in South San Francisco, California, and its genomic tests for prostate and bladder cancer in its College of American Pathologists, or CAP, accredited and CLIA-certified laboratory in San Diego, California. In 2019, the Company acquired from NanoString, Inc. the exclusive global diagnostics license to the nCounter Analysis System and the Prosigna Breast Cancer Prognostic Gene Signature Assay, which is commercially available, along with the LymphMark lymphoma subtyping assay, which is in development for use as a companion diagnostic with Acerta Pharma's and AstraZeneca's Calquence. Both tests are designed for use on the nCounter Analysis System. The Prosigna test kits and associated products are sold to laboratories and hospitals globally. Additionally, the Company's Immunoscore Colon Cancer test is performed in Veracyte's CLIA-certified laboratories in Marseille, France, and Richmond, Virginia.

Veracyte's scientific approach and capabilities in genomics and immuno-oncology also provide multiple opportunities for partnerships with biopharmaceutical and diagnostic testing companies. In developing and commercializing its products, the Company has built or gained access to unique data and sample biorepositories, and proprietary technology and bioinformatics that it believes are important to the development of new targeted therapies, determining clinical trial eligibility and guiding treatment selection.

On August 2, 2021, Veracyte acquired HalioDx SAS, a French société par actions simplifiée, or HalioDx, an immuno-oncology diagnostics company providing oncologists and drug development organizations with diagnostic products and biopharmaceutical services to guide cancer care and contribute to precision medicine. Veracyte believes the acquisition provides three strategic benefits to the company: 1.) it provides Veracyte with the expertise to develop and manufacture IVD test kits for the nCounter diagnostics platform; 2.) it deepens the company's scientific capabilities into immuno-oncology; and 3.) it expands Veracyte's cancer diagnostic scope to eight of the top 10 cancers by U.S. incidence. Veracyte paid $321 million

in total consideration to HalioDx security holders, consisting of $170 million in cash, $147 million in stock and $4 million in incurred liabilities.

Basis of Presentation

The Company's condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. Certain information and note disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. The condensed consolidated balance sheet as of September 30, 2021 the condensed consolidated statements of operations for the three and nine months ended September 30, 2021 and 2020, the condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2021 and 2020, the condensed consolidated statements of stockholders' equity for the three and nine months ended September 30, 2021 and 2020, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2021 and 2020 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation of its financial position, operating results, stockholders' equity and cash flows for the periods presented. The condensed consolidated balance sheet as of December 31, 2020 has been derived from audited financial statements. The results for the three and nine months ended September 30, 2021 are not necessarily indicative of the results expected for the full year or any other period. The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. The Company operates in one segment.

The accompanying interim period condensed consolidated financial statements and related financial information included in this Quarterly Report on Form 10-Q should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

Use of Estimates

The preparation of unaudited interim 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 liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Items subject to such estimates include: revenue recognition; write-down of supplies; the useful lives of property and equipment; the recoverability of long-lived assets; the incremental borrowing rate for leases; accounting for acquisitions; the estimation of the fair value of intangible assets and contingent consideration; stock options; income tax uncertainties, including a valuation allowance for deferred tax assets; an allowance for credit losses and contingencies. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities and recorded revenue and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and assumptions.

Issuance of Common Stock in a Public Offering

On February 9, 2021, the Company issued and sold 8,547,297 shares of common stock in a registered public offering, including 1,114,864 shares issued and sold upon the underwriters' exercise in full of their option to purchase additional shares, at a price to the public of $74.00 per share. The Company's net proceeds from the offering were approximately $593.8 million, after deducting underwriting discounts and commissions and offering expenses of $38.7 million.

Cash and Cash Equivalents

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

Concentrations of Credit Risk and Other Risks and Uncertainties

The worldwide spread of coronavirus, or COVID-19, has created significant uncertainty in the global economy. There have been no comparable recent events that provide guidance as to the effect the spread of COVID-19 as a global pandemic may have. As a result, the ultimate impact of COVID-19 and the extent to which COVID-19 impacts the Company's business, results of operations and financial condition will depend on future developments, which are highly uncertain and difficult to

predict. If the financial markets or the overall economy are impacted for an extended period, the Company's liquidity, revenues, supplies, goodwill and intangibles may be adversely affected. The Company considers the effects, to the extent knowable, of the COVID-19 pandemic in developing our estimates.

The majority of the Company's cash and cash equivalents are deposited with one major financial institution in the United States. Deposits in this institution may exceed the amount of insurance provided on such deposits. The Company has not realized any losses on its deposits of cash and cash equivalents other than exchange rate losses related to foreign currency denominated accounts.

Several of the components of the Company's sample collection kits and test reagents, and the nCounter system and related diagnostic kits are obtained from single-source suppliers. If these single-source suppliers fail to satisfy the Company's requirements on a timely basis, it could suffer delays in being able to deliver its diagnostic solutions, suffer a possible loss of revenue, or incur higher costs, any of which could adversely affect its operating results.

Through September 30, 2021, most of the Company's revenue has been derived from the sale of Afirma and Decipher testing. To date, Afirma and Decipher testing have been delivered primarily to physicians in the United States.

The Company is also subject to credit risk from its accounts receivable related to its sales. Credit risk for accounts receivable from testing revenue is incorporated in testing revenue accrual rates as the Company assesses historical collection rates and current developments to determine accrual rates and amounts the Company will ultimately collect. The Company generally does not perform evaluations of customers' financial condition for testing revenue and generally does not require collateral. The Company assesses credit risk and the amount of accounts receivable the Company will ultimately collect for product, biopharmaceutical and collaboration revenue based on collection history, current developments and credit worthiness of the customer. The estimate of credit losses is not material at September 30, 2021.

The Company's third-party payers and other customers in excess of 10% of total revenue and their related revenue as a percentage of total revenue were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Medicare	31 %	25 %	31 %	24 %
UnitedHealthcare	9 %	11 %	10 %	11 %
	40 %	36 %	41 %	35 %

The Company's third-party payers and other customers in excess of 10% of accounts receivable and their related accounts receivable balance as a percentage of total accounts receivable were as follows at the following dates:

	September 30, 2021	December 31, 2020
Medicare	11 %	13 %
UnitedHealthcare	9 %	12 %

Restricted Cash

The Company had deposits of $749,000 and $603,000 included in long-term assets as of September 30, 2021 and December 31, 2020, respectively, restricted from withdrawal and held by banks in the form of collateral for irrevocable standby letters of credit held as security for the Company's leases.

Revenue Recognition

Testing Revenue

The Company recognizes testing revenue in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers*, or ASC 606. The Company bills for testing services at the time of test completion as defined by the delivery of test results. The Company recognizes revenue based on estimates of the amount that will ultimately be realized. In determining the amount to accrue for a delivered test, the Company considers factors such as payment history, payer coverage, whether there is a reimbursement contract between the payer and the Company, payment as a percentage of agreed upon rate (if applicable), amount paid per test and any current developments or changes that could impact reimbursement. These estimates require significant judgment by management. Actual results could differ from those estimates and assumptions.

During 2021, the Company changed its revenue estimates due to actual and anticipated cash collections for tests delivered in prior quarters and recognized additional revenue of $0.5 million and $0.9 million for the three and nine months ended September 30, 2021, respectively. These adjustments resulted in decreases in the Company's loss from operations of $0.5 million and $0.9 million for the three and nine months ended September 30, 2021, respectively. These adjustments resulted in a decrease in basic and diluted net loss per share of $0.01 for each of the three and nine months ended September 30, 2021.

During 2020, the Company changed its revenue estimates due to actual and anticipated cash collections for tests delivered in prior quarters and recognized additional revenue of $0.3 million and $1.2 million for the three and nine months ended September 30, 2020, respectively. These adjustments resulted in decreases in the Company's loss from operations of $0.3 million and $1.2 million and a decrease in basic and diluted net loss per share of zero and $0.02 for the three and nine months ended September 30, 2020, respectively.

Product Revenue

Product revenue from instruments and diagnostic kits is recognized generally upon shipment or when the instrument is ready for use by the end customer. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. Performance obligations are considered satisfied once the Company has transferred control of a product to the customer, meaning the customer has the ability to use and obtain the benefit of the product. The Company recognizes product revenue for satisfied performance obligations only when there are no uncertainties regarding payment terms or transfer of control. Shipping and handling costs incurred for product shipments are included in product revenue. Revenues are presented net of the taxes that are collected from customers and remitted to governmental authorities. There was no revenue from instrument sales for nine months ended September 30, 2021 or 2020.

Biopharmaceutical and Other Revenue

The Company enters into arrangements for research and development, commercialization, contract manufacturing and contract testing services. Such arrangements may require the Company to deliver various rights, manufactured diagnostic test kits, services and/or samples, including intellectual property rights/licenses, research and development services, and/or commercialization services. The underlying terms of these arrangements generally provide for consideration to the Company in the form of nonrefundable upfront license fees; payments on delivery of data, test results or manufactured products; costs of service plus margin; development and commercial performance milestone payments; royalty payments; and/or profit sharing. Net sales of data or other services to customers are recognized in accordance with ASC 606 and are classified under biopharmaceutical and other revenue. Milestone payments which fall under the scope of ASC Topic 808, *Collaborative Arrangements*, or ASC 808, are classified under collaboration revenue. Payments received that are not related to sales or services to a customer or collaboration revenue are recorded as offsets against research and development expense or cost of biopharmaceutical and other revenue in the Company's condensed consolidated statements of operations.

In arrangements involving more than one good or service, each required good or service is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from

other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects the Company's best estimate of what the selling price would be if the deliverable was regularly sold by the Company on a stand-alone basis or using an adjusted market assessment approach if selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control is transferred which may be at a point in time or over time. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. Should there be royalties, the Company utilizes the sales and usage-based royalty exception in arrangements that resulted from the license of intellectual property, recognizing revenues generated from royalties or profit sharing as the underlying sales occur.

As part of the accounting for these arrangements, the Company must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. Generally, the estimation of the stand-alone selling price may include such estimates as independent evidence of market price, forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation to determine if they can be satisfied at a point in time or over time, and it measures the services delivered to the collaborative partner which are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated input component and, therefore revenue or expense recognized, would be recorded as a change in estimate. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Up-front Fees: If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time.

Milestone Payments: At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within either party's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of milestones that are within either party's control, such as operational developmental milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. Revisions to the Company's estimate of the transaction price may also result in negative revenues and earnings in the period of adjustment.

Accounts receivable from biopharmaceutical and other revenue was $9.2 million at September 30, 2021 and $0.4 million at December 31, 2020. There was $4.0 million and $1.0 million of deferred revenue related to these agreements at September 30, 2021 and December 31, 2020, respectively. Revenues included in biopharmaceutical and other revenue for the three and nine months ended September 30, 2021 and 2020 were as follows (in thousands of dollars):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Development services	$ 3,849	$ 549	$ 5,242	$ 1,780
Provision of data	1,392	275	1,839	1,545
Milestones	—	—	350	1,000
Development rights	—	—	—	1,000
Contract manufacturing	1,221	—	1,221	—
Contract testing	52	—	52	—
Total	$ 6,514	$ 824	$ 8,704	$ 5,325

Diagnostic Development Agreement with Johnson & Johnson

The Company has entered into contracts with the Lung Cancer Initiative at Johnson & Johnson to cooperate on the development of clinical data, to provide data generated by the Company and to license the right to use data under the Company's intellectual property rights. Under the terms of the agreements, the Company will provide data in exchange for up to $18.0 million in payments from Johnson & Johnson. The Company is also entitled to additional payments of up to $13.0 million, conditioned upon the achievement of certain milestones.

The agreements are considered to be within the scope of ASC 808 with respect to the milestone payments, as the parties are active participants and exposed to the risks and rewards of the collaborative activity. The delivery of data under the collaborative arrangement, which the Company believes is a distinct service for which Johnson & Johnson meets the definition of a customer is within the scope of ASC 606. Using the concepts of ASC 606, the Company has identified the delivery of data as its only performance obligation. The grant of the license is not distinct from other performance obligations as the customer receives benefit only when other performance obligations are met. The Company further determined that the transaction prices under the arrangements are the $18.0 million in payments which was allocated to the obligation to deliver data. The $13.0 million in future potential payments is considered variable consideration because the Company determined that the potential payments are contingent upon regulatory, development and commercialization milestones that are uncertain to occur and, as such, were not included in the transaction price, and will be recognized accordingly as each potential payment becomes probable.

For the three and nine months ended September 30, 2021, the Company recognized $0.1 million and $0.4 million, respectively, of revenue under these contracts, which is included in biopharmaceutical and other revenue. For the three and nine months ended September 30, 2020, the Company recognized $0.3 million and $1.9 million, respectively, of revenue under these contracts. Accounts receivable from Johnson & Johnson related to these contracts was $0.1 million at September 30, 2021 and zero at December 31, 2020. There was $1.1 million and $1.0 million of deferred revenue related to these agreements at September 30, 2021 and December 31, 2020, respectively.

Cost of Testing Revenue

The components of our cost of testing services are laboratory expenses, sample collection expenses, compensation expense, license fees and royalties, depreciation and amortization, other expenses such as equipment and laboratory supplies, and allocations of facility and information technology expenses. Costs associated with performing tests are expensed as the test is processed regardless of whether and when revenue is recognized with respect to that test.

Cost of Product Revenue

Cost of product revenue consists primarily of costs of purchasing instruments and diagnostic kits from *third*-party contract manufacturers, installation, service and packaging and delivery costs. In addition, cost of product includes royalty costs for licensed technologies included in the Company’s products and labor expenses. Cost of product revenue for instruments and diagnostic kits is recognized in the period the related revenue is recognized. Shipping and handling costs incurred for product shipments are included in cost of product in the condensed consolidated statements of operations.

Cost of Biopharmaceutical and Other Revenue

Cost of biopharmaceutical and other revenue consists of costs of performing activities under arrangements that require the Company to perform research and development, commercialization, contract manufacturing and contract testing services on behalf of a customer.

French Research Tax Credits

The French research tax credits (“crédit d’impôt recherche” or “CIR”) is generated by the Company’s wholly owned subsidiary, HalioDx, in connection with its research efforts performed in Marseille, France. The Company recognizes other income from the CIR over time based on when the research and development expenses are incurred and includes the CIR in prepaids and other current assets on the condensed consolidated balance sheets.

VERACYTE, INC.
Notes to Financial Statements
(unaudited)

Foreign Currency Translation

The functional currency of the Company's foreign subsidiary HalioDx is the Euro. Assets and liabilities denominated in foreign currencies are translated to U.S. dollars using the exchange rates at the balance sheet date. Foreign currency translation adjustments are recorded as a component of accumulated other comprehensive income (loss) within stockholders' equity. Revenues and expenses from the Company's foreign subsidiaries are translated using the monthly average exchange rates in effect during the period in which the transactions occur. Foreign currency transaction gains and losses are recorded in other (loss) income, net, on the condensed consolidated statements of operations.

Pension Liability

The Company offers a defined benefit pension plan to certain non-U.S. employees of its HalioDx subsidiary. As of September 30, 2021, the total pension obligation is $1.1 million and is included in other liabilities on the condensed consolidated balance sheets.

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This standard simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. This ASU removes the following exceptions: (1) exception to the incremental approach for intraperiod tax allocation when there is a loss from continuing operations and income or a gain from other items; (2) exception to the requirement to recognize a deferred tax liability for equity method investments when a foreign subsidiary becomes an equity method investment; (3) exception to the ability not to recognize a deferred tax liability for a foreign subsidiary when a foreign equity method investment becomes a subsidiary; and (4) exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. The amendments in this ASU also improve consistency and simplify other areas of Topic 740 by clarifying and amending existing guidance. The revised guidance will be applied prospectively and became effective for the Company beginning January 1, 2021. The adoption of ASU 2019-12 did not have a material impact on our condensed consolidated financial statements.

2. Net Loss Per Common Share

Basic net loss per common share is calculated by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury stock method. The following outstanding common stock equivalents have been excluded from diluted net loss per common share because their inclusion would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Shares of common stock subject to outstanding options	3,668,179	4,492,414	3,817,351	4,691,424
Employee stock purchase plan	14,445	15,673	16,686	20,151
Restricted stock units	1,246,888	891,087	1,011,466	929,968
Total common stock equivalents	4,929,512	5,399,174	4,845,503	5,641,543

3. Balance Sheet Components

Goodwill

The changes in the carrying amounts of goodwill were as follows (in thousands of dollars):

	Amounts
Balance as of December 31, 2020	$ 2,725
Goodwill acquired - Decipher Biosciences	468,253
Goodwill acquired - HalioDx	249,612
Effect of foreign currency translation on Goodwill acquired - HalioDx	(6,317)
Balance as of September 30, 2021	$ 714,273

Intangible Assets, Net

Intangible assets include finite-lived product technology, customer relationships, licenses and trade names and indefinite-lived in-process research and development. Intangible assets consisted of the following (in thousands of dollars):

	September 30, 2021			December 31, 2020			Weighted Average Amortization Period (Years)
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	
Percepta product technology	$ 16,000	$ (6,933)	$ 9,067	$ 16,000	$ (6,133)	$ 9,867	15
Prosigna product technology	4,120	(504)	3,616	4,120	(298)	3,822	15
Prosigna customer relationships	2,430	(891)	1,539	2,430	(526)	1,904	5
nCounter Dx license	46,880	(5,730)	41,150	46,880	(3,386)	43,494	15
LymphMark product technology	990	(259)	731	990	(153)	837	7
Decipher product technology	90,000	(4,984)	85,016	—	—	—	10
Decipher trade names	4,000	(443)	3,557	—	—	—	5
HalioDx developed technology	46,720	(772)	45,948	—	—	—	10
HalioDx customer relationships	4,985	(318)	4,667	—	—	—	6
HalioDx customer backlog	7,072	(142)	6,930	—	—	—	4
Total finite-lived intangibles	223,197	(20,976)	202,221	70,420	(10,496)	59,924	10.9
In-process research and development	7,300	—	7,300	—	—	—	
Total intangible assets	$ 230,497	$ (20,976)	$ 209,521	$ 70,420	$ (10,496)	$ 59,924	

Amortization of the finite-lived intangible assets is recognized on a straight-line basis. Amortization expense of $5.0 million and $1.3 million was recognized for the three months ended September 30, 2021 and 2020, respectively. Amortization expense of $10.5 million and $3.8 million was recognized for the nine months ended September 30, 2021 and 2020, respectively.

The estimated future aggregate amortization expense as of September 30, 2021 is as follows (in thousands of dollars):

Year Ending December 31,	Amounts
2021 remainder of year	$ 5,542
2022	22,165
2023	22,165
2024	22,125
2025	21,679
Thereafter	108,545
Total	$ 202,221

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands of dollars):

	September 30, 2021	December 31, 2020
Accrued compensation expenses	$ 22,628	$ 9,201
Accrued other	6,416	2,504
Total accrued liabilities	$ 29,044	$ 11,705

4. Business Combinations

HalioDx

On August 2, 2021, the Company acquired 100% of the equity interests (the "HalioDx Acquisition") of HalioDx SAS and 100% of the equity interest of HalioDx Inc., historically a wholly owned subsidiary of HalioDx SAS, (collectively referred to as “HalioDx”). HalioDx was a privately-held company providing immune-based diagnostic products and services. The consideration to acquire HalioDx was $320.9 million, comprised of $147.1 million in the form of 3.3 million shares of the Company’s common stock based on the Company's share price on the closing date, $4.2 million in liabilities, and the remainder in cash. The Company incurred $7.7 million of transaction costs related to the acquisition of HalioDx, which were recorded as general and administrative expense during the nine months ended September 30, 2021.

In connection with the HalioDx Acquisition, 11,031 unvested HalioDx free ordinary share awards, or free shares, were modified to provide the Company the right to purchase the vested free shares (call option) from the holders and the holders the right to sell the vested free shares to the Company (put option) from time to time through late 2023. As a result of the call and put options, the free shares are liability classified with an initial fair value of $5.1 million, based on the expected settlement amount. As the free shares require the holders to continue to provide services post-combination, the Company included $3.5 million, attributed to pre-combination services, in the purchase price and the remainder will be recorded in post-combination compensation expense, which will be recognized over the period the holders provide services to the Company.

Additionally, in connection with the HalioDx Acquisition, all of HalioDx's equity-classified options that were outstanding prior to the HalioDx Acquisition were terminated and cancelled at the acquisition date. The Company paid holders of vested options cash consideration of $0.4 million and as the payment is related to pre-combination services, the amount was included in the purchase price. The Company also committed to pay cash consideration of $1.5 million to holders of unvested options on the date the employee satisfies the original service requirement. As this payment requires continuing services and is forfeited if the holders' employment is terminated, the amount was considered nonrecurring post-combination compensation expense and will be recognized over the remaining service period.

As part of the agreement, the Company held back $16.8 million of the cash consideration, or the holdback, which will be payable to the founders of HalioDx based on their continuous employment with the Company. Fifty percent of the holdback will be placed in escrow on the founders' behalf on the first anniversary of the closing date and the remainder will be paid directly to the founders on the second anniversary. As this payment is dependent on the founders’ continuing employment and

is forfeited if the employment is terminated, the holdback is not included in the purchase price and will be recognized as post-combination compensation expense over the two-year service period.

For both the three months and nine months ended September 30, 2021, the Company recognized post-combination expense of $1.6 million, of which $0.1 million was recorded as cost of revenue, $0.3 million was recorded as research and development, $0.5 million was recorded as sales and marketing, and the remainder was recorded as general and administrative.

The Company included the financial results of HalioDx in its condensed consolidated financial statements from the acquisition date, which contributed $4.7 million and $6.3 million of revenue and operating loss, respectively, during both the three months and nine months ended September 30, 2021.

The following table summarizes the purchase price and post-combination compensation expense as a part of the HalioDx Acquisition (in thousands):

	Purchase Price	Post-Combina Compensation Expens
Cash transferred	$ 169,583	$
Liabilities incurred	4,194	
Common stock transferred	147,089	
Total	$ 320,866	$

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed in the acquisition of HalioDx at the date of acquisition (in thousands):

Cash and cash equivalents	$	5,938
Accounts receivable		10,793
Supplies inventory		3,610
Prepaids and other current assets		7,045
Property and equipment, net		2,716
Right-of-use assets, financing lease		733
Right-of-use assets, operating lease		2,136
Intangible assets		60,303
Other assets		524
Total identifiable assets acquired		93,798
Accounts payable		(2,645)
Accrued liabilities		(5,628)
Current portion of financing lease liability		(245)
Current portion of operating lease liability		(448)
Long-term debt		(1,171)
Deferred revenue		(3,250)
Financing lease liability, net of current portion		(488)
Operating lease liability, net of current portion		(1,687)
Deferred tax liability		(6,982)
Net identifiable assets acquired		71,254
Goodwill		249,612
Total purchase price	$	320,866

VERACYTE, INC.
Notes to Financial Statements
(unaudited)

Based on the guidance provided in ASC 805, the Company accounted for the acquisition of HalioDx as a business combination in which the Company determined that HalioDx was a business which combines inputs and processes to create outputs, and substantially all of the fair value of gross assets acquired was not concentrated in a single identifiable asset or group of similar identifiable assets.

The Company's purchase price allocation for the HalioDx Acquisition is preliminary and subject to revision as additional information about the fair value of the assets and liabilities becomes available. The fair values assigned to tangible and intangible assets acquired, and liabilities assumed, are based on management's estimates and assumptions and may be subject to change as additional information is received. Primary areas that are not yet finalized are related to certain income tax items, intangible assets, deferred revenue, accounts receivable, other assets, commitments and contingencies and goodwill. Additional information that existed as of the closing date but not known at the time of this filing may become known to the Company during the remainder of the measurement period, a period not to exceed 12 months from the closing date.

The intangible assets acquired include three developed technology assets (related to diagnostics, biopharma, and contract IVD), two customer relationships assets (related to biopharma and contract IVD), and two customer backlog assets (related to biopharma and contract IVD). The fair value of our intangible assets acquired as of the acquisition date and the method used to value these assets as well as the estimated economic lives for amortizable intangible assets were as follows (in thousands, except estimated useful life which is in years):

	Fair value	Estimated useful life	Valuation method
Developed technology – diagnostics	$ 4,163	10	Multi-period excess earnings
Developed technology – biopharma	42,224	10	Multi-period excess earnings
Developed technology – contract IVD	1,546	10	Multi-period excess earnings
Customer relationships – biopharma	2,141	7	With-and-without
Customer relationships – contract IVD	2,973	5	With-and-without
Customer backlog – biopharma	2,736	4	Multi-period excess earnings
Customer backlog – contract IVD	4,520	4	Multi-period excess earnings
Total	$ 60,303		

The amortization expense for all acquired intangible assets will be recognized on a straight-line basis and recorded within intangible asset amortization.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The HalioDx Acquisition resulted in the recognition of $249.6 million of goodwill which the Company believes consists primarily of expanded market and product opportunities, including new areas of testing, as well as the potential manufacturing of the Company's product offerings for international markets. Goodwill created as a result of the HalioDx Acquisition is not deductible for tax purposes. The HalioDx Acquisition allows the Company to continue to develop and further enhance its business as a global diagnostics company and continues the Company's ability to inform the diagnosis and treatment decisions related to cancer. The HalioDx portfolio complements and expands the existing business and allows for vertical integration through the addition of manufacturing capabilities for the Company's test kits.

In connection with the HalioDx acquisition, a net deferred tax liability was assumed with a fair value of $7.0 million which primarily relates to future intangible asset amortization which is not deductible for income tax purposes.

The Company also granted restricted stock units, or RSUs, to new employees who joined the Company in connection with the HalioDx Acquisition with a fair value of $16.5 million, net of estimated forfeitures. As the number of shares that are expected to be issued is fixed, the awards are equity-classified. The RSUs vest over four years, subject to the employees' continuous service. During the three and nine months ended September 30, 2021, the Company recorded $2.6 million in stock-based compensation expense which includes $2.0 million related to one employee whose continuing services were deemed non-substantive.

Decipher Biosciences

On March 12, 2021, the Company acquired 100% of the equity interests of Decipher Biosciences, a privately-held company developing diagnostic tests in urologic cancers, for approximately $594.7 million, comprised of approximately $550.5 million in the form of upfront cash consideration and the remainder in cash payable post-acquisition of which $43.8 million was paid prior to June 30, 2021 (the "Decipher Acquisition"). The Company incurred approximately $10.6 million of transaction costs related to the acquisition of Decipher Biosciences which were recorded as general and administrative expense during the nine months ended September 30, 2021.

In connection with the Decipher Acquisition, certain of Decipher Biosciences' equity awards that were outstanding and unvested prior to the Decipher Acquisition became fully vested per the terms of the merger agreement. The acceleration of vesting required the Company to allocate the fair value of the historical Decipher Biosciences' employee stock awards attributable to pre-combination service to the purchase price and the remaining amount was considered the Company's nonrecurring post-combination expense. In March 2021, the Company recognized nonrecurring post-combination expense related to the acceleration and cash settlement of unvested historical Decipher Biosciences' employee stock awards of $25.1 million, all of which was recorded as general and administrative expense during the quarter ended March 31, 2021.

The Company included the financial results of Decipher Biosciences in its condensed consolidated financial statements from the acquisition date, which contributed $21.3 million and $5.4 million of revenue and operating income, respectively, during the three months ended September 30, 2021 and $44.0 million and $10.3 million of revenue and operating income, respectively, during the nine months ended September 30, 2021.

The following table summarizes the purchase price and nonrecurring post-combination compensation expense recorded as a part of the Decipher Acquisition (in thousands):

	Purchase Price	Nonrecurring Post-Combination Compensati Expense
Upfront cash consideration	$ 550,515	$
Liabilities incurred	44,179	24
Total	$ 594,694	$ 25

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the fair values of

assets acquired and liabilities assumed through the Company's acquisition of Decipher Biosciences at the date of acquisition (in thousands):

Cash and cash equivalents	$	19,782
Accounts receivable		7,562
Supplies inventory		1,641
Prepaids and other current assets		778
Property and equipment, net		1,737
Right-of-use assets, operating lease		7,601
Finite-lived intangible assets		94,000
Indefinite-lived intangible assets		7,300
Restricted cash		146
Other assets		3,075
Total identifiable assets acquired		143,622
Accounts payable		(2,351)
Accrued liabilities		(4,322)
Operating lease obligations (current)		(1,241)
Operating lease obligations, net of current portion		(4,540)
Deferred tax liability		(4,727)
Net identifiable assets acquired		126,441
Goodwill		468,253
Total purchase price	$	594,694

Based on the guidance provided in ASC 805, the Company accounted for the acquisition of Decipher Biosciences as a business combination in which the Company determined that Decipher Biosciences was a business which combines inputs and processes to create outputs, and substantially all of the fair value of gross assets acquired was not concentrated in a single identifiable asset or group of similar identifiable assets.

The Company's purchase price allocation for the Decipher Acquisition is preliminary and subject to revision as additional information about the fair value of the assets and liabilities becomes available. The fair values assigned to tangible and intangible assets acquired and liabilities assumed are based on management’s estimates and assumptions and may be subject to change as additional information is received. Primary areas that are not yet finalized are related to accounts receivable, and goodwill. Additional information that existed as of the closing date but not known at the time of this filing may become known to the Company during the remainder of the measurement period, a period not to exceed 12 months from the closing date.

During the nine months ended September 30, 2021, the Company recorded certain measurement period adjustments due to new information becoming available pertaining to the valuation of accounts receivable and certain other assets. These adjustments were recorded as decreases to goodwill and did not impact the condensed consolidated statement of operations. One of these adjustments relates to cash collections of accounts receivable that existed as of the acquisition date exceeding the initial fair value of accounts receivable recorded on the acquisition date by $1.8 million.

The intangible assets acquired are two in-process research and development, or IPR&D, assets (Metastatic Hormone Sensitive Cancer and Castrate Resistant Cancer), developed technology, and trade names. Additionally, the Company identified certain off-market leases and an intangible asset of $1.8 million is included in operating lease assets which will be amortized over the remaining lease term.

The estimated fair value of the IPR&D is determined using the multi-period excess earnings method which calculates the present value of the estimated revenues and net cash flows derived from the IPR&D once the technologies are developed. The IPR&D is not amortized until it becomes commercially viable and placed in service. At the time when the intangible assets are placed in service the Company will determine a useful life.

VERACYTE, INC.
Notes to Financial Statements
(unaudited)

The fair value of the finite-lived intangible assets was estimated as follows: (i) the developed technology of $90.0 million was based on a multi-period excess earnings method, and (ii) the trade names of $4.0 million was based on the relief from royalty method. The estimated useful life for the developed technology is 10 years, and the estimated useful life for the trade names is five years. The amortization expense related to finite-lived intangible assets is recorded within the intangible asset amortization financial statement line item.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The Decipher Acquisition resulted in the recognition of $468.3 million of goodwill which the Company believes consists primarily of expanded market and product opportunities, including new areas of genomic testing, as well as the potential expansion of the Company's product offerings in international markets. Furthermore, the acquisition of Decipher Biosciences bolsters the Company's presence to seven of the ten most common cancers impacting patients in the United States, which in turn enhances the Company’s overall prominence in the genomic testing arena. Goodwill created as a result of the Decipher Acquisition is not deductible for tax purposes. The Decipher Acquisition advances the Company's objective to improve the lives of patients through innovations in genomic technology tailored for diagnostic, prognostic, and treatment decisions related to urologic cancers.

We recorded an income tax benefit primarily due to net deferred tax liabilities assumed in connection with the Decipher Acquisition, which provided a future source of income to support the realization of our deferred tax assets and resulted in a release of $3.5 million in the Company's valuation allowance.

Supplemental Pro Forma Information (unaudited)

The unaudited pro forma financial information in the table below summarizes the combined results of operations for Veracyte, Decipher and HalioDx as though the companies had been combined as of January 1, 2020. The pro forma amounts have been adjusted for:

- day 1 expense related to the accelerated vesting of unvested legacy Decipher and HalioDx equity awards,
- transaction expenses incurred by Decipher, HalioDx and us,
- lease expense resulting from the fair value adjustments to the operating lease obligation and operating lease asset for both Decipher and HalioDx,
- depreciation expense resulting from the fair value adjustments to fixed asset for both Decipher and HalioDx,
- amortization expense resulting from the acquired intangible assets for both Decipher and HalioDx,
- the elimination of historical interest expense incurred on debt and debt-like items for both Decipher and HalioDx,
- income tax benefits resulting from the deferred tax liabilities acquired related to Decipher, and
- compensation expense recognized in relation to the equity awards granted in connection with both acquisitions.

The following unaudited pro forma financial information is for informational purposes only and is not necessarily indicative of the results of operations that would have been achieved as if the acquisitions had taken place as of January 1, 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Total revenues	$ 62,608	$ 47,402	$ 178,525	$ 124,863
Net Loss	$ (7,672)	$ (9,971)	$ (27,858)	$ (106,397)

Related Party Transactions

Members of Veracyte's board of directors, Dr. Tina S. Nova, Ph.D. and Dr. Robert S. Epstein, M.D., M.S., served on the board of directors of Decipher Biosciences prior to the acquisition of Decipher Biosciences, with Dr. Nova additionally serving as President and Chief Executive Officer of Decipher Biosciences. Pursuant to Veracyte's related party transactions policy, Dr. Nova and Dr. Epstein recused themselves from all discussions of its board of directors related to the Decipher Acquisition, and the Decipher Acquisition was approved by each of the non-interested members of the board of directors. In connection with the Decipher Acquisition, certain Decipher Biosciences equity awards held by Dr. Nova and Dr. Epstein were fully-accelerated and certain incentive bonus payments were made to Dr. Nova pursuant to a management incentive plan established by the Decipher Biosciences board of directors, resulting in payments of approximately $26.5 million and $1.4 million to each of them,

respectively. Dr. Nova resigned from Veracyte's board of directors and now serves as Veracyte's General Manager, Thyroid and Urologic Cancers. Dr. Epstein continues to serve on Veracyte's board of directors.

5. Fair Value Measurements

The Company records its financial assets and liabilities at fair value. The carrying amounts of certain financial instruments of the Company, including cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities. The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value, and expands disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

- Level I: Inputs which include quoted prices in active markets for identical assets and liabilities;
- Level II: Inputs other than Level I that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level III: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The fair value of the Company's financial assets includes money market funds and deposits for leases of the Company's facilities. Money market funds, included in cash and cash equivalents in the accompanying condensed consolidated balance sheets, were $150.8 million and $346.8 million as of September 30, 2021 and December 31, 2020, respectively, and are Level I assets as described above. Included in prepaid expenses and other current assets as of September 30, 2021 were time deposits with a bank valued at amortized cost of $4.1 million, which approximates fair value, and are Level II assets as described above. The deposits for the leases, included in restricted cash in the accompanying condensed consolidated balance sheets, were $749,000 and $603,000 as of September 30, 2021 and December 31, 2020, respectively, and are a Level I assets as described above.

On December 3, 2019, the Company acquired from NanoString the exclusive global diagnostics license to the nCounter Analysis System, the Prosigna breast cancer prognostic gene signature assay, and the LymphMark lymphoma subtyping assay. Pursuant to the terms of the agreement, Veracyte paid NanoString $40.0 million in cash and $10.0 million in Veracyte common stock, and may pay up to an additional $10.0 million in cash, contingent upon the commercial launch of Veracyte diagnostic tests for use on the platform. This contingency was valued at $6.1 million as of the acquisition date and is remeasured to fair value at each reporting date until the contingent consideration is settled. As of September 30, 2021 and December 31, 2020, this contingency was remeasured to $7.9 million and $7.6 million, respectively, with the corresponding changes included in general and administrative expense in the Company's condensed consolidated statements of operations. As of September 30, 2021, the achievement of one of the milestones is forecasted to occur within the next 12 months. As a result, $2.6 million of the contingent consideration is included in short term liabilities at September 30, 2021. The fair value of the contingent consideration includes inputs that are not observable in the market and thus represents a Level III financial liability. The estimation of the fair value of the contingent consideration is based on the present value of the expected payments calculated by assessing the likelihood of when the related milestones would be achieved and estimating the Company's borrowing rate. These estimates form the basis for making judgments about the carrying value of the contingent consideration that are not readily apparent from other sources. Changes to the forecasts for the achievement of the milestones and the borrowing rate can significantly affect the estimated fair value of the contingent consideration. As of September 30, 2021 and December 31, 2020, the Company calculated the estimated fair value of the milestones using the following significant unobservable inputs:

	Value or Range (Weighted-Average)	
Unobservable input	**September 30, 2021**	**December 31, 2020**
Discount rate	5.7%	6.9%
Probability of achievement	80% - 100% (88%)	70% - 100% (86%)

VERACYTE, INC.
Notes to Financial Statements
(unaudited)

6. Commitments and Contingencies

Operating Leases

The Company leases office and laboratory facilities in South San Francisco and San Diego, California, Austin, Texas, Marseille, France, and Richmond, Virginia, and leases certain equipment under various non-cancelable lease agreements. The lease terms extend to January 2029 and contain extension of lease term and expansion options. The leases have a weighted average remaining lease term of 5.2 years as of September 30, 2021. The Company had deposits of $749,000 and $603,000 included in long-term assets as of September 30, 2021, and December 31, 2020, respectively, restricted from withdrawal and held by banks in the form of collateral for irrevocable standby letters of credit held as security for the leases.

The Company determined its operating lease liabilities using payments through their current expiration dates and a weighted average discount rate of 6.5% based on the rate that the Company would have to pay to borrow, on a collateralized basis, an amount equal to the lease payments in a similar economic environment. Operating lease liabilities along with the associated right-of-use assets are disclosed in the accompanying condensed consolidated balance sheets. After the adoption of ASC 842, *Leases*, or ASC 842, the Company classified its deferred rent for tenant improvements with its operating lease right-of-use assets on the consolidated balance sheets. In connection with the acquisition of Decipher Biosciences, the Company identified certain off-market rate leases and has estimated an intangible asset of $1.8 million which is included in operating lease assets and will be amortized over the remaining lease term. See Note 4 for more information on the acquisition of Decipher Biosciences.

Future minimum lease payments under non-cancelable operating leases as of September 30, 2021 are as follows (in thousands of dollars):

Year Ending December 31,	**Amounts**
Remainder of 2021	$ 1,042
2022	4,226
2023	4,296
2024	4,310
2025	4,380
Thereafter	2,487
Total future minimum lease payments	20,741
Less: amount representing interest	3,040
Present value of future lease payments	17,701
Less: short-term lease liabilities	3,465
Long-term lease liabilities	$ 14,236

The Company recognizes operating lease expense on a straight-line basis over the non-cancelable lease period. The following table summarizes operating lease expense and cash paid for amounts included in the measurement of lease liabilities (in thousands of dollars):

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2021	**2020**	**2021**	**2020**
Operating lease expense	$ 982	$ 472	$ 2,460	$ 1,417
Cash paid for amounts included in the measurement of lease liabilities	$ 1,011	$ 587	$ 2,518	$ 1,744

The company has leased laboratory equipment under various financing leases. The total right-of-use assets and total financing lease liabilities for these financing leases were each $0.7 million as of September 30, 2021, and are included in property and equipment, net and other liabilities in the accompanying condensed consolidated balance sheets.

As of September 30, 2021, the Company's wholly owned foreign subsidiary has entered into an arrangement under which it expects to sign a lease agreement for facilities which will be constructed in Marseille, France. The lease will commence upon completion of the construction of the office building which the Company currently expects to occur in the fourth quarter of 2023. The initial term of the lease will be twelve years with annual rent of approximately $1.4 million, which is subject to change based on final construction.

Contingencies

From time to time, the Company may be involved in legal proceedings arising in the ordinary course of business. The Company assesses contingencies to determine the degree of probability and range of possible loss for potential accrual in its condensed consolidated financial statements. An estimated loss contingency is accrued in the financial statements if it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company believes there are no legal proceedings pending that could have, either individually or in the aggregate, a material adverse effect on the Company's condensed consolidated financial statements.

7. Debt

Loan and Security Agreement

On November 3, 2017, the Company entered into a loan and security agreement, or Loan and Security Agreement, with Silicon Valley Bank. The Loan and Security Agreement allows the Company to borrow up to $35.0 million, with a $25.0 million advance term loan, or Term Loan Advance, and a revolving line of credit of up to $10.0 million, or Revolving Line of Credit. The Term Loan Advance was advanced upon the closing of the Loan and Security Agreement and was used to pay the outstanding balance of the Company's existing long-term debt, which was canceled at that date. The Company had not drawn on the Revolving Line of Credit as of September 30, 2021. Borrowings under the Loan and Security Agreement mature on October 1, 2022. Amounts may be borrowed and repaid under the Revolving Line of Credit up until the earliest of full repayment or maturity of the Loan and Security Agreement, termination of the Loan and Security Agreement, or October 1, 2022.

The Term Loan Advance bears interest at a variable rate equal to (i) the thirty-day U.S. London Interbank Offer Rate, or LIBOR, plus (ii) 4.20%, with a minimum rate of 5.43% per annum. Principal amounts outstanding under the Revolving Line of Credit bear interest at a variable rate equal to (i) LIBOR plus (ii) 3.50%, with a minimum rate of 4.70% per annum.

The Company may prepay the outstanding principal amount under the Term Loan Advance plus accrued and unpaid interest and, if the Term Loan Advance is repaid in full, a prepayment premium of $250,000. In 2019 and 2020, the Company prepaid $24.9 million and $0.1 million, respectively, of the principal amount of the Term Loan Advance. These prepayments did not trigger any prepayment premium because they were partial, not full, repayments of the principal amount. If the Loan and Security Agreement is terminated before maturity, then a termination fee equal to 1% of the Revolving Line of Credit, or $0.1 million, will be due.

In addition, a final payment on the Term Loan Advance in the amount of $1.2 million is due upon the earlier of the maturity date of the Term Loan Advance or its payment in full. The Loan and Security Agreement contains customary representations, warranties, and events of default, as well as affirmative and negative covenants. As of September 30, 2021, the Company was in compliance with the loan covenants. The Company's obligations under the Loan and Security Agreement are secured by substantially all of its assets (excluding intellectual property), subject to certain customary exceptions.

The debt obligation for borrowings made under the Loan and Security Agreement was as follows (in thousands of dollars):

	September 30, 2021	December 31, 2020
Debt principal	$ —	$ —
End-of-term debt obligation	971	810
Total debt obligation	$ 971	$ 810

As of September 30, 2021, the principal balance outstanding was one dollar. Future principal and end-of-term debt obligation payments under the Loan and Security Agreement are $1.2 million and due in 2022. As of September 30, 2021 and December 31, 2020, the accrued interest payable under the Loan and Security Agreement was immaterial.

The end-of-term debt obligation accretes over the term of the Loan and Security Agreement until maturity and is included in interest expense in the Company's condensed consolidated statements of operations.

8. Stockholders' Equity

Common Stock

The Company had reserved shares of common stock for issuance as follows:

	September 30, 2021	December 31, 2020
Stock options and restricted stock units issued and outstanding	4,961,248	4,867,303
Stock options and restricted stock units available for grant under stock option plans	4,439,910	3,061,589
Common stock available for the Employee Stock Purchase Plan	1,490,130	1,571,395
Total	10,891,288	9,500,287

9. Components of Other Income (Loss)

Other income (loss), net consists of the following (in thousands of dollars):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
French research tax credits	$ 419	$ —	$ 419	$ —
Interest income	27	3	46	21
Interest expense	(61)	(55)	(177)	(175)
Gain (loss) on currency revaluation	708	(8)	(1,159)	17
Other	109	2	109	589
	$ 1,202	$ (58)	$ (762)	$ 452

10. Income Taxes

The Company recorded an income tax benefit of approximately $1.4 million and $5.3 million for the three and nine months ended September 30, 2021, and no income tax provision or benefit for the three and nine months ended September 30, 2020. The income tax benefit for 2021 was primarily impacted by a discrete tax adjustment related to the release of certain valuation allowances on the Company's deferred tax assets upon recording of the deferred tax liabilities for the acquisition of Decipher Biosciences and a benefit on the current year loss of HalioDx, while 2020 had a full valuation allowance on all net deferred tax assets.

On March 27, 2020, and on December 27, 2020, respectively, the Coronavirus Aid, Relief, and Economic Security Act and the Consolidated Appropriations Act were enacted in response to the COVID-19 pandemic. The Company does not expect the provisions of such legislation to have a significant impact on the effective tax rate, the results of operations or the financial position of the Company.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of financial condition and results of operations should be read together with the condensed consolidated financial statements and the related notes included in Item 1 of Part I of this Quarterly Report on Form 10-Q, and with our audited financial statements and the related notes included in our Annual Report on Form 10-K for the year ended December 31, 2020.

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this report, the words "expects," "anticipates," "intends," "estimates," "plans," "believes," "continuing," "ongoing," and similar expressions are intended to identify forward-looking statements. These are statements that relate to future events and include, but are not limited to, the factors that may impact our financial results; our expectations regarding revenue; our expectations with respect to our future research and development, general and administrative and selling and marketing expenses and our anticipated uses of our funds; the impact of the COVID-19 pandemic on our business and the U.S. and global economies; our expectations regarding the return to pre-COVID-19 volume and revenue levels; our ability to successfully integrate HalioDx into our business; changes in our executive officers; our beliefs with respect to the optimization of our processes for the analysis of ribonucleic acid, or RNA, samples; our integration of Decipher Biosciences Inc. and the assets acquired from NanoString Technologies, Inc.; our ability to deploy the nCounter Analysis System successfully and run our tests on this platform worldwide; our collaboration with Johnson & Johnson Services, Inc.; our belief in the importance of maintaining libraries of clinical evidence; our expectations regarding the nasal swab classifier for early lung cancer detection, the Percepta Lung Cancer Atlas, the Envisia classifier on the nCounter system and the LymphMark lymphoma subtyping test; our expectations regarding our diagnostic company partnerships; our ability to have the targeted Atlas platform transferred to our pulmonology indications; our expectations regarding the Percepta Lung Cancer Atlas; our expectations regarding capital expenditures; our anticipated cash needs and our estimates regarding our capital requirements; the timing and success of our transition to a single platform for all of our classifiers and tests; our ability to maintain Medicare coverage for each of our tests; our need for additional financing; potential future sources of cash; our business strategy and our ability to execute our strategy; our ability to achieve and maintain reimbursement from third-party payers at acceptable levels and our expectations regarding the timing of reimbursement; the estimated size of the global markets for our tests; the estimated number of patients who are candidates for our test; the attributes and potential benefits of our tests and any future tests we may develop to patients, physicians and payers; the factors we believe drive demand for and reimbursement of our tests; our ability to sustain or increase demand for our tests; our intent to expand into other clinical areas; our ability to develop new tests, and the timeframes for development or commercialization; our ability to get our data and clinical studies accepted in peer-reviewed publications; our dependence on and the terms of our agreement with Thyroid Cytopathology Partners, or TCP, and on other strategic relationships, and the success of those relationships; our beliefs regarding our laboratory capacity; the potential for future clinical studies to contradict or undermine previously published clinical study results; the applicability of clinical results to actual outcomes; our expectations regarding our international expansion; the occurrence, timing, outcome or success of clinical trials or studies; the ability of our tests to impact treatment decisions; our beliefs regarding our competitive position; our compliance with federal, state and international regulations; the potential impact of regulation of our tests by the Food and Drug Administration, or FDA, or other regulatory bodies; the impact of new or changing policies, regulation or legislation, or of judicial decisions, on our business; the impact of seasonal fluctuations and economic conditions on our business; our belief that we have taken reasonable steps to protect our intellectual property; our belief that our intellectual property will develop and maintain our competitive position; the impact of accounting pronouncements and our critical accounting policies, judgments, estimates, models and assumptions on our financial results; and anticipated trends and challenges in our business and the markets in which we operate. We caution you that the foregoing list does not contain all of the forward-looking statements made in this report.

Forward-looking statements are based on our current plans and expectations and involve risks and uncertainties which could cause actual results to differ materially. These risks and uncertainties include, but are not limited to, those risks discussed in Part II, Item 1A of this report. These forward-looking statements speak only as of the date hereof. We expressly disclaim any obligation or undertaking to update any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

When used in this report, all references to "Veracyte," the "company," "we," "our" and "us" refer to Veracyte, Inc.

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This report contains statistical data and estimates that we obtained from industry publications and reports. These publications typically indicate that they have obtained their information from sources they believe to be reliable, but do not guarantee the accuracy and completeness of their information. Some data contained in this report is also based on our internal estimates.

Overview

We are a global diagnostics company that improves patient care by answering important clinical questions to inform diagnosis and treatment decisions throughout the patient journey in cancer and other diseases. Our growing menu of tests leverage advances in genomic science and machine learning technology to change care for patients, enabling them to avoid unnecessary and potentially harmful procedures and interventions, and accelerate time to more appropriate treatment. In addition to making our genomic tests available in the United States through our central laboratories, we believe our exclusive access to the nCounter Analysis System, a best-in-class diagnostics platform, positions us to deliver our tests to patients worldwide through laboratories and hospitals that can perform them locally.

In August 2021, we acquired HalioDx SAS, a Marseille, France based immuno-oncology diagnostics company with robust in vitro diagnostics, or IVD, test development and manufacturing, as well as biopharmaceutical service offerings, to augment our international growth and strengthen our global leadership in cancer diagnostics. We believe the HalioDx acquisition provides three key strategic benefits to Veracyte:

- *Enables Veracyte to develop and manufacture tests for the nCounter diagnostic platform*. We plan to transition manufacturing of our tests, currently produced by NanoString in the U.S., to HalioDx's manufacturing facility in France. We believe that this will accelerate the expansion of our test menu on the nCounter platform in Europe and other strategic global markets.
- *Deepens Veracyte's scientific capabilities*. HalioDx's immuno-oncology platform offers potential pipeline development opportunities in a range of clinical indications and can serve as a platform to grow our biopharma partnering business.
- *Expands Veracyte's cancer diagnostics portfolio to 8 of the 10 most common cancers in the United States*. The addition of HalioDx's Immunoscore test to guide treatment decisions in colorectal cancer will further expand our menu of high-value advanced diagnostic tests that address unmet needs at multiple points in the patient care continuum.

We design our tests to address specific unmet needs in the diagnosis, prognosis and treatment of cancer and other diseases to thus improve patient outcomes, while delivering clinical and economic utility to physicians, payers and the healthcare system. We develop and publish extensive clinical performance and utility data for our tests, or classifiers, which has enabled us to secure Medicare reimbursement for each of our genomic classifiers in our commercial indications. We endeavor to position our tests to integrate seamlessly into the way physicians currently evaluate patients in order to facilitate adoption.

We develop our genomic tests using advanced scientific methods, such as RNA whole-transcriptome analysis and machine learning. Most of our genomic tests are performed in our CLIA certified laboratories in South San Francisco and San Diego, California. In December 2019, we acquired from NanoString Technologies, Inc. the exclusive global diagnostics rights to the nCounter Analysis System, a fully-automated, easy-to-use instrument that can analyze up to 800 genes simultaneously. Through the transaction, we also acquired two genomic tests – one commercialized and one in development – for use on the instrument. We expect to adapt select tests that are currently performed in our CLIA certified labs to be performed as in vitro diagnostics on the nCounter Analysis System to make them available to physicians and patients in global markets. Additionally, we perform our immuno-oncology tests obtained through the HalioDx acquisition in our CLIA certified labs in Marseille, France, and Richmond, Virginia.

Clinical Diagnostic Tests

We currently offer clinical tests that are improving diagnosis and patient care in thyroid cancer; prostate cancer; bladder cancer; breast cancer; lung cancer; interstitial lung diseases, or ILD, including idiopathic pulmonary fibrosis, or IPF; and colon cancer.

- ***Thyroid Cancer - Afirma Genomic Sequencing Classifier, or GSC.*** Our Afirma GSC provides physicians with clinically actionable results from a single fine needle aspiration, or FNA biopsy, to improve thyroid cancer diagnosis. The Afirma GSC was developed with RNA whole-transcriptome sequencing and machine learning, and is used to identify patients with benign thyroid nodules among those with indeterminate cytopathology results in order to rule out unnecessary thyroid surgery. As part of this offering, the Afirma Xpression Atlas provides genomic alteration content

from the same FNA samples used in Afirma GSC testing to help physicians decide with greater confidence on the surgical or therapeutic pathway for their patients.

- ***Prostate Cancer - Decipher Prostate Biopsy and Radical Prostatectomy, or RP, Genomic Classifiers.*** The Decipher Prostate cancer tests, developed through RNA whole-transcriptome analysis, predict a patient's risk of progressing to metastatic disease, which helps physicians determine an appropriate treatment plan. The Decipher Prostate Biopsy test is used for patients following a cancer diagnosis to inform whether the patient is a candidate for active surveillance, needs monotherapy or may benefit from multi-modal or intensified therapy. The Decipher Prostate RP test is used following surgery to guide decision-making regarding treatment timing following radical prostatectomy and whether patients undergoing salvage radiotherapy may benefit from the addition of hormone therapy.
- ***Breast Cancer - Prosigna Breast Cancer Prognostic Gene Signature Assay.*** The Prosigna test uses advanced genomic technology to inform next steps for patients with early-stage breast cancer, based on the genomic make-up of their disease. The test uses a set of 50 genes known as the PAM50 gene signature and can provide a breast cancer patient and their physician with a prognostic score that indicates the probability of cancer recurrence over ten years. The Prosigna test is performed as an IVD test on the nCounter Analysis System and is offered in the U.S. and global markets. Patient test results outside of the United States include intrinsic breast cancer subtypes to complement the risk-of-recurrence score.
- ***Lung Cancer - Percepta Genomic Sequencing Classifier (GSC).*** The Percepta GSC improves lung cancer diagnosis when diagnostic bronchoscopy results are inconclusive. The test, developed with RNA whole-transcriptome sequencing, identifies patients with lung nodules who are at low risk of cancer and may avoid further, invasive procedures as well as patients at high risk of cancer so they may obtain faster diagnosis and treatment. The test is built upon foundational "field of injury" science - through which genomic changes associated with lung cancer in current and former smokers can be identified with a simple brushing of a patient's airway - without the need to sample the often hard-to-reach nodule directly.
- ***ILD/IPF - Envisia Genomic Classifier.*** The Envisia classifier improves diagnosis of ILDs, including IPF, without the need for surgery. The test identifies the genomic pattern of usual interstitial pneumonia, or UIP, a hallmark of IPF, with high accuracy on patient samples that are obtained through transbronchial biopsy, a nonsurgical procedure that is commonly used in lung evaluation.
- ***Colon Cancer - Immunoscore Colon Cancer Test.*** The Immunoscore platform combines advances in immuno-oncology science and digital pathology to assess lymphocytic infiltration in human tumors and is used to predict patient outcomes in several indications. The Immunoscore Colon Cancer test is available as a CLIA or CE-marked test that can be used in Stage II localized colon cancer to help physicians identify patients who may be spared adjuvant chemotherapy, and in Stage III localized colon cancer to guide physicians in their adjuvant chemotherapy prescription.
- ***Bladder Cancer - Decipher Bladder Genomic Classifier.*** Decipher Bladder is a genomic test that measures the molecular profile of bladder cancer using gene expression analysis from transurethral resected bladder tumor specimens. It was developed for bladder cancer patients with high-grade non-muscle-invasive disease who are being considered for treatment and patients with muscle-invasive disease who face the question of immediate cystectomy or systemic treatment in the neoadjuvant setting prior to cystectomy (NAC). Decipher Bladder reports the molecular subtype of the tumor specimen as Luminal or Non-Luminal (Luminal Infiltrated, Basal, Basal Claudin-Low or Neuroendocrine-like), with each subtype having distinct biological composition, clinical behavior and predicted benefit from NAC.

Patients access our tests through their physician. Our Afirma, Decipher, Percepta, Envisia and Immunoscore tests are marketed as laboratory developed tests. Cytopathology services for Afirma testing are performed in our CLIA-certified laboratory in Austin, Texas. Prosigna is an FDA-cleared IVD test that is performed on the nCounter Analysis System in laboratories globally.

We expect to continue expanding our offerings in our current indications, as well as potentially in others that we believe will benefit from our technology and approach. Our product development pipelines address what we believe to be significant market opportunities in early detection, diagnosis, staging/prognosis, therapy selection/surgery and disease monitoring across the aforementioned indications. We plan to commercially introduce multiple products in the near term. These include our Percepta Nasal Swab test to improve early lung cancer detection and our Percepta Genomic Atlas which, together with the Percepta GSC, form a comprehensive lung cancer testing portfolio that we believe may improve lung cancer diagnosis and treatment decisions. We began making the Percepta Nasal Swab test available to a limited number of sites in the U.S. in the fourth quarter of 2021. We recently received Medicare coverage for our Decipher Bladder test to help guide treatment decisions for patients with bladder cancer and initiated expanded commercialization of the test in the fourth quarter of 2021. We believe

Decipher Bladder will be the only genomic subtyping tool available to physicians in the United States treating patients with locally advanced bladder cancer.

Scientific Platform

We believe our powerful scientific expertise, technology and biorepositories form the foundation of our business, fueling development of our clinical diagnostic tests and our biopharmaceutical partnerships.

- ***Genomics*** – Our comprehensive approach to developing new genomic classifiers includes building and leveraging robust biorepositories of patient samples to inform our discovery and validation efforts. We extract extensive genomic information from these patient samples using our RNA whole-transcriptome approach, including RNA sequencing, and then apply our proprietary machine-learning algorithms to answer specific clinical questions. We believe this comprehensive approach enables the algorithm to determine which genomic, clinical or other features are most relevant for developing high-performing tests, versus relying on a pre-determined set of genes derived from the literature. In addition, our bioinformatics pipelines are built to extract genomic variant content from the same assay to develop tests that may inform therapeutic selection.
- ***Immuno-Oncology*** – By combining cutting-edge spatial molecular analysis and bioinformatics with novel immuno-oncology science, we convert complex immune monitoring data into actionable insights to clarify decision-making and resolve unmet medical needs. Our foundational Immunoscore platform assesses lymphocytic infiltration in human tumors and is used to predict patient outcomes and response to therapies in several indications. The Immunoscore Colon Cancer test is our first commercially available test using this approach. Additionally, our multi-modal Immunogram platform integrates genomic, transcriptomic and spatial immunohistochemistry biomarkers to provide actionable data visualization at the patient level. Outputs for biopharmaceutical partners are key insights into drug mode of action, key biomarker signatures for companion diagnostics development, including predicting response or toxicity to new agents in clinical development.
- ***Machine Learning/Artificial Intelligence*** – Our machine learning approach recognizes patterns of genes that correspond with clinical characteristics. We use next-generation RNA sequencing to extract rich feature sets – gene expression, DNA variants, RNA fusions, mitochondrial DNA content and loss of heterozygosity – from the RNA transcriptome of patient samples obtained through minimally invasive procedures. These feature sets enable us to create the highest-resolution genomic picture possible.

  We train our proprietary machine learning algorithms to interpret this vast genomic data using large numbers of diverse patient samples that represent the broad spectrum of disease that our genomic tests may likely encounter in a clinical setting. In some cases, we deploy ensemble algorithms to differentiate between complex biologies.

  As scientific understanding continues to progress, additional features that inform disease status, such as more-refined genomic features or even imaging data, can potentially help us identify clinical attributes with ever-more precision, enabling development of tests that provide even clearer answers to important clinical questions.

- ***Unique Biorepositories*** – Through our capabilities in executing large-scale, prospectively enrolled, multisite clinical trials, we are able to curate large amounts of data and clinical information that can be used to inform new products or biopharmaceutical programs for new therapies or clinical trials. Our biorepositories may include RNA, DNA, variant, fusion and other genomic data; immune-response data; and well-curated clinical, radiological, outcome and other information. In urologic cancers, for example, our Decipher GRID (Genomic Resource for Intelligent Discovery) platform contains over 300 proprietary gene expression signatures that are run on each patient's tumor, with data analyzed and stored as part of our commercial operations.

Biopharmaceutical Partnerships

We have formed multiple biopharmaceutical partnerships, which leverage our scientific expertise and unique biorepositories. These include our collaboration with the Lung Cancer Initiative at Johnson & Johnson, which began in 2018, has helped advance our pipeline, including the launch in 2019 of our Percepta GSC on our RNA whole-transcriptome sequencing platform and development of the first noninvasive nasal swab test designed to improve early lung cancer detection. In December 2020, we expanded our program with Johnson & Johnson to potentially develop future tests designed to detect lung disease before cancer develops. We have a biopharmaceutical partnership with Acerta Pharma, the hematology research and development arm of AstraZeneca, for a companion diagnostic program for our LymphMark lymphoma subtyping test, which is in development. We also support pharmaceutical companies in urological clinical trials. These include SPARTAN, a pivotal clinical trial of ERLEADA, which has been approved by the FDA and is marketed by Janssen for the treatment of nonmetastatic castration-resistant prostate cancer, or nmCRPC, as well as clinical trials being conducted by Astellas and

Dendreon in localized prostate cancer. Additionally, we support biopharmaceutical companies with our immuno-oncology offerings. These include a strategic collaboration with Kite Pharma, a Gilead company, aimed at developing and validating immune-based biomarkers for Kite's investigational therapies in blood cancer.

IVD Development and Manufacturing

We combine our strong expertise and 15-year track record in IVD test development and manufacturing to offer a complete range of IVD, companion diagnostics and clinical trial assay services to biopharmaceutical companies and diagnostic companies whose products are not competitive to Veracyte. Test development is performed using a mature, efficient and proven design control process. We also provide full-coverage IVD manufacturing capabilities, which include quality control, assay and process transfer and supply chain management. These services are provided and performed using regulatory-compliant processes in our Marseille, France, and Richmond, Virginia, facilities.

Impact of COVID-19

While our business has continued to rebound following an April 2020 low in reported test volumes, we believe the continuation of the COVID-19 outbreak and its recent escalation due to the Delta variant has impacted our test volumes. Our customers, third-party contract manufacturers, suppliers and collaboration partners have been affected by the closure of hospitals, doctors' offices, manufacturing sites, or country borders, among other measures put in place around the world. Layoffs, furloughs and unplanned loss of staff (due to vaccination status or other reasons) in the medical industry and otherwise during the pandemic have had, and will continue to have, negative impacts on the demand for and supply of medical care and diagnostic tests, which affects the frequency with which tests are ordered, and the ability of doctors and hospitals to administer such tests. Further the inability to travel and conduct face-to-face meetings can also make it more difficult to expand utilization of our products into new geographies and to drive awareness of our products.

Our Decipher Prostate test has been least impacted by the pandemic because our customers are mostly community-based urology practices, which generally remain more accessible to patients and our sales reps. Our Afirma thyroid cancer test has been impacted by COVID because a majority of our samples come from institutions, which are less accessible to patients and our reps. Our pulmonology business continues to be most impacted since the bronchoscopy procedures used to collect samples for our Percepta and Envisia tests are performed in hospital settings, which continue to be more restrictive, and these tests are ordered by pulmonologists who are currently largely preoccupied with caring for COVID patients. Our Prosigna breast cancer business has continued to recover.

The rapid increase in daily COVID-19 testing consumes reagents and supplies otherwise available to diagnostic testing companies like ours across the United States. When not limited by the expiration date of products and when we feel it reasonable and feasible to do so, we are taking steps to manage our level of stock reserves, to develop alternative sources of supply and to implement procedures to mitigate the impact on our supply chain and our ability to process samples in our laboratories. Though we are in regular contact with our key suppliers, we do not have, nor expect to have, the necessary insight into our vendors' supply chain issues that we may need to know to effectively mitigate the impact to our business. Though we attempt to mitigate the impact to our business, these interruptions in manufacturing (including the sourcing of reagents or supplies) may negatively impact our test volumes or levels of revenue.

The extent of the impact of COVID-19 on our future liquidity and operational performance will depend on certain developments, including the deployment and long-term efficacy of vaccines; the duration and spread of the outbreak particularly in the form of more transmissible variants; the impact on our customers' operations; and the impact to our sales and renewal cycles. See Risk Factors for further discussion of the possible impact of the COVID-19 pandemic on our business.

Factors Affecting Our Performance

Reported Test Volume

Our performance depends on the number of tests that we perform and report as completed in our CLIA-certified laboratories and Prosigna tests processed on the nCounter Analysis System. Factors impacting the number of tests that we report as completed include, but are not limited to:

- the impact of COVID-19 on patients seeking to have tests performed;
- the availability of hospital staff to perform and support procedures needed to collect samples for our tests;
- the number of samples that we receive that meet the medical indication for each test performed;

- the quantity and quality of the sample received;
- receipt of the necessary documentation, such as physician order and patient consent, required to perform, bill and collect for our tests;
- the patient's ability to pay or provide necessary insurance coverage for the tests performed;
- the time it takes us to perform our tests and report the results;
- the seasonality inherent in our business, such as the impact of work days per period, timing of industry conferences and the timing of when patient deductibles are exceeded, which also impacts the reimbursement we receive from insurers; and
- our ability to obtain prior authorization or meet other requirements instituted by payers, benefit managers, or regulators necessary to be paid for our tests.

We generate a substantial amount of our revenue from Afirma genomic testing services, including the rendering of a cytopathology diagnosis as part of the Afirma solution. For the Afirma classifier, we do not accrue revenue for approximately 5% - 10% of the tests that we perform and report as complete due principally to insufficient RNA from which to render a result and tests performed for which we do not reasonably expect to be paid.

Continued Adoption of and Reimbursement for our Products

Revenue growth depends on our ability to secure coverage decisions, achieve broader reimbursement at increased levels from third-party payers, expand our base of prescribing physicians and increase our penetration in existing accounts. Because some payers consider our products experimental and investigational, we may not receive payment for tests and payments we receive may not be at acceptable levels. We expect our revenue growth to increase if more payers make a positive coverage decision and as payers enter into contracts with us, which should enhance our revenue and cash collections. To drive increased adoption of our products, we increased our sales force and marketing efforts over the last several years. Our sales teams are aligned under our general manager-based structure to focus on specific products and global markets. If we are unable to expand the base of prescribing physicians and penetration within these accounts at an acceptable rate, or if we are not able to execute our strategy for increasing reimbursement, we may not be able to effectively increase our revenue. We expect to continue to see pressure from payers to limit the utilization of tests, generally, and we believe more payers are deploying cost containment tactics, such as pre-authorization, reduction of the payer portion of reimbursement and employing laboratory benefit managers to reduce utilization rates.

Integrating acquired assets and advances to our collaborations

Revenue growth, operational results and advances to our business strategy depends on our ability to integrate any acquired assets into our existing business. The integration of acquired assets may impact our revenue growth, increase the cost of operations, cause significant write-offs of intangible assets, or may require management resources that otherwise would be available for ongoing development of our existing business. The integration of assets acquired from NanoString in December 2019, Decipher Biosciences in March 2021 and HalioDx in August 2021 may impact our revenue and operating results through integration of various functions, development of a product supply operation and manufacturing operations and the expansion of our business internationally with a broad menu of advanced tests that may be offered.

Revenue growth or reimbursement from our collaborations depends on our ability to deliver services or information and achieve milestones required from our collaborative partners. Our collaboration partners pay us for the provision of data and other services and the achievement of milestones. Under a collaboration with Johnson & Johnson in 2018, we provided data services required under this agreement in 2019 and 2020; however, there remains $9.0 million of revenue associated with development and commercialization milestones yet to be achieved.

How We Recognize Revenue

Testing Revenue

We recognize testing revenue in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers*, or ASC 606. We bill for testing services at the time of test completion as defined by the delivery of test results. We recognize revenue on an accrual basis based on estimates of the amount that will ultimately be realized. In determining the amount to accrue for a delivered test, we consider factors such as payment history, payer coverage, whether there is a reimbursement contract between the payer and us, payment as a percentage of the agreed upon rate (if applicable), amount paid per test and any current developments or changes that could impact reimbursement. These estimates require significant judgment by management.

Generally, cash we receive is collected within 12 months of the date the test is billed. We cannot provide any assurance as to when, if ever, or to what extent any of these amounts will be collected. Notwithstanding our efforts to obtain payment for these tests, payers may deny our claims, in whole or in part, and we may never receive payment for these tests.

We bill list price regardless of contract rate, but only recognize revenue from amounts that we estimate are collectible and meet our revenue recognition criteria. Revenue may not be equal to the billed amount due to a number of factors that we consider when determining revenue accrual rates, including differences in reimbursement rates, the amounts of patient co-payments and co-insurance, the existence of secondary payers, claims denials and the amount we expect to ultimately collect. Finally, when we increase our list price, it will increase the cumulative amounts billed but may not positively impact accrued revenue. In addition, payer contracts generally include the right of offset and payers may offset payments prior to resolving disputes over tests performed.

Generally, we calculate the average reimbursement from our products from all payers, for tests that are on average a year old since it can take a significant period of time to collect from some payers. Except in situations where we believe the rate we reasonably expect to collect to vary due to a coverage decision, contract, more recent reimbursement data or evidence to the contrary, we use an average of reimbursement for tests provided over four quarters as it reduces the effects of temporary volatility and seasonal effects. Thus, the average reimbursement per product represents the total cash collected to date against tests performed during the relevant period divided by the number of these tests performed during that same period.

The average test reimbursement rates will change over time due to a number of factors, including medical coverage decisions by payers, the effects of contracts signed with payers, changes in allowed amounts by payers, our ability to successfully win appeals for payment, and our ability to collect cash payments from third-party payers and individual patients. Historical average reimbursement is not necessarily indicative of future average reimbursement.

We incur expense for tests in the period in which the test is conducted and recognize revenue for tests in the period in which our revenue recognition criteria are met.

Product Revenue

We recognize product revenue in accordance with the provisions of ASC 606. Our products consist of the Prosigna breast cancer assay, the nCounter Analysis System and related diagnostic kits.

We recognize product revenue when control of the promised goods is transferred to our customers, in an amount that reflects the consideration expected to be received in exchange for those products. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. Performance obligations are considered satisfied once we have transferred control of a product to the customer, meaning the customer has the ability to use and obtain the benefit of the product. We recognize product revenue for satisfied performance obligations only when there are no uncertainties regarding payment terms or transfer of control. Shipping and handling costs incurred for product shipments are charged to our customers and included in product revenue. Revenues are presented net of the taxes that are collected from customers and remitted to governmental authorities.

Biopharmaceutical and Other Revenues

We enter into arrangements to license or provide access to our assets or services, including testing services, clinical and medical services, research and development, contract manufacturing and other services. Such arrangements may require us to deliver various rights, data, services, access and/or testing services to partner biopharmaceutical companies. The underlying terms of these arrangements generally provide for consideration paid to us in the form of nonrefundable fees; payments on delivery of data, test results or manufactured products; costs of service plus margin; performance milestone payments; expense reimbursements and possibly royalty and/or other payments. Net sales of data or other services to our customers are recognized in accordance with ASC 606 and are classified under biopharmaceutical and other revenue. Milestone payments which fall under the scope of ASC Topic 808, Collaborative Arrangements, or ASC 808, are classified under collaboration revenue. Payments received that are not related to sales or services to a customer or collaboration revenue are recorded as offsets against research and development expense or cost of biopharmaceutical and other revenue in our consolidated statements of operations.

In arrangements involving more than one good or service, each good or service is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on

its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis or using an adjusted market assessment approach if the selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control is transferred which may be at a point in time or over time. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. Should there be royalties, we utilize the sales and usage-based royalty exception in arrangements that resulted from the license of intellectual property, recognizing revenues generated from royalties or profit sharing as the underlying sales occur.

Development of Additional Tests

We continue to advance our portfolio of diagnostic tests to further improve patient guidance and care globally. For this, we leverage innovations in genomic science, sequencing technology, digital pathology and machine learning, as well as our robust biorepositories and our exclusive diagnostics rights to the nCounter Analysis System.

Our Afirma tests provide physicians with a comprehensive solution for thyroid nodule diagnosis. In May 2017, we introduced the Afirma GSC, supported by rigorous clinical validation data showing that the RNA sequencing-based test can help significantly more patients avoid unnecessary surgery in thyroid cancer diagnosis, compared to the original Afirma classifier. The Afirma GSC was developed with RNA whole-transcriptome sequencing and machine learning and is performed on fine needle aspiration, or FNA, samples. The test helps identify patients with benign thyroid nodules among those with indeterminate cytopathology so that they may be monitored noninvasively.

When the Afirma GSC deems a patient’s thyroid nodule as suspicious for cancer, our medullary thyroid cancer, or MTC, and BRAF V600E classifiers provide additional information that can help guide surgical strategy and treatment decisions. MTC is an aggressive form of thyroid cancer, for which clinical guidelines recommend specific preoperative assessment protocols, as well as more extensive surgery: a total thyroidectomy with lymph node dissection. When the diagnosis of MTC is unknown, patients often do not receive appropriate initial surgery. Patients who are positive for BRAF V600E have a very high risk of malignancy, along with increased risk of invasive cancer. Such conditions may guide the physician to perform a more comprehensive, total thyroidectomy as opposed to a more conservative operation that may be appropriate for less aggressive tumors.

For those patients with suspected thyroid cancer the Afirma Xpression Atlas, or XA, may be performed. This genomic profiling test provides physicians with additional genomic alteration content from the same FNA sample as the original Afirma GSC and may help physicians decide with greater confidence on the surgical or therapeutic pathway for their patients. The Afirma XA can identify 905 DNA variants and 235 RNA fusion partners in 593 genes. Several drugs that target molecular alterations reported by the Afirma XA are available and others are currently under investigation. Our broad ability to serve the thyroid diagnostic market also enables us to enter research collaborations with biopharmaceutical companies, which are intended to support their development of targeted therapies for genetically defined cancers, including thyroid cancer.

In pulmonology, our Percepta Genomic Sequencing Classifier, or GSC, improves lung cancer diagnosis following an inconclusive bronchoscopy by identifying patients with lung nodules who are at low risk of cancer and may avoid further, invasive procedures and those with a high risk of lung cancer, so they may obtain faster diagnosis and treatment. The test is built upon foundational "field of injury" science - through which genomic changes associated with lung cancer in current and former smokers can be identified with a simple brushing of a person's airway - without the need to sample the often hard-to-reach nodule directly. We commercially introduced the Percepta classifier in 2015, with clinical validation data subsequently published in the *New England Journal of Medicine*. In June 2019, we launched the next-generation Percepta test, providing expanded lung cancer risk information to further inform treatment decisions. The Percepta classifier is the first product of its kind to be available commercially and the first to obtain Medicare coverage for improved lung cancer diagnosis.

We are currently leveraging the same “field of injury” technology that powers our Percepta GSC to develop a novel, noninvasive nasal swab test that can enable earlier lung cancer diagnosis and ultimately, we believe, help reduce lung cancer deaths. In May 2021, we reported clinical validation data for our nasal swab classifier showing that the novel genomic test could identify, with a high degree of accuracy, patients whose lung nodules were low risk of cancer so they could avoid unnecessary invasive procedures and those who were high risk for cancer so they could obtain prompt diagnosis and potential treatment. In October 2021, we shared expanded clinical validation data showing that the Percepta Nasal Swab test delivers strong clinical performance across different lung nodule sizes and cancer stages, and for patients who already had other

cancer(s) except for lung cancer. We are also developing the Percepta Genomic Atlas, which is intended to inform treatment decisions by detecting gene alterations in small samples collected at the time of diagnosis.

Additionally, our Envisia Genomic Classifier, launched in October 2016, is the first commercial test to improve the diagnosis of IPF among patients with a suspected interstitial lung disease. The Envisia test is also covered for Medicare patients.

Further, our LymphMark lymphoma subtyping test is being developed as a companion diagnostic for Acerta Pharma and AstraZeneca's acalabrutinib (Calquence®). In April 2021, Veracyte announced that the first patient has been enrolled and randomized in Acerta Pharma's Phase 3 ESCALADE trial, which is using the investigational LymphMark test to identify patients with untreated diffuse large B-cell lymphoma (DLBCL) who may benefit from Calquence in combination with rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP) therapy. The LymphMark test utilizes gene-expression profiling of RNA extracted from formalin-fixed paraffin-embedded tissue to classify the "cell of origin" subtype of DLBCL tumors.

In 2015, Decipher Biosciences received a Local Coverage Determination, or LCD, for its first commercial product, Decipher Prostate RP, for use in the early salvage setting. Decipher Biosciences expanded into biopsy and received an LCD for the first two Decipher Prostate Biopsy products in May 2019 covering the Very Low and Low National Comprehensive Cancer Network, or NCCN, risk groups and a second LCD in January 2020 covering Decipher Prostate Biopsy for Favorable Intermediate and Unfavorable Intermediate NCCN risk groups. In November 2020, Decipher Biosciences received another expanded LCD and launched its High and Very High biopsy product and now covers the entire localized and biochemically recurrent prostate cancer care continuum.

We have also developed Decipher Bladder, which helps determine which patients with muscle-invasive bladder cancer may benefit from neoadjuvant chemotherapy prior to radical cystectomy. Veracyte believes its test is the only genomic subtyping tool available to physicians in the United States treating patients with locally advanced bladder cancer. Recently, we also received a final Medicare coverage policy for the Decipher Bladder test from Noridian, a Medicare Administrative Contractor, through the MolDX program. The Decipher Bladder test is available in Veracyte's CLIA laboratory and the Company has recently expanded its commercial launch of the test.

HalioDx introduced the Immunoscore Colon Cancer test, marking the first commercial application of the company's novel Immunoscore technology platform. The Immunoscore Colon Cancer test is used in Stage II localized colon cancer to help physicians identify patients who may be spared adjuvant chemotherapy, and in Stage III localized colon cancer to guide physicians in their adjuvant chemotherapy prescription. In 2020, the European Society for Medical Oncology (ESMO) included the Immunoscore Colon Cancer test in its clinical practice guidelines for the diagnosis, treatment and follow-up of colon cancer.

Timing of Our Research and Development Expenses

We deploy state-of-the-art and costly genomic technologies in our biomarker discovery experiments, and our spending on these technologies may vary substantially from quarter to quarter. We also spend a significant amount to secure clinical samples that can be used in discovery and product development, as well as clinical validation studies. The timing of these research and development activities is difficult to predict, as is the timing of sample acquisitions. If a substantial number of clinical samples are acquired in a given quarter or if a high-cost experiment is conducted in one quarter versus the next, the timing of these expenses can affect our financial results. We conduct clinical studies to validate our new products as well as on-going clinical studies to further the published evidence to support our commercialized tests. As these studies are initiated, start-up costs for each site can be significant and concentrated in a specific quarter. Spending on research and development, for both experiments and studies, may vary significantly by quarter depending on the timing of these various expenses.

Financial Overview

Revenue

Through September 30, 2021, we had derived most of our revenue from the sale of Afirma and the Decipher urologic tests, delivered primarily to physicians in the United States. We generally invoice third-party payers upon delivery of a patient report to the prescribing physician. As such, we take the assignment of benefits and the risk of cash collection from the third-

party payer and individual patients. Third-party payers and other customers in excess of 10% of total revenue and their related revenue as a percentage of total revenue were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Medicare	31 %	25 %	31 %	24 %
UnitedHealthcare	9 %	11 %	10 %	11 %
	40 %	36 %	41 %	35 %

For tests performed, we recognize the related revenue upon delivery of a patient report to the prescribing physician based on the amount that we expect to ultimately receive. In determining the amount to accrue for a delivered test, we consider factors such as payment history, payer coverage, whether there is a reimbursement contract between the payer and us, payment as a percentage of agreed upon reimbursement rate (if applicable), amount paid per test and any current development or changes that could impact reimbursement. Upon ultimate collection, the amount received is compared to previous estimates and the amount accrued is adjusted accordingly. Our ability to increase our revenue will depend on our ability to penetrate the market, obtain positive coverage policies from additional third-party payers, obtain reimbursement and/or enter into contracts with additional third-party payers for our current and new tests, and increase reimbursement rates for tests performed. Finally, should the judgments underlying our estimated reimbursement change, our accrued revenue and financial results could be negatively impacted in future periods.

Cost of Revenue

The components of our cost of testing revenue are laboratory expenses, sample collection kit costs, sample collection expenses, compensation expense, license fees and royalties, depreciation and amortization, other expenses such as equipment and laboratory supplies, and allocations of facility and information technology expenses. Costs associated with performing tests are recorded as the test is processed regardless of whether and when revenue is recognized with respect to that test. As a result, our cost of testing revenue as a percentage of testing revenue may vary significantly from period to period because we may not recognize all revenue in the period in which the associated costs are incurred. We expect cost of testing revenue in absolute dollars to increase as the number of tests we perform increases. However, we expect that the cost per test will decrease over time due to leveraging fixed costs, efficiencies we may gain as test volume increases and from automation, process efficiencies and other cost reductions. As we introduce new tests, initially our cost of testing revenue will be high as we expect to run suboptimal batch sizes, run quality control batches, test batches, registry samples and generally incur costs that may suppress or reduce gross margins. This will disproportionately increase our aggregate cost of testing revenue until we achieve efficiencies in processing these new tests.

Our cost of product revenue consists primarily of costs of purchasing instruments and diagnostic kits from third-party contract manufacturers, installation, warranty, service and packaging and delivery costs. In addition, cost of product revenue includes royalty costs for licensed technologies included in our products and labor expenses. As our Prosigna test kits are sold in various configurations with different number of tests, our product cost per test will vary based on the specific kit configuration purchased by customers.

Our cost of biopharmaceutical and other revenue are the costs of performing activities under arrangements that require us to perform research and development, commercialization, contract manufacturing and contract testing services on behalf of a customer, and is mainly comprised of compensation expense, laboratory supplies and pass through costs.

Research and Development

Research and development expenses include expenses incurred to develop our technology, collect clinical samples and conduct clinical studies to develop and support our products and pipeline. These expenses consist of compensation expenses, direct research and development expenses such as prototype materials, laboratory supplies and costs associated with setting up and conducting clinical studies at domestic and international sites, professional fees, depreciation and amortization, other miscellaneous expenses and allocation of facility and information technology expenses. We expense all research and development costs in the periods in which they are incurred. We expect to incur significant research and development expenses as we continue to invest in research and development activities related to developing additional products and evaluating various platforms. We incurred a majority of our research and development expenses in support of our pipeline products in 2020 and in the nine months ended September 30, 2021, and expect this to continue in the remainder of 2021 and beyond.

Selling and Marketing

Selling and marketing expenses consist of compensation expenses, direct marketing expenses, professional fees, other expenses such as travel and communications costs and allocation of facility and information technology expenses. Our sales team of approximately 150 representatives is organized by business unit, with separate teams calling on thyroid cancer, urologic cancers, breast cancer, pulmonology and colorectal cancers physicians. The business units have dedicated marketing support, as well as a marketing operations team that serves the commercial organization broadly. Prosigna sales outside of the U.S. are led by country managers that call on laboratories and breast cancer oncologists, and have dedicated marketing support.

General and Administrative

General and administrative expenses include compensation expenses for executive officers and administrative, billing and client service personnel, professional fees for legal and audit services, occupancy costs, depreciation and amortization, and other expenses such as information technology and miscellaneous expenses offset by allocation of facility and information technology expenses to other functions. For the nine months ended September 30, 2021, costs related to the acquisitions of Decipher Biosciences and HalioDx were included in general and administrative compensation expense and professional fees. For the nine months ended September 30, 2021, approximately 53% of the headcount classified as general and administrative encompass our billing and customer care teams. We expect general and administrative expenses to continue to increase as we build our general and administration infrastructure and to stabilize thereafter.

Intangible Asset Amortization

Our finite-lived intangible assets, acquired in business combinations, are being amortized over 4 to 15 years, using the straight-line method. Amortization expense is expected to be approximately $16.0 million in 2021, approximately $22.2 million per year through 2024 and decrease thereafter.

Interest Expense

Interest expense is attributable to our borrowings under debt agreements and costs associated with the prepayment of debt.

Other (Loss) Income, Net

Other (loss) income, net consists primarily of realized and unrealized gains and losses on foreign currency transactions and interest income from our cash held in interest bearing accounts.

Foreign Currency Translation

The functional currency of our foreign subsidiary HalioDx is the Euro. Assets and liabilities denominated in foreign currencies are translated to U.S. dollars using the exchange rates at the balance sheet date. Foreign currency translation adjustments are recorded as a component of accumulated other comprehensive income (loss) within stockholders' equity. Revenues and expenses from our foreign subsidiaries are translated using the monthly average exchange rates in effect during the period in which the transactions occur. Foreign currency transaction gains and losses are recorded in other (loss) income, net, on the condensed consolidated statements of operations.

Results of Operations

Comparison of the three and nine months ended September 30, 2021 and 2020 (in thousands of dollars, except percentages and test volume):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2020	Change	%	2021	2020	Change	%
Revenue:								
Testing revenue	$ 50,897	$ 28,270	$ 22,627	80%	$ 134,768	$ 70,473	$ 64,295	91%
Product revenue	2,959	2,027	932	46%	8,706	7,149	1,557	22%
Biopharmaceutical and other revenue	6,514	824	5,690	691%	8,704	5,325	3,379	63%
Total revenue	60,370	31,121	29,249	94%	152,178	82,947	69,231	83%
Operating expense:								
Cost of testing revenue	16,073	9,118	6,955	76%	42,494	26,157	16,337	62%
Cost of product revenue	1,491	1,048	443	42%	4,304	3,539	765	22%
Cost of biopharmaceutical and other revenue	4,079	204	3,875	1,900%	4,720	572	4,148	725%
Research and development	8,006	4,042	3,964	98%	19,591	12,618	6,973	55%
Selling and marketing	21,670	10,955	10,715	98%	57,628	39,240	18,388	47%
General and administrative	20,749	8,546	12,203	143%	82,504	24,316	58,188	239%
Intangible asset amortization	4,983	1,274	3,709	291%	10,507	3,822	6,685	175%
Total operating expenses	77,051	35,187	41,864	119%	221,748	110,264	111,484	101%
Loss from operations	(16,681)	(4,066)	(12,615)	310%	(69,570)	(27,317)	(42,253)	155%
Other income (loss), net	1,202	(58)	1,260	(2,172)%	(762)	452	(1,214)	(269)%
Loss before income tax benefit	(15,479)	(4,124)	(11,355)	275%	(70,332)	(26,865)	(43,467)	162%
Income tax benefit	(1,350)	—	(1,350)	NM	(5,297)	—	(5,297)	NM
Net loss	$ (14,129)	$ (4,124)	$ (10,005)	243%	$ (65,035)	$ (26,865)	$ (38,170)	142%
Other Operating Data:								
Diagnostic tests reported	18,842	10,242	8,600	84%	50,127	26,180	23,947	91%
Product tests sold	2,130	1,448	682	47%	6,138	5,179	959	19%
Total test volume	20,972	11,690	9,282	79%	56,265	31,359	24,906	79%
Depreciation and amortization expense	$ 6,138	$ 1,990	$ 4,148	208%	$ 13,189	$ 5,919	$ 7,270	123%
Stock-based compensation expense	$ 8,234	$ 3,090	$ 5,144	166%	$ 16,154	$ 9,354	$ 6,800	73%

Revenue

Revenue increased $29.2 million for the three months ended September 30, 2021 compared to the same period in 2020. This was primarily due to a $22.6 million increase in testing revenue from an 84% volume increase in our genomic tests, as well as a $0.9 million increase in sales of Prosigna. Tests reported for the three months ended September 30, 2021 increased primarily due to the addition of the Decipher Prostate Biopsy and Decipher Prostate RP genomic tests following our acquisition of Decipher Biosciences on March 12, 2021, which contributed $21.3 million of revenue during the period. Biopharmaceutical and other revenue increased $5.7 million for the three months ended September 30, 2021 compared to the same period in 2020. Biopharmaceutical and other revenue for the three months ended September 30, 2021 includes the operations of HalioDx following its acquisition on August 2, 2021, which contributed approximately $4.7 million of revenue.

Revenue increased $69.2 million for the nine months ended September 30, 2021 compared to the same period in 2020. This was primarily due to a $64.3 million increase in testing revenue from a 91% volume increase in our Afirma, Decipher, Envisia and Percepta genomic tests, as well as a $1.6 million increase in sales of Prosigna. Tests reported for the nine months ended September 30, 2021 also includes the Decipher Prostate Biopsy and Decipher Prostate RP genomic tests, which contributed $44.0 million of revenue during the nine months ended September 30, 2021. Biopharmaceutical and other revenue increased $3.4 million for the nine months ended September 30, 2021 compared to the same period in 2020. Biopharmaceutical and other revenue for the nine months ended September 30, 2021 includes the operations of HalioDx following its acquisition.

Revenues included in biopharmaceutical and other revenue for the three and nine months ended September 30, 2021 and 2020 were as follows (in thousands of dollars):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Development services	$ 3,849	$ 549	$ 5,242	$ 1,780
Provision of data	1,392	275	1,839	1,545
Milestones	—	—	350	1,000
Development rights	—	—	—	1,000
Contract manufacturing	1,221	—	1,221	—
Contract testing	52	—	52	—
Total	$ 6,514	$ 824	$ 8,704	$ 5,325

Cost of revenue

Comparison of the three and nine months ended September 30, 2021 and 2020 is as follows (in thousands of dollars, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2020	Change	%	2021	2020	Change	%
Cost of testing revenue:								
Laboratory costs	$ 8,777	$ 5,002	$ 3,775	75 %	$ 23,489	$ 14,103	$ 9,386	67 %
Sample collection costs	1,337	1,134	203	18 %	3,989	3,048	941	31 %
Compensation expense	3,111	1,707	1,404	82 %	8,381	5,164	3,217	62 %
License fees and royalties	332	11	321	2,918 %	585	38	547	1,439 %
Depreciation and amortization	291	271	20	7 %	830	790	40	5 %
Other expenses	972	377	595	158 %	2,032	1,174	858	73 %
Allocations	1,253	616	637	103 %	3,188	1,840	1,348	73 %
Total	$ 16,073	$ 9,118	$ 6,955	76 %	$ 42,494	$ 26,157	$ 16,337	62 %
Cost of product revenue:								
Product costs	$ 1,201	$ 885	$ 316	36 %	$ 3,459	$ 2,916	$ 543	19 %
License fees and royalties	271	163	108	66 %	789	623	166	27 %
Depreciation and amortization	19	—	19	NM	56	—	56	NM
Total	$ 1,491	$ 1,048	$ 443	42 %	$ 4,304	$ 3,539	$ 765	22 %
Cost of biopharmaceutical and other revenue:								
Compensation expense	$ 1,770	$ 51	$ 1,719	3,371 %	$ 1,862	$ 127	$ 1,735	1,366 %
Laboratory expense	861	—	861	NM	861	—	861	NM
License fees and royalties	6	—	6	NM	6	—	6	NM
Depreciation and amortization	84	—	84	NM	84	—	84	NM
Other expenses	1,358	153	1,205	788 %	1,907	445	1,462	329 %
Total	$ 4,079	$ 204	$ 3,875	1,900 %	$ 4,720	$ 572	$ 4,148	725 %

Cost of testing revenue increased $7.0 million for the three months ended September 30, 2021 compared to the same period in 2020. Following the acquisition of Decipher Biosciences in March 2021, its operations are included in cost of testing revenue and contributed approximately $5.0 million for the three months ended September 30, 2021. The increase in laboratory costs was primarily related to an 84% increase in the volume of diagnostic tests reported, including Decipher tests. The increase in compensation expense related to a headcount increase of 143%, including the addition of Decipher employees.

Cost of testing revenue increased $16.3 million for the nine months ended September 30, 2021 compared to the same period in 2020. The increase in the cost of testing results primarily from an increase in laboratory costs primarily related to a

91% increase in the volume of diagnostic tests reported and an increase in compensation expense related to a headcount increase of 69%. Following the acquisition of Decipher Biosciences, its operations also contributed to the increase in the cost of testing revenue. Laboratory costs for the nine months ended September 30, 2020 include a $1.1 million write-down of supplies for the potential expiration of reagents due to an anticipated decline in volumes resulting from the COVID-19 pandemic.

Cost of product revenue is related to sales of Prosigna. Cost of product revenue increased $0.4 million, or 42%, for the three months ended September 30, 2021 compared to the same period in 2020, primarily due to a 47% increase in product tests sold.

Cost of product revenue increased $0.8 million, or 22%, for the nine months ended September 30, 2021 compared to the same period in 2020 primarily due to a 19% increase in product tests sold.

Cost of biopharmaceutical and other revenue includes labor costs incurred by our employees working on customer projects and laboratory supplies and pass-through expenses incurred on these projects. Cost of biopharmaceutical and other revenue includes the operations of HalioDx following its acquisition on August 2, 2021, which contributed approximately $4.0 million of cost of revenue.

Research and development

Comparison of the three and nine months ended September 30, 2021 and 2020 is as follows (in thousands of dollars, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2020	Change	%	2021	2020	Change	%
Research and development expense:								
Compensation expense	$ 5,422	$ 2,783	$ 2,639	95%	$ 13,863	$ 8,340	$ 5,523	66 %
Direct research and development expense	1,382	684	698	102%	2,840	2,557	283	11 %
Professional fees	98	167	(69)	(41)%	601	450	151	34 %
Depreciation and amortization	285	53	232	438%	405	189	216	114 %
Other expenses	225	26	199	765%	326	127	199	157 %
Allocations	594	329	265	81%	1,556	955	601	63 %
Total	$ 8,006	$ 4,042	$ 3,964	98%	$ 19,591	$ 12,618	$ 6,973	55 %

Research and development expense increased $4.0 million, or 98%, for the three months ended September 30, 2021 compared to the same period in 2020. The increase in compensation expense was primarily due to an increase in headcount including the addition of Decipher and HalioDx employees.

Research and development expense increased $7.0 million, or 55%, for the nine months ended September 30, 2021 compared to the same period in 2020. The increase in compensation expense was primarily due to an increase in headcount, including the addition of Decipher and HalioDx employees.

Selling and marketing

Comparison of the three and nine months ended September 30, 2021 and 2020 is as follows (in thousands of dollars, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2020	Change	%	2021	2020	Change	%
Selling and marketing expense:								
Compensation expense	$ 15,335	$ 8,484	$ 6,851	81 %	$ 40,951	$ 29,334	$ 11,617	40 %
Direct marketing expense	1,629	751	878	117 %	5,683	2,456	3,227	131 %
Professional fees	842	318	524	165 %	2,225	1,005	1,220	121 %
Other expenses	2,378	568	1,810	319 %	5,316	3,616	1,700	47 %
Allocations	1,486	834	652	78 %	3,453	2,829	624	22 %
Total	$ 21,670	$ 10,955	$ 10,715	98 %	$ 57,628	$ 39,240	$ 18,388	47 %

Selling and marketing expense increased $10.7 million, or 98%, for the three months ended September 30, 2021 compared to the same period in 2020. The increase in compensation expense was primarily due to temporary furloughs and terminations of employees in 2020 as a result of the COVID-19, pandemic and by the addition of Decipher employees in March 2021 and HalioDx employees in August 2021. The increase in other expenses and direct marketing expenses were primarily due to increased travel and entertainment expenses as COVID-19 travel restrictions have eased.

Selling and marketing expense increased $18.4 million, or 47%, for the nine months ended September 30, 2021 compared to the same period in 2020. The increase in compensation expense was primarily due to temporary furloughs and terminations of employees in 2020 as a result of the COVID-19 pandemic, and by the addition of Decipher employees in March 2021 and HalioDx employees in August 2021. The increase in direct marketing expenses were primarily due to increased travel and entertainment expenses as COVID-19 travel restrictions have eased.

General and administrative

Comparison of the three and nine months ended September 30, 2021 and 2020 is as follows (in thousands of dollars, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2020	Change	%	2021	2020	Change	%
General and administrative expense:								
Compensation expense	$ 12,135	$ 5,706	$ 6,429	113 %	$ 52,871	$ 15,798	$ 37,073	235 %
Professional fees	7,924	2,023	5,901	292 %	27,635	7,458	20,177	271 %
Occupancy expenses	1,502	673	829	123 %	3,622	1,994	1,628	82 %
Depreciation and amortization	476	391	85	22 %	1,307	1,118	189	17 %
Other expenses	2,045	1,532	513	33 %	5,266	3,572	1,694	47 %
Allocations	(3,333)	(1,779)	(1,554)	87 %	(8,197)	(5,624)	(2,573)	46 %
Total	$ 20,749	$ 8,546	$ 12,203	143 %	$ 82,504	$ 24,316	$ 58,188	239 %

General and administrative expense increased $12.2 million for the three months ended September 30, 2021 compared to the same period in 2020. General and administrative expense for the three months ended September 30, 2021 includes costs related to the acquisition of HalioDx, including $2.0 million of stock-based compensation and $3.9 million of professional fees and other costs associated with the transaction. Following the acquisitions of Decipher Biosciences in March 2021 and HalioDx in August 2021, their operations also contributed to the increase in general and administrative expenses. The increase in compensation expense was primarily due to an increase in headcount, including the addition of Decipher and HalioDx employees. The increase in other expenses was primarily due to increased IT costs partially offset by a decrease in the revaluation of the contingent consideration for the NanoString transaction.

General and administrative expense increased $58.2 million for the nine months ended September 30, 2021 compared to the same period in 2020. General and administrative expense for the nine months ended September 30, 2021 includes costs related to the acquisitions of Decipher Biosciences and HalioDx including $27.0 million of stock-based compensation and $18.3 million of professional fees and other costs associated with the transactions. Following the acquisitions, Decipher Biosciences and HalioDx operations also contributed to the increase in general and administrative expenses. The increase in compensation expense was also due to an increase in headcount, including the addition of Decipher and HalioDx employees. The increase in other expenses was primarily due to increased IT costs.

Other income (loss), net

Other income (loss), net, increased $1.3 million for the three months ended September 30, 2021 compared to the same period in 2020, due to an increase of $0.4 million from operations in France related to the French research tax credit during the period and an increase of $0.7 million of unrealized foreign currency gain (loss). The French research tax credits (“crédit d’impôt recherche” or “CIR”) are generated by our wholly owned subsidiary, HalioDx, in connection with its research efforts performed in Marseille, France. The Company recognizes other income from the CIR over time based on when the research and development expenses are incurred.

Other income (loss), net, decreased $1.2 million for the nine months ended September 30, 2021 compared to the same period in 2020, due to a decrease of $1.2 million of unrealized foreign currency gain(loss) partially offset by an increase of $0.4 million from the French research tax credit during the period.

Income tax benefit

We recorded an income tax benefit of approximately $1.4 million and $5.3 million for the three and nine months ended September 30, 2021 primarily due to to a partial release of the valuation allowance from the acquisition of Decipher Biosciences which provided a future source of income to support the realization of our deferred tax assets and a current year loss from HalioDx.

Liquidity and Capital Resources

From inception through September 30, 2021, we have been financed primarily through net proceeds from the sale of our equity securities. We have incurred net losses since our inception. For the nine months ended September 30, 2021, we had a net loss of $65.0 million, and as of September 30, 2021, we had an accumulated deficit of $346.6 million. We expect to incur additional losses for the remainder of 2021 and potentially in future years.

We believe our existing cash and cash equivalents of $164.0 million as of September 30, 2021, our available revolving line of credit, and our revenue during the next 12 months will be sufficient to meet our anticipated cash requirements for at least the next 12 months from the filing date of this report. We expect that our near- and longer-term liquidity requirements will continue to consist of costs to run our laboratories, research and development expenses, selling and marketing expenses, general and administrative expenses, working capital, costs to service our Loan and Security Agreement (See Note 7 to our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for more information about our Loan and Security Agreement), capital expenditures and general corporate expenses associated with the growth of our business. However, we may also use cash to acquire or invest in complementary businesses, technologies, services or products that would change our cash requirements. If we are not able to generate revenue to finance our cash requirements, including due to the impacts of the COVID-19 pandemic, we will need to finance future cash needs primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations or licensing arrangements. If we raise funds by issuing equity securities, dilution to stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, restrictions on our cash pursuant to the terms of our Loan and Security Agreement and other operating restrictions that could adversely affect our ability to conduct our business. Our Loan and Security Agreement imposes restrictions on our operations, increases our fixed payment obligations and has restrictive covenants. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third-party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for

future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives, or forgo potential acquisitions or investments. In addition, we may have to work with a partner on one or more of our products or development programs, which could lower the economic value of those programs to us.

Public Offering of Common Stock

On February 9, 2021, the Company issued and sold 8,547,297 shares of common stock in a registered public offering, including 1,114,864 shares issued and sold upon the underwriters' exercise in full of their option to purchase additional shares, at a price to the public of $74.00 per share. The Company's net proceeds from the offering were approximately $593.8 million, after deducting underwriting discounts and commissions and offering expenses of $38.7 million.

Loan and Security Agreement

On November 3, 2017, we entered into the Loan and Security Agreement with Silicon Valley Bank. The Loan and Security Agreement allows us to borrow up to $35.0 million, with a $25.0 million term loan, or Term Loan, and a revolving line of credit of up to $10.0 million, or the Revolving Line of Credit, subject to, with respect to the Revolving Line of Credit, a borrowing base of 85% of eligible accounts receivable. The Term Loan was advanced upon the closing of the Loan and Security Agreement. Borrowings under the Loan and Security Agreement mature in October 2022. The Term Loan bears interest at a variable rate equal to (i) the thirty-day U.S. London Interbank Offer Rate, or LIBOR, plus (ii) 4.20%, with a minimum rate of 5.43% per annum. Principal amounts outstanding under the Revolving Line of Credit bear interest at a variable rate equal to (i) LIBOR plus (ii) 3.50%, with a minimum rate of 4.70% per annum. We are also required to pay an annual facility fee on the Revolving Line of Credit of $25,000.

We may prepay the outstanding principal amount under the Term Loan plus accrued and unpaid interest and, if the Term Loan is repaid in full, a prepayment premium of $250,000. If the Loan and Security Agreement is terminated before maturity, then a termination fee equal to 1% of the Revolving Line of Credit, or $0.1 million, will be due. In addition, a final payment on the Term Loan in the amount of $1.2 million is due upon the earlier of the maturity date of the Term Loan or its payment in full. In January 2019, May 2019 and August 2020, we prepaid $12.5 million, $12.4 million and $0.1 million of the principal amount of the Term Loan Advance, respectively, and did not incur any prepayment premium as we did not repay the Term Loan Advance in full. As of September 30, 2021, the principal balance outstanding was one dollar.

The Loan and Security Agreement contains customary representations, warranties, and events of default, as well as affirmative and negative covenants. As of September 30, 2021, we were in compliance with debt covenants.

Our obligations under the Loan and Security Agreement are secured by substantially all of our assets (excluding intellectual property), subject to certain customary exceptions.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2021 and 2020 (in thousands of dollars):

	Nine Months Ended September 30,	
	2021	**2020**
Net cash used in operating activities	$ (40,067)	$ (11,972)
Net cash used in investing activities	(739,591)	(2,949)
Net cash provided by financing activities	596,147	200,684

Cash Flows from Operating Activities

Cash used in operating activities for the nine months ended September 30, 2021 was $40.1 million. The net loss of $65.0 million includes non-cash charges of $15.8 million of stock-based compensation expense, $13.2 million of depreciation and amortization, which includes $10.5 million of intangible asset amortization, noncash lease expense of $1.6 million, a $0.3 million expense for the revaluation of the contingent consideration related to the NanoString transaction and $5.3 million of deferred income taxes. Cash used as a result of changes in operating assets and liabilities was $2.3 million primarily

comprised of an increase in accounts receivable of $6.3 million, an increase in prepaid expense and other current assets of $1.9 million and a decrease in operating lease liability of $1.7 million partially offset by an increase in accounts payable of $3.9 million and an increase in accrued liabilities and deferred revenue of $3.3 million.

Cash used in operating activities for the nine months ended September 30, 2020 was $12.0 million. The net loss of $26.9 million includes non-cash charges of $9.4 million of stock-based compensation expense, $5.9 million of depreciation and amortization, which includes $3.8 million of intangible asset amortization, a $1.1 million write-down of supplies, noncash lease expense of $0.7 million and a $0.3 million expense for the revaluation of the contingent consideration related to the NanoString transaction. Cash used as a result of changes in operating assets and liabilities was $2.7 million, primarily comprised of a decrease in accrued liabilities of $3.3 million, a decrease in operating lease liability of $1.0 million, and an increase in prepaid expense and other current assets of $0.9 million, partially offset by a decrease in accounts receivable of $1.7 million and a decrease in supplies of $1.3 million.

Cash Flows from Investing Activities

Cash used in investing activities for the nine months ended September 30, 2021 was $739.6 million consisting of $574.4 million for the acquisition of Decipher Biosciences, $163.6 million for the acquisition of HalioDx and $4.5 million for the acquisition of property and equipment partially offset by $3.0 million of proceeds from the sale of an equity investment.

Cash used in investing activities for the nine months ended September 30, 2020 was $1.9 million for the acquisition of property and equipment and $1.0 million for the purchase of equity securities.

Cash Flows from Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2021 was $596.1 million, consisting of $593.8 million in net proceeds from the issuance of common stock in a public offering in February 2021 and $10.6 million in proceeds from the exercise of options to purchase our common stock and the purchase of stock under our Employee Stock Purchase Plan, or ESPP, partially offset by $8.3 million in tax payments during the period related to the vesting of restricted stock units granted to employees.

Cash provided by financing activities for the nine months ended September 30, 2020 was $200.7 million, consisting of $193.8 million in net proceeds from the issuance of common stock in a public offering in August 2020 and $10.1 million in proceeds from the exercise of options to purchase our common stock and the purchase of stock under our ESPP, partially offset by $3.2 million in tax payments during the period related to the vesting of restricted stock units granted to employees.

Contractual Obligations

As of September 30, 2021, our future principal and end-of-term debt obligation payments due under the Loan and Security Agreement were limited to $1.2 million in 2022. Following the acquisitions of Decipher Biosciences in March 2021 and HalioDx in August 2021, our payments due under our lease obligations are $1.0 million for the remainder of 2021, $8.5 million for the year 2022 to 2023, $8.7 million for the year 2024 to 2025, and $2.5 million for the year 2026 and beyond.

Off-balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This standard simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. This ASU removes the following exceptions: (1) exception to the incremental approach for intraperiod tax allocation when there is a loss from continuing operations and income or a gain from other items; (2) exception to the requirement to recognize a deferred tax liability for equity method investments when a foreign subsidiary becomes an equity method investment; (3) exception to the ability not to recognize a deferred tax liability for a foreign subsidiary when a foreign equity method investment becomes a subsidiary; and (4) exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. The amendments in this ASU also improve consistency and simplify other areas of Topic 740 by clarifying and amending existing guidance. The revised guidance will be applied prospectively and became

effective for us beginning January 1, 2021 and the adoption of ASU 2019-12 did not have a material impact on our condensed consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. We had cash and cash equivalents of $164.0 million as of September 30, 2021 which include bank deposits and money market funds. Such interest-bearing instruments carry a degree of risk; however, a hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our unaudited interim condensed financial statements.

Foreign Currency Risk

Included in our cash and cash equivalents as of September 30, 2021 were $5.6 million of bank deposits denominated in Euros. Such Euro denominated deposits carry a degree of risk from changes in currency exchange rates as the gains or losses from changes in exchange rates are included in our net loss and comprehensive loss. In addition, in connection with our acquisition of HalioDx, our exposure to foreign currency risk will increase. As of September 30, 2021 a hypothetical 10% appreciation or depreciation of the U.S. dollar relative to the Euro would have increased or decreased our net loss by $0.6 million for nine months ended September 30, 2021.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(b) Changes in Internal Control over Financial Reporting

We continuously seek to improve the efficiency and effectiveness of our internal controls. This results in refinements to processes throughout our Company. We acquired Decipher Biosciences in March 2021 and HalioDx in August 2021. We are in the process of incorporating Decipher Biosciences and HalioDx into our evaluation of internal control over financial reporting. Other than the two acquisitions, there were no changes in our internal control over financial reporting (as such term is defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation identified above that occurred during the quarter ended September 30, 2021, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. — OTHER INFORMATION

ITEM 1A. RISK FACTORS

Summary of Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully review the "Risk Factors" section before you invest in shares of our common stock. Listed below are some of the more significant risks relating to an investment in our common stock.

- We have a history of losses, and we expect to incur net losses for the foreseeable future and may never achieve or sustain profitability.
- Our financial results currently depend mainly on sales of our Afirma and Decipher Prostate tests, and we will need to generate sufficient revenue from these and other diagnostic solutions to grow our business.
- If we are unable to grow sales of our portfolio of tests including Percepta, Envisia, Decipher Bladder, Prosigna and Immunoscore, our business may suffer.
- We depend on a few payers for a significant portion of our revenue and if one or more significant payers stops providing reimbursement or decreases the amount of reimbursement for our tests, our revenue could decline.
- If payers do not provide reimbursement, rescind or modify their reimbursement policies, delay payments for our tests, recoup past payments, or if we are unable to successfully negotiate additional reimbursement contracts, our commercial success could be compromised.
- We may experience limits on our revenue if physicians decide not to order our tests or if patients decide not to use our tests.
- If we fail to comply with federal, state and foreign licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.
- If our general strategy of seeking growth through acquisitions and collaborations is not successful, or if we do not successfully integrate companies or assets that we acquire into our business, our prospects and financial condition will suffer.
- Our future success and international growth depends, in part, on our ability to adapt select tests to be performed on the nCounter Analysis System.
- If we are not successful in advancing our collaborations with Johnson & Johnson and others, or if our general strategy of seeking growth through such collaborations is not successful, our prospects and financial condition will suffer.
- COVID-19 has had an adverse effect on our business, results of operations and financial condition.
- We rely on sole suppliers for some of the reagents, equipment, and other materials used to perform our tests, and we may not be able to find replacements or transition to alternative suppliers.
- We depend on a specialized cytopathology practice to perform the cytopathology component of our Afirma test, and our ability to perform our diagnostic solution would be harmed if we were required to secure a replacement.
- Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts for various reasons, including in response to the way we recognize revenue, which may cause our stock price to fluctuate or decline.
- We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy.
- If we are unable to support demand for our commercial tests, our business could suffer.
- Changes in healthcare policy, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition and operations.
- Because of Medicare billing rules, we may not receive reimbursement for all tests provided to Medicare patients.
- If the FDA or foreign authorities were to begin regulating those of our tests that are not currently regulated, we could incur substantial costs and delays associated with trying to obtain premarket clearance, approval or certification.
- Obtaining marketing authorization or certification by the FDA and foreign regulatory authorities for our diagnostic tests will take significant time and require significant research, development and clinical study expenditures and ultimately may not succeed.
- If we are unable to obtain marketing authorizations, approvals, clearances or certifications to market Prosigna in additional countries or if regulatory limitations are placed on our diagnostic kit products, our business and growth will be harmed.

- We are subject to ongoing and extensive regulatory requirements, and our failure to comply with these requirements could substantially harm our business.
- If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability.
- We have experienced significant changes in our senior management team, the loss of one or more of our executive officers, or any inability to attract and retain highly-skilled employees and other key personnel could adversely affect our business.
- Billing for our diagnostic tests is complex, and we must dedicate substantial time and resources to the billing process to be paid.
- If our internal sales force is less successful than anticipated, our business expansion plans could suffer and our ability to generate revenues could be diminished. In addition, we have limited history selling our molecular diagnostics tests on a direct basis and our limited history makes forecasting difficult.
- Developing new products involves a lengthy and complex process, and if we do not achieve our projected development and commercialization goals in the time frames we announce and expect, our business will suffer and our stock price may decline.
- International expansion of our business exposes us to business, personnel, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States.
- Security breaches, loss of data and other disruptions to us or our third-party service providers could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.
- If we are unable to protect our intellectual property effectively, our business would be harmed.
- We may be involved in litigation related to intellectual property, which could be time-intensive and costly and may adversely affect our business, operating results or financial condition.
- The recently completed acquisitions of HalioDx and Decipher Biosciences presents risks and we must successfully integrate the HalioDx and Decipher Biosciences businesses to realize the financial goals that we currently anticipate.
- If we are unable to implement and maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.
- Our stock price may be volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

Risks Related to Our Business

We have a history of losses, and we expect to incur net losses for the foreseeable future and may never achieve or sustain profitability.

We have incurred net losses since our inception. For the nine months ended September 30, 2021, we had a net loss of $65 million and as of September 30, 2021, we had an accumulated deficit of $347 million. We expect to incur additional losses in the future, and we may never achieve revenue sufficient to offset our expenses. We expect to continue to devote substantially all of our resources to increase adoption of and reimbursement for our Afirma, Percepta, Decipher, Envisia, Immunoscore and Prosigna tests, and the development of additional tests. We may never achieve or sustain profitability, and our failure to achieve and sustain profitability in the future could cause the market price of our common stock to decline.

Our financial results currently depend mainly on sales of our Afirma and Decipher Prostate tests, and we will need to generate sufficient revenue from these and other diagnostic solutions to grow our business.

Most of our revenue to date has been derived from the sale of our Afirma tests, which are used in the diagnosis of thyroid cancer. Our second largest source of revenue in the third quarter of 2021 was our urological tests, which we began marketing and selling following our acquisition of Decipher Biosciences in March 2021. Over the next few years, we expect to continue to derive a substantial portion of our revenue from sales of our Afirma and Decipher tests. To date, we have derived a smaller portion of our revenue from our Percepta, Prosigna and Envisia tests. Once tests are clinically validated and commercially available for patient testing, we must continue to develop and publish evidence that our tests are informing clinical decisions in order for them to receive positive coverage decisions by payers. Without coverage policies, our tests may not be reimbursed and we will not be able to recognize revenue. We cannot guarantee that tests we commercialize will gain and maintain positive coverage decisions and therefore, we may never realize revenue from tests we commercialize. In addition, we are in various stages of research and development for other diagnostic solutions that we may offer, but there can be no assurance that we will be able to identify other diseases that can be effectively addressed or, if we are able to identify such diseases, whether or when

we will be able to successfully commercialize solutions for these diseases and obtain the evidence and coverage decisions from payers. If we are unable to increase sales and expand reimbursement for our Afirma, Percepta, Envisia, Decipher, Immunoscore and Prosigna tests, or develop and commercialize other solutions, our revenue and our ability to achieve and sustain profitability would be impaired, and the market price of our common stock could decline.

If we are unable to grow sales of our portfolio of tests including Percepta, Envisia, Decipher Bladder, Prosigna and Immunoscore, our business may suffer.

We have focused on developing a robust pulmonology business, led by our Percepta and Envisia products. In addition, in 2020, we acquired the Prosigna breast cancer test and, in 2021 we acquired the Decipher Bladder and Immunoscore tests. Although these products have not contributed significant revenue to date, we expect them to grow and become an increasingly important component of our strategic focus, as well as our results of operations. We plan to introduce a nasal swab test for early lung cancer detection which, together with our Percepta Genomic Atlas and the Percepta GSC, we expect to form a comprehensive lung cancer testing portfolio that we believe may improve lung cancer diagnosis and treatment decisions. However, due to the COVID-19 pandemic, pulmonologists have been focused on treatment planning and care for COVID-19 patients and we believe fewer bronchoscopy procedures have been performed where Percepta and Envisia brushings and biopsies have been taken and sent to us for genomic testing. There can be no assurance that physicians will perform bronchoscopy procedures or send brushings or biopsies to us in sufficient volumes for our revenue to recover to pre-pandemic levels or to meet our projections. Additionally, we anticipate expanding the reach of our lung, urology, bladder and breast cancer tests to international markets through the distribution of the nCounter Analysis System; if our distribution of this platform is unsuccessful, or if our products are not widely adopted internationally, our business and results of operations may be adversely affected.

We depend on a few payers for a significant portion of our revenue and if one or more significant payers stops providing reimbursement or decreases the amount of reimbursement for our tests, our revenue could decline.

Revenue for tests performed on patients covered by Medicare and UnitedHealthcare Group was 31% and 10%, respectively, of our revenue for the nine months ended September 30, 2021, compared with 24% and 11%, respectively, for the nine months ended September 30, 2020. The percentage of our revenue derived from significant payers is expected to fluctuate from period to period as our revenue fluctuates, as additional payers provide reimbursement for our tests or if one or more payers were to stop reimbursing for our tests or change their reimbursed amounts. Effective January 2012, Palmetto GBA, the regional Medicare Administrative Contractor, or MAC, that handled claims processing for Medicare services over our jurisdiction at that time, issued coverage and payment determinations for our Afirma Classifiers now covered by Noridian Healthcare Solutions, the current MAC for our jurisdiction, through the Molecular Diagnostics Services Program, or MolDX program, administered by Palmetto GBA, under an LCD.

Noridian Healthcare Solutions issued an LCD for Percepta effective for services performed on or after May 2017. This coverage policy requires us to establish and maintain a Certification and Training Registry program and make Percepta available only to certain Medicare patients through physicians who participate in this program. Failure by us or physicians to comply with the requirements of the Certification and Training Registry program could lead to loss of Medicare coverage for Percepta, which could have an adverse effect on our revenue.

We submitted the dossier of clinical evidence needed to obtain Medicare coverage for the Envisia Genomic Classifier through the MolDX technical assessment process in 2018, and received Medicare coverage for the classifier, with an effective date of April 1, 2019.

An LCD was issued for Prosigna by Palmetto GBA in August 2015, which has been in effect since October 1, 2015.

Decipher Prostate Biopsy and Decipher Prostate RP are currently reimbursed by Medicare pursuant to LCDs issued by Palmetto GBA and adopted by Noridian Healthcare Solutions, each acting as a MAC, as well as by a number of commercial payers. However, there are many commercial payers who currently do not provide reimbursement for our prostate genomic tests, or provide only limited reimbursement, and we have contracts for reimbursement with only a limited number of commercial payers for our prostate tests. Our Decipher Prostate tests were assigned a new American Medical Association Current Procedural Terminology code, or CPT code, 81542, for 2020. CPT code changes can result in a risk of an error being made in the claim adjudication process. Such errors can occur with claims submission, third-party transmission or in the processing of the claim by the payer. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment we receive.

Effective July 18, 2021, Decipher Bladder is reimbursed by Medicare pursuant to LCDs issued by three MACs and Decipher Bladder is covered by a fourth MAC, Noridian Healthcare Solutions, effective as of July 25, 2021. We have not yet contracted with any commercial payers for reimbursement of Decipher Bladder. Our Decipher Bladder test was assigned a new CPT code, 0016M, for 2020.

HalioDx's Immunoscore test is not subject to a coverage policy from Medicare or any of the MACs. Immunoscore has been assigned CPT code 0261U effective October 1, 2021.

On a five-year rotational basis, Medicare requests bids for its regional MAC services. Any future changes in the MAC processing or coding for Medicare claims for the Afirma, Percepta, Decipher or Envisia tests, for Prosigna, or for Immunoscore, could result in a change in the coverage or reimbursement rates for such products, or the loss of coverage, and could also result in increased difficulties in obtaining and maintaining coverage for future products.

On March 1, 2015, CPT code 81545 for the Afirma GEC was issued. On January 1, 2018, the Medicare Clinical Laboratory Fee Schedule payment rate for the Afirma classifier increased from $3,220 to $3,600. This rate is based on the volume-weighted median of private payer rates based on final payments made between January 1 and June 30, 2016, which we reported to the Centers for Medicare & Medicaid Services, or CMS, in 2017 as required under the Protecting Access to Medicare Act of 2014, or PAMA. In December 2019, through the Further Consolidated Appropriations Act of 2020, Congress delayed the next data reporting period from 2020 to 2021 for final payments made between January 1 and June 30, 2019, extending the applicability of the payment rates based on 2017 reporting by one year through December 31, 2021. In March 2020, through the Coronavirus Aid, Relief, and Economic Security, or CARES Act, Congress further delayed the next reporting period to 2022 for final payments made between January 1 and June 30, 2019, extending the applicability of the payment rates based on 2017 reporting through December 31, 2022. If going forward the rate is negatively updated, it may materially impact our average selling price of the test and therefore revenue.

As a result of the transition from Afirma GEC to Afirma GSC, a new CPT Category I code (81546) was established for the Afirma classifier, effective January 1, 2021. This code went through the national payment determination process for Medicare in 2020, through which CMS priced 81546 at the same rate of $3,600 as 81545. New CPT Proprietary Laboratory Analyses, or PLA, codes have also been established for Afirma Xpression Atlas (0204U) and Afirma MTC (0208U), effective October 1, 2020. CMS has priced 0204U at the same rate of $2,919.60 as CPT 81455. The new payment rates for 81546 and 0204U became effective January 1, 2021. In 2020 CMS did not price 0208U, and instead assigned the code to the "gapfilling" process, under which the individual MACs will set the payment rate for the test in 2021 based on the following four factors: 1) charges for the test and routine discounts to charges; 2) resources required to perform the test; 3) payment amounts determined by other payers; and 4) charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. In July 2021, Veracyte submitted an application to the CPT Editorial Panel to request deletion of 0208U in order to replace the code with two new CPT codes, one for each distinct clinical situation in which Afirma MTC is provided. On October 1, the CPT Editorial Panel deleted CPT code 0208U effective January 1, 2022, so the median of MAC gapfill rates will not take effect on January 1, 2022.

There can be no assurance that the Afirma or Prosigna rates (or the rates for Afirma Xpression Atlas or Afirma MTC) will not decrease during subsequent reporting cycles under PAMA.

We submit claims to Medicare for Percepta using an unlisted code under the MolDX program. A specific CPT code assigned to Percepta may be required to go through the national payment determination process, and there can be no assurance that the Medicare payment rate Percepta receives through this process will not be lower than its current rate. There can also be no assurance that the Medicare payment rate for Percepta will not be reduced when it is set based on the volume-weighted median of private payer rates when we are required to report private payer rates for Percepta under PAMA.

We submit claims to Medicare for Envisia using CPT code 81554, which became effective January 1, 2021. We applied for New ADLT designation for Envisia, and the test was approved as a New ADLT on September 17, 2020. Effective October 1, 2020 through June 30, 2021, the Medicare payment rate for Envisia was set at $5,500, the "actual list charge" for the test. Veracyte reported private payer rates for Envisia in March 2021, reflecting final payments between October 1, 2020 and February 28, 2021. The volume-weighted median of these reported rates, which was $5,500, will set the payment rate for Envisia from July 1, 2021 through December 31, 2022, after which Envisia will be priced based on private payer rates collected and reported annually. There can be no assurance that the Medicare payment rate for Envisia will not be reduced when it is set based on the volume-weighted median of private payer rates when we are required to report private payer rates for Envisia under PAMA in subsequent reporting cycles.

We submit claims to Medicare for Decipher Prostate Biopsy and Decipher Prostate RP using CPT code 81542. CMS assigned 81542 to the gapfilling process in 2020, and it has been priced effective January 1, 2021 at $3,873, based on CMS' revision of the median of payment rates set by the MACs through the gapfilling process. There can be no assurance that the Medicare payment rates for Decipher Prostate Biopsy and Decipher Prostate RP will not decrease during a future reporting cycle under PAMA.

We will submit claims to Medicare for Decipher Bladder using CPT code 0016M. CMS assigned 0016M to the gapfilling process in 2021. There is no assurance that the gapfilling process will not result in a lower than expected payment rate for 0016M, or that the Medicare payment rate for Decipher Bladder will not decrease during a future reporting cycle under PAMA.

HalioDx's Immunoscore test has been assigned CPT code 0261U effective October 1, 2021. The Immunoscore code is currently going through the national payment determination process and will be either crosswalked or assigned to gapfill effective January 1, 2022. There is no assurance that the payment determination process will not result in a lower than expected payment rate for 0261U, or that the Medicare payment rate for Immunoscore will not decrease during a future reporting cycle under PAMA.

Moreover, federal Medicare funding and state budgets are limited and have been placed under tremendous strain in recent years, which is likely to be further exacerbated as a result of reduced tax receipts and greater deficit spending as a result of the COVID-19 pandemic. Such budgetary pressures may force Medicare or state agencies to reduce payment rates or change coverage policies. If there is a decrease in Medicare or other payers' payment rates for our tests, our revenue from Medicare and such payers will decrease and the payment rates for some of our commercial payers may also decrease if they tie their allowable rates to the Medicare rates. These changes could have an adverse effect on our business, financial condition and results of operations.

Although we have entered into contracts with certain third-party payers that establish in-network allowable rates of reimbursement for our Afirma tests, payers may suspend or discontinue reimbursement at any time, may require or increase co-payments from patients, or may reduce the reimbursement rates paid to us. Reductions in private payer amounts could decrease the Medicare payment rates for our tests under PAMA. In addition, private payers have begun requiring prior authorization for molecular diagnostic tests. Potential reductions in reimbursement rates or increases in the difficulty of achieving payment could have a negative effect on our revenue.

If payers do not provide reimbursement, rescind or modify their reimbursement policies, delay payments for our tests, recoup past payments, or if we are unable to successfully negotiate additional reimbursement contracts, our commercial success could be compromised.

Physicians might not order our tests unless payers reimburse a substantial portion of the test price. There is significant uncertainty concerning third-party reimbursement of any test incorporating new technology, including our tests. Reimbursement by a payer may depend on a number of factors, including a payer's determination that these tests are:

- not experimental or investigational;
- pre-authorized and appropriate for the specific patient;
- cost-effective;
- supported by peer-reviewed publications; and
- included in clinical practice guidelines.

Since each payer makes its own decision as to whether to establish a coverage policy or enter into a contract to reimburse our tests, seeking these approvals is a time-consuming and costly process.

We do not have a contracted rate of reimbursement with some payers for our tests. Without a contracted rate for reimbursement, our claims are often denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive, and may not result in payment. In cases where there is no contracted rate for reimbursement, there is typically a greater patient co-insurance or co-payment requirement which may result in further delay or decreased likelihood of collection. Payers may attempt to recoup prior payments after review, sometimes after significant time has passed, which would impact future revenue.

We expect to continue to focus substantial resources on increasing adoption, coverage and reimbursement for the Afirma, Percepta, Envisia, Immunoscore and Decipher tests, Prosigna and any other future tests we may develop. We believe it will take several years to achieve coverage and contracted reimbursement with a majority of third-party payers. We cannot predict whether, under what circumstances, or at what payment levels payers will reimburse for our tests. Also, payer consolidation is underway and creates uncertainty as to whether coverage and contracts with existing payers will remain in effect. Finally, if there is a decrease in the Medicare payment rates for our tests, the payment rates for some of our commercial payers may also decrease if they tie their allowable rates to the Medicare rates. Reductions in private payer amounts could decrease the Medicare payment rates for our tests under PAMA. Our failure to establish broad adoption of and reimbursement for our tests, or our inability to maintain existing reimbursement from payers, will negatively impact our ability to generate revenue and achieve profitability, as well as our future prospects and our business.

We may experience limits on our revenue if physicians decide not to order our tests.

If we are unable to create or maintain demand for our tests in sufficient volume, we may not become profitable. To generate demand, we will need to continue to educate physicians about the benefits and cost-effectiveness of our tests through published papers, presentations at scientific conferences, marketing campaigns and one-on-one education by our sales force. In addition, our ability to obtain and maintain adequate reimbursement from third-party payers will be critical to generating revenue. Moreover, many patients have been deferring elective procedures and medical visits as a result of the COVID-19 pandemic, and we have experienced, and expect to continue to experience, a significant reduction in patient demand or physician recommendations, which has and may continue to adversely affect our business.

The Afirma genomic classifier is included in most physician practice guidelines in the United States for the assessment of patients with thyroid nodules. However, historical practice recommended a full or partial thyroidectomy in cases where cytopathology results were indeterminate to confirm a diagnosis. Our lung products are not yet integrated into practice guidelines and physicians may be reluctant to order tests that are not recommended in these guidelines. The Prosigna test is included in practice guidelines in the United States and internationally but faces competition from other products globally. Because our Afirma, Percepta, Envisia, Decipher Prostate Biopsy, Decipher Prostate RP, Decipher Bladder, and Immunoscore testing services are performed by our certified laboratories under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, rather than by the local laboratory or pathology practice, pathologists may be reluctant to support our testing services as well. Guidelines that include our tests currently may subsequently be revised to recommend another testing protocol, and these changes may result in physicians deciding not to use our tests. Lack of guideline inclusion could limit the adoption of our tests and our ability to generate revenue and achieve profitability. To the extent international markets have existing practices and standards of care that are different than those in the United States, we may face challenges with the adoption of our tests in international markets.

The strength of the clinical data supporting the use of the Decipher Prostate Biopsy and Decipher Prostate RP tests have led to the tests' inclusion in national guidelines. For example, in the 2020 NCCN Practice Guidelines for Prostate Cancer, the Decipher Prostate RP test is "recommended" for use to improve therapy decision making. It is the only test to achieve this designation for post-surgery patients with localized prostate cancer. Further, in September 2021, the 2022 NCCN guidelines were released and recommend specific treatment decisions for patients based on their Decipher Prostate RP score.

Although Decipher Prostate Biopsy and Decipher Prostate RP have been integrated into the NCCN guidelines, if we are unsuccessful in maintaining and increasing the level of recommendation of our genomic tests within these guidelines, are unable to cause any new genomic tests we develop to be included in these guidelines, or are unable to cause our genomic tests to be included in other influential guidelines, we may be at a disadvantage in gaining market acceptance and market share relative to our competitors.

We may experience limits on our revenue if patients decide not to use our tests.

Some patients may decide not to use our tests because of price, all or part of which may be payable directly by the patient if the patient's insurer denies reimbursement in full or in part. There is a growing trend among insurers to shift more of the cost of healthcare to patients in the form of higher co-payments or premiums, and this trend is accelerating which puts patients in the position of having to pay more for our tests. We expect to continue to see pressure from payers to limit the utilization of tests, generally, and we believe more payers are deploying costs containment tactics, such as pre-authorization and employing laboratory benefit managers to reduce utilization rates. Implementation of provisions of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively the ACA, has also resulted in increases in premiums and reductions in coverage for some patients. These events may result in patients delaying or forgoing medical checkups or treatment due to their inability to pay for our tests, which could have an adverse effect on our revenue. Many patients have been deferring elective procedures and medical visits as a result of the COVID-19 pandemic, and

we have experienced, and may continue to experience, a significant reduction in patient demand, which has and may continue to adversely affect our business.

If we fail to comply with federal and state licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations mandate specific personnel qualifications, facilities administration, quality systems, inspections, and proficiency testing. CLIA certification is also required for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payers. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories. If we fail to maintain CLIA certificates in our South San Francisco, California, San Diego, California, Austin, Texas, Marseille, France or Richmond, Virginia laboratory locations, we would be unable to bill for services provided by state and federal healthcare programs, as well as many private third-party payers, which may have an adverse effect on our business, financial condition and results of operations.

We are also required to maintain state licenses to conduct testing in our laboratories. California, New York, and Texas, among other states' laws, require that we maintain a license and comply with state regulation as a clinical laboratory. Other states may have similar requirements or may adopt similar requirements in the future. In addition, all of our clinical laboratories are required to be licensed on a test-specific basis by New York State. We have received approval for the Afirma, Percepta, Envisia, Decipher Prostate and Decipher Bladder tests, and will be seeking approval for the Immunoscore test. We will be required to obtain approval for other tests we may offer in the future. If we were to lose our CLIA certificate or California license for our South San Francisco, San Diego, or Richmond laboratories, whether as a result of revocation, suspension or limitation, we would no longer be able to perform our molecular tests, which would eliminate our primary source of revenue and harm our business. If we fail to meet the state licensing requirements for our Austin laboratory, we would need to move the receipt and storage of fine needle aspirations, or FNAs, as well as the slide preparation for cytopathology, to South San Francisco, which could result in a delay in processing tests during that transition and increased costs. If we were to lose our CLIA certificate for our Marseille or Richmond laboratories, whether as a result of revocation, suspension or limitation, we would no longer be able to perform our Immunoscore test. If we were to lose our licenses issued by New York or by other states where we are required to hold licenses, we would not be able to test specimens from those states. New tests we may develop may be subject to new approvals by regulatory bodies such as New York State, and we may not be able to offer our new tests until such approvals are received.

If our general strategy of seeking growth through acquisitions and collaborations is not successful, or if we do not successfully integrate companies or assets that we acquire into our business, our prospects and financial condition will suffer.

As an element of our growth strategy, we may pursue opportunities to license assets or purchase companies or assets that we believe would complement our current business or help us expand into new markets. For example, in December 2019, we acquired the nCounter Analysis System and Prosigna test from NanoString, in March 2021, we acquired Decipher Biosciences, and in August 2021, we acquired HalioDx. We may pursue additional acquisitions of complementary businesses or assets as part of our business strategy. There can be no assurance that we will successfully integrate the assets acquired from such acquisitions into our existing business, in general, or that our exclusive worldwide license to the nCounter Analysis System for in vitro diagnostic use granted by NanoString will allow us to expand our international reach as anticipated. This and any future acquisitions made by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of acquired companies or businesses we may acquire in the future also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment.

To finance any acquisitions or investments, we have previously issued and may choose in the future to issue shares of our stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all. If these funds are raised through the sale of equity or convertible debt securities, dilution to our stockholders could result. Our Loan and Security Agreement with Silicon Valley Bank contains covenants that could limit our ability to sell debt securities or obtain additional debt financing arrangements, which could affect our ability to finance acquisitions or investments other than through the issuance of stock.

Our future success and international growth depends, in part, on our ability to adapt select tests to be performed on the nCounter Analysis System.

Our strategy to expand into international markets depends on our ability to successfully distribute the nCounter Analysis System, adapt our menu of diagnostic tests for the platform, and secure necessary regulatory approvals. Currently, the Prosigna breast cancer assay is the only commercially-available test on the platform. If we are not able to adapt our other current or future genomic classifiers to be performed on the nCounter Analysis System, or if the nCounter Analysis System fails to be competitive against other diagnostic tests, our prospects for growth could suffer. In addition, to the extent international markets have existing practices and standards of care that are different than those in the United States, we may face challenges with the adoption of the nCounter Analysis System in international markets.

If we are not successful in advancing our collaborations with Johnson & Johnson and others, our prospects and financial condition will suffer.

We have previously entered into technology licensing and collaboration arrangements, such as our collaborations with Johnson & Johnson in December 2018, with Acerta Pharma, the hematology research and development arm of AstraZeneca, in December 2019 and with CareDx in May 2020, as well as our investment in MAVIDx in July 2020, which reflect an important element of our business strategy. We also may pursue additional strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. However, we have limited experience with respect to the formation of strategic alliances and joint ventures. There can be no assurance that we will successfully identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any technology license, strategic alliance, joint venture or investment.

COVID-19 has had an adverse effect on our business, results of operations and financial condition.

COVID-19 has caused significant volatility in financial markets and has raised the prospect of an extended global recession. Public health problems resulting from COVID-19 and precautionary measures instituted by governments and businesses to mitigate its spread, including travel restrictions and quarantines, have contributed to a general slowdown in the global economy, adversely impacted patients, physicians, customers, suppliers, third-party contract manufacturers, and collaboration partners, and disrupted our operations. Changes in our operations in response to COVID-19 or employee illnesses resulting from the pandemic may result in inefficiencies or delays, including in sales and product development efforts and additional costs related to business continuity initiatives, that cannot be fully mitigated through succession planning, employees working remotely or teleconferencing technologies. As of September 30, 2021, the FDA has approved one vaccine and issued Emergency Use Authorizations, or EUAs, for two vaccines. Although vaccines are increasingly available in the United States and Europe, there can be no guarantee that the vaccines will be effective against new strains of the virus or that the vaccines will be broadly accepted. Also there can be no guarantee that federal, state, local and foreign agencies will not continue to take other cautionary steps to combat the virus to reduce the incidence of new cases, which could negatively impact our volumes and revenue and limit our ability to reliably forecast our test volumes and levels of revenue.

COVID-19 and related governmental reactions have had and may continue to have a negative impact on our business, liquidity, results of operations, and stock price due to the occurrence of some or all of the following events or circumstances among others:

- We may not be able to manage our business effectively due to key employees becoming ill, working from home inefficiently and being unable to travel to our facilities.

- We and our customers, suppliers, third-party contract manufacturers, and collaboration partners may be prevented from operating worksites, including manufacturing facilities, due to employee illness, reluctance to appear at work or “stay-at-home” regulations.

- Interruptions in manufacturing (including the sourcing of reagents or supplies) and shipment of our products. We believe the rapid increase in daily testing volumes is consuming reagents and supplies otherwise available to genomic testing companies like ours across the United States. In October 2020, we experienced supply chain disruptions in the supply of plastic materials used in the processing of samples. When not limited by the expiration date of products and when we feel it reasonable and feasible to do so, we are taking steps to increase our level of supplies and inventory reserves, to develop alternative sources of supply and to implement procedures to mitigate the impact on our supply chain or our ability to process samples in our laboratories. Though we are in regular contact with our key suppliers, we do not have, nor expect to have, the necessary insight into our vendors’ supply chain issues that we may need to know to effectively mitigate the impact to our business. Though we attempt to mitigate the impact to our business,

these interruptions in manufacturing (including the sourcing of reagents or supplies) may negatively impact our test volumes or levels of revenue.

- Reduced patient demand for, or provider capacity to deliver, diagnostic testing and elective procedures generally (which may impact our ability to deliver to our revenue estimates).
- Disruptions of the operations of our third-party contract manufacturers and suppliers, which could impact our ability to purchase components at efficient prices and in sufficient amounts.
- We may need to raise capital, and if we raise capital by issuing equity securities, our common stock may be diluted.
- The market price of our common stock may drop or remain volatile.
- Inability of healthcare providers to deliver anticipated testing volumes due to temporary or permanent staff attrition as a result of vaccine mandates.
- We may incur significant employee health care costs under our insurance programs.

The extent of the impact of COVID-19 on our business and financial results will depend largely on future developments, including the deployment, efficacy, availability and utilization of vaccines, the impact on capital and financial markets and the related impact on the financial circumstances of patients, physicians, suppliers, third-party contract manufacturers, and collaboration partners, all of which are highly uncertain and cannot be predicted. This situation is changing rapidly, and additional impacts may arise that we are not aware of at this time.

We rely on sole suppliers for some of the reagents, equipment and other materials used to perform our tests, and we may not be able to find replacements or transition to alternative suppliers.

We rely on sole suppliers for critical supply of reagents, equipment and other materials that we use to perform our tests and for the manufacture of the nCounter Analysis System for diagnostic use and Prosigna test kits sold to customers. We also purchase components used in our sample collection kits from sole-source suppliers. Some of these items are unique to these suppliers and vendors. In addition, we utilize a sole source to assemble and distribute our sample collection kits. We rely on NanoString for the supply of the nCounter Analysis System for diagnostic use and Prosigna test kits. As part of the HalioDx Acquisition we intend to migrate manufacture of the test kits for the nCounter from NanoString to HalioDx. While we have developed alternate sourcing strategies for these materials and vendors, we cannot be certain whether these strategies will be effective or the alternative sources will be available when we need them. Moreover, the supply of key reagents and testing materials has been severely challenged by the COVID-19 pandemic. Over the course of the COVID-19 pandemic, we experienced supply chain disruptions in the supply of plastic materials used in the processing of samples, although this has not resulted in delays in our ability to timely return test results. If these suppliers can no longer provide us with the materials we need to perform the tests and for our sample collection kits, if the materials do not meet our quality specifications or are otherwise unusable, if we cannot obtain acceptable substitute materials, or if we elect to change suppliers, an interruption in test processing or system and test kit deliveries could occur, we may not be able to deliver patient reports and we may incur higher one-time switching costs. Any such interruption may significantly affect our future revenue, cause us to incur higher costs, and harm our customer relationships and reputation. In addition, in order to mitigate these risks, we maintain inventories of these supplies at higher levels than would be the case if multiple sources of supplies were available. If our test volume decreases or we switch suppliers, we may hold excess supplies with expiration dates that occur before use which would adversely affect our losses and cash flow position. As we introduce any new test, we may experience supply issues as we ramp test volume. Moreover, the COVID-19 pandemic has disrupted supply chains globally, and could adversely affect our ability to source essential reagents, equipment and other materials in a timely manner or at all.

We depend on a specialized cytopathology practice to perform the cytopathology component of our Afirma test, and our ability to perform our diagnostic solution would be harmed if we were required to secure a replacement.

We rely on TCP to provide cytopathology professional diagnoses on thyroid FNA samples pursuant to a pathology services agreement. Pursuant to this agreement, as amended, TCP has the exclusive right to provide our cytopathology diagnoses on FNA samples at a fixed price per test. Until February 2019, TCP also previously subleased a portion of our facility in Austin, Texas. Our agreement with TCP is effective through October 31, 2022, and thereafter automatically renews every year unless either party provides notice of intent not to renew at least 12 months prior to the end of the then-current term.

If TCP were not able to support our current test volume or future increases in test volume or to provide the quality of services we require, or if we were unable to agree on commercial terms and our relationship with TCP were to terminate, our business would be harmed until we were able to secure the services of another cytopathology provider. There can be no assurance that we would be successful in finding a replacement that would be able to conduct cytopathology diagnoses at the same volume or with the same high-quality results as TCP. Locating another suitable cytopathology provider could be time consuming and would result in delays in processing Afirma tests until a replacement was fully integrated with our test processing operations.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts for various reasons, including in response to the way we recognize revenue, which may cause our stock price to fluctuate or decline.

Our quarterly financial and operating results depend on sales of our products in the markets we operate and are sensitive to a number of factors, including patient and clinician demand, market condition, and the prevalence of the indications we seek to address. In addition, we cannot be sure that we will be able to successfully complete development of or commercialize any of our planned future products, or that they will prove to be capable of reliably being used. Before we can successfully develop and commercialize any of our currently planned or other new diagnostic solutions, we will need to:

- conduct substantial research and development;
- obtain the necessary testing samples and related data;
- conduct clinical validation studies;
- expend significant funds;
- expand and scale-up our laboratory processes;
- expand and train our sales force;
- gain acceptance from ordering clinicians at a larger number of hospitals;
- gain acceptance from ordering laboratories associated with hospitals and payers; and
- seek and obtain regulatory clearances, approvals or certifications of our new solutions, as required by applicable regulations.

This process involves a high degree of risk and may take up to several years or more. Our test development and commercialization efforts may be delayed or fail for many reasons, including:

- failure of the test at the research or development stage;
- difficulty in accessing suitable testing samples, especially testing samples with known clinical results;
- lack of clinical validation data to support the effectiveness of the test;
- delays resulting from the failure of third-party suppliers or contractors to meet their obligations in a timely and cost-effective manner;
- failure to obtain or maintain necessary clearances, approvals or certifications to market the test; or
- lack of commercial acceptance by patients, clinicians or third-party payers.

Few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of new diagnostic solutions, or we may be required to expend considerable resources repeating clinical studies, which would adversely impact the timing for generating potential revenues from those new diagnostic solutions. In addition, as we develop diagnostic solutions, we will have to make additional investments in our sales and marketing operations, which may be prematurely or unnecessarily incurred if the commercial launch of a test is abandoned or delayed. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we would likely abandon the development of the test or test feature that was the subject of the clinical trial, which could harm our business.

In addition, we recognize test revenue upon delivery of the patient report to the prescribing physician based on the amount we expect to ultimately realize. We determine the amount we expect to ultimately realize based on payer reimbursement history, contracts, and coverage. Upon ultimate collection, the amount received is compared to the estimates and the amount accrued is adjusted accordingly. We cannot be certain as to when we will receive payment for our diagnostic tests, and we must appeal negative payment decisions, which delays collections. Should judgments underlying estimated reimbursement change or be incorrect at the time we accrued such revenue, our financial results could be negatively impacted in future quarters. As a result, comparing our operating results on a period-to-period basis may not be meaningful. You should not rely on our past

results as an indication of our future performance. In addition, these fluctuations in revenue may make it difficult for us, for research analysts and for investors to accurately forecast our revenue and operating results. If our revenue or operating results fall below expectations, the price of our common stock would likely decline.

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

In addition to the need to scale our testing capacity, future growth, including our transition to a multi-product company with international operations, will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees with the necessary skills to support the growing complexities of our business. Rapid and significant growth may place strain on our administrative, financial and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We have implemented an internally-developed data warehouse, which is critical to our ability to track our diagnostic services and patient reports delivered to physicians, as well as to support our financial reporting systems. The time and resources required to optimize these systems is uncertain, and failure to complete optimization in a timely and efficient manner could adversely affect our operations. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

If we are unable to support demand for our commercial tests, our business could suffer.

As demand for our tests grows, we will need to continue to scale our testing capacity and processing technology, expand customer service, billing and systems processes and enhance our internal quality assurance program. We will also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our tests. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs of processing tests, quality control issues or inability to meet demand. There can be no assurance that we will be able to perform our testing on a timely basis at a level consistent with demand, or that our efforts to scale our operations will not negatively affect the quality of test results. If we encounter difficulty meeting market demand or quality standards, our reputation could be harmed and our future prospects and our business could suffer.

Changes in healthcare policy, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition and operations.

The ACA, enacted in March 2010, made changes that significantly affected the pharmaceutical and medical device industries and clinical laboratories. Along with the now-repealed 2.3% excise tax on the sale of certain medical devices sold outside of the retail setting, other significant measures contained in the ACA include, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The ACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, various efforts to amend the ACA are ongoing. We cannot predict if, or when, the ACA will be amended, and cannot predict the impact that an amendment of the ACA will have on our business.

In addition to the ACA, various healthcare reform proposals have also periodically emerged from federal and state governments. For example, in February 2012, Congress passed the Middle Class Tax Relief and Job Creation Act of 2012, which in part reset the clinical laboratory payment rates on the Medicare Clinical Laboratory Fee Schedule, or CLFS, by 2% in 2013. In addition, under the Budget Control Act of 2011, which is effective for dates of service on or after April 1, 2013, Medicare payments, including payments to clinical laboratories, are subject to a reduction of 2% due to the automatic expense reductions (sequester) until fiscal year 2024. In March 2020, Congress passed the CARES Act, which suspended the 2% reduction in Medicare fee-for-service payments from May 1, 2020 through December 31, 2020. To account for this temporary suspension, the legislation also extends the effect of sequestration by a year (now through fiscal year 2030). Reductions resulting from the Congressional sequester are applied to total claims payment made; however, they do not currently result in a rebasing of the negotiated or established Medicare or Medicaid reimbursement rates. In December 2020, Congress passed the Consolidated Appropriations Act of 2021, or CAA, which extended the suspension through March 31, 2021. Legislation enacted April 14, 2021 further extended the suspension through December 31, 2021.

State legislation on reimbursement applies to Medicaid reimbursement and managed Medicaid reimbursement rates within that state. Some states have passed or proposed legislation that would revise the reimbursement methodology for clinical laboratory payment rates under those Medicaid programs. For example, effective July 2015, California’s Department of Health Care Services implemented a new rate methodology for clinical laboratories and laboratory services. This methodology

involves the use of a range of rates that fell between zero and 80% of the calculated California-specific Medicare rate and the calculation of a weighted average (based on units billed) of such rates.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we do or may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation, cost reduction measures and the expansion in the role of the U.S. government in the healthcare industry may result in decreased revenue, lower reimbursement by payers for our tests or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations. In addition, sales of our tests outside the United States subject our business to foreign regulatory requirements and cost-reduction measures, which may also change over time.

Ongoing calls for deficit reduction at the federal government level and reforms to programs such as the Medicare program to pay for such reductions may affect the pharmaceutical, medical device and clinical laboratory industries. Currently, clinical laboratory services are excluded from the Medicare Part B co-insurance and co-payment as preventative services. Any requirement for clinical laboratories to collect co-payments from patients may increase our costs and reduce the amount ultimately collected.

CMS bundles payments for clinical laboratory diagnostic tests together with other services performed during hospital outpatient visits under the Hospital Outpatient Prospective Payment System. CMS currently maintains an exemption for molecular pathology tests from this bundling provision. It is possible that this exemption could be removed by CMS in future rule making, which might result in lower reimbursement for tests performed in this setting.

PAMA includes a substantial new payment system for clinical laboratory tests under the CLFS. Under PAMA, laboratories that receive the majority of their Medicare revenues from payments made under the CLFS and the Physician Fee Schedule would report on a triennial basis (or annually for ADLTs), private payer rates and volumes for their tests with specific CPT codes based on final payments made during a set data collection period (the first of which was January 1 through June 30, 2016). We believe that PAMA and its implementing regulations are generally favorable to us. We reported to CMS the data required under PAMA before the March 31, 2017 deadline. The new payment rate for the Afirma genomic classifier based on the volume-weighted median of private payer rates took effect January 1, 2018, increasing from $3,220 to $3,600 through December 31, 2020. In December 2019, through the Further Consolidated Appropriations Act of 2020, Congress delayed the next data reporting period from 2020 to 2021 for final payments made between January 1 and June 30, 2019, extending the applicability of the current rate for Afirma through December 31, 2021. In March 2020, through the CARES Act, Congress further delayed the next reporting period to 2022 for final payments made between January 1 and June 30, 2019, extending the applicability of the payment rates based on 2017 reporting through December 31, 2022. There can be no assurance that the payment rate for Afirma or Prosigna will not decrease in the future or that the payment rates for Afirma Xpression Atlas, Afirma MTC, Percepta, Decipher Prostate Biopsy, Decipher Prostate RP, Decipher Bladder or Immunoscore will not be adversely affected by the PAMA law and regulations.

Our Envisia classifier was approved by CMS as a New ADLT on September 17, 2020. The initial payment rate (for a period not to exceed nine months) under PAMA for a New ADLT (an ADLT for which payment has not been made under the CLFS prior to January 1, 2018) will be set at the “actual list charge” for the test as reported by the laboratory. Effective July 1, 2021, Envisia is priced based on private payer rates collected and reported annually. We can determine whether to seek ADLT status for our tests, but there can be no assurance that our tests will be designated ADLTs or that the payment rates for our tests, including Envisia, will not be adversely affected by such designation.

There have also been substantial changes to the payment structure for physicians, including those passed as part of the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which was signed into law on April 16, 2015. MACRA created the Merit-Based Incentive Payment System which, beginning in 2019, more closely aligns physician payments with composite performance on performance metrics similar to three existing incentive programs (i.e., the Physician Quality Reporting System, the Value-based modifier program and the Electronic Health Record Meaningful Use program) and incentivizes physicians to enroll in alternative payment methods. At this time, we do not know whether these changes to the physician payment systems will have any impact on orders or payments for our tests.

In December 2016, Congress passed the 21st Century Cures Act, which, among other things, revised the process for LCDs. Additionally, effective June 11, 2017, a MAC is required to, among other things, publish a summary of the evidence that it considered when developing an LCD, including a list of sources, and an explanation of the rationale that supports the MAC’s determinations. In October 2018, CMS issued additional guidance revising the requirements for the development of LCDs. We cannot predict whether these revisions will delay future LCDs and result in impeded coverage for our test products, which could have a material negative impact on revenue.

In December 2020, in its enactment of the CAA, Congress enacted the No Surprises Act. This law, which takes effect January 1, 2022, prohibits an out-of-network provider from billing a patient at an amount in excess of the in-network cost sharing for services furnished with respect to a visit at certain in-network health care facilities. The law establishes an independent dispute resolution process between the provider and the payer to determine the appropriate payment rate to the provider. As written, the No Surprises Act may apply to laboratory tests furnished by an independent laboratory with respect to a hospital visit. The law establishes a notice and consent exception that generally does not apply to laboratory tests, although it allows for the Secretary of the Department of Health and Human Services, or HHS, to apply the exception to certain advanced tests. Details on the applicability of the No Surprises Act, any applicability of the notice and consent exception to advanced tests, and the rules governing the independent dispute resolution process may be determined in rulemaking and subregulatory guidance from HHS, the Department of Labor, and the Department of the Treasury in 2021. The first set of regulations was issued as an Interim Final Rule on July 1, 2021, and the second set was issued as an Interim Final Rule on September 30, 2021. The No Surprises Act, and regulations and subregulatory guidance promulgated thereunder, could limit our ability to achieve payment in full for our testing services.

Because of Medicare billing rules, we may not receive reimbursement for all tests provided to Medicare patients.

Under previous Medicare billing rules, hospitals were required to bill for our tests when performed on Medicare beneficiaries who were hospital outpatients at the time of tissue specimen collection when these tests were ordered less than 14 days following the date of the patient's discharge.

Effective January 1, 2018, CMS revised its billing rules to allow the performing laboratory to bill Medicare directly for molecular pathology tests performed on specimens collected from hospital outpatients, even when those tests are ordered less than 14 days after the date of discharge, if certain conditions are met. We believe that our Afirma, Percepta, Envisia, Decipher Prostate Biopsy, Decipher Prostate RP and Decipher Bladder classifiers, along with Prosigna, should be covered by this policy. Accordingly, we bill Medicare for these tests when we perform them on specimens collected from hospital outpatients and meet the conditions set forth in CMS's revised billing rules.

This change does not apply to tests performed on specimens collected from hospital inpatients. We will continue to bill hospitals for tests performed on specimens collected from hospital inpatients when the test was ordered less than 14 days after the date of discharge.

In the CY 2020 Hospital Outpatient Prospective Payment System Proposed Rule, CMS solicited comments on potential revisions to these billing rules that could have impacted our ability to bill Medicare directly for our Afirma, Percepta, Envisia, Decipher Prostate Biopsy, Decipher Prostate RP and Decipher Bladder classifiers, as well as for Prosigna, when performed on specimens collected from hospital outpatients. Although these changes were not finalized, if CMS makes similar changes in the future, it could negatively impact our business.

In addition, we must maintain CLIA compliance and certification to sell our tests and be eligible to bill for diagnostic services provided to Medicare beneficiaries.

If the FDA or foreign authorities were to begin regulating those of our tests that are not currently regulated, we could incur substantial costs and delays associated with trying to obtain premarket clearance, approval or certification.

Clinical laboratory tests have long been subject to comprehensive regulations under CLIA, as well as by applicable state laws. Most laboratory developed tests, or LDTs, are not currently subject to regulation under the FDA's enforcement discretion policy, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation. While the FDA maintains its authority to regulate LDTs, it has chosen to exercise its enforcement discretion not to enforce the premarket review and other applicable medical device requirements for LDTs. We believe that the Afirma, Percepta, Envisia, Decipher Prostate Biopsy, Decipher Prostate RP, and Decipher Bladder classifiers, as well as Immunoscore, are LDTs that fall under the FDA's enforcement discretion policy. In October 2014, the FDA issued draft guidance, entitled "Framework for Regulatory Oversight of LDTs," proposing a risk-based framework of oversight and a phased-in enforcement of premarket review requirements for most LDTs. In 2016, the FDA announced that it would not be finalizing the guidance.

In January 2017, the FDA issued a "Discussion Paper on Laboratory Developed Tests" following input it received from multiple stakeholders who had commented on its 2014 draft guidance. The FDA specifically states in its Discussion Paper that the proposals contained in the document do not represent a final version of the LDT draft guidance documents and are only designed to provide a possible approach to spark further dialogue. The suggested LDT framework could grandfather many

types of LDTs without requiring new premarket review or quality management requirements but would subject some grandfathered tests to adverse event and malfunction reporting requirements. It also suggests a four-year phased implementation of the premarket review requirements for some types of tests. In a December 2018 statement, the FDA said that there is a need for “a unified approach to the regulation of in vitro clinical tests to protect patient safety, support innovation, and keep pace with the rapidly evolving technology that’s helping us find new treatments for disease.” The FDA listed key principles of an approach it would support.

In March 2017, a draft bill on the regulation of LDTs, entitled "The Diagnostics Accuracy and Innovation Act", or DAIA, was released for discussion. In December 2018, the sponsors of DAIA released a new version of the legislation called the “Verifying Accurate, Leading-edge IVCT Development Act", or VALID Act. The VALID Act proposes a risk-based approach to regulate LDTs and creates a new in vitro clinical test category, which includes LDTs, and a new regulatory structure under the FDA. Similar versions of the VALID Act have since been introduced. The most recent version was released in June 2021. As proposed, the bill would create a precertification program for lower risk tests not otherwise required to go through premarket review. It would grandfather existing tests but would allow the FDA to subject otherwise grandfathered tests to premarket review under certain conditions. Similarly, the Verified Innovative Testing in American Laboratories (VITAL) Act was introduced in December 2020 and re-introduced in May 2021. In contrast with the VALID Act, the VITAL Act would prevent FDA from regulating LDTs and would instead assign regulatory authority over LDTs entirely to CMS. We cannot predict whether either of these or other draft bills governing LDTs will become legislation and cannot quantify the effect of such draft bills on our business.

The HHS issued a public statement on August 9, 2020 purporting to rescind FDA’s policies regarding the premarket review of LDTs. According to the HHS statement, FDA will not require premarket review of LDTs unless it first engages in notice-and-comment rulemaking. Questions remain regarding the scope of the HHS statement’s applicability and whether other FDA regulatory requirements may apply to LDTs. It is also unclear to what extent this remains the policy of HHS since the change in Administration following the U.S. general election in November 2020. There is no guarantee that the HHS policy will not be revised, that legislation reforming the federal government’s regulation of LDTs will not be passed, or that LDTs will otherwise continue to be able to operate without first receiving FDA premarket review. How the HHS policy as well as future legislation by federal and state governments and actions by the FDA will impact the industry remain unclear.

In addition, changes in the way the European Union, or EU, regulates LDTs could result in additional expenses for offering our current and any future tests or possibly delay or suspend development, or commercialization of such tests. In the EU, LDTs are exempt from the regulations that govern medical devices and in vitro diagnostic medical devices under certain conditions. The EU In Vitro Diagnostic Medical Devices Directive (Directive 98/79/EC), or IVDD, currently governs the exemptions applicable to LDTs. However, the EU regulatory landscape is evolving and when the EU Regulation (EU) 2017/746 of April 5, 2017, repealing Directive 98/79/EC and Commission Decision 2010/227/EU, referred to as the IVD Medical Devices Regulation, or IVDR, becomes applicable on May 26, 2022, the general safety and performance requirements set out in Annex I will also be applicable to devices manufactured and used only within health institutions. The exemptions provided under the IVDR for LDTs remain to be further interpreted and clarified. If our tests do not qualify for an exemption, we may be subject to the full application of the IVDR with respect to some or all of our existing, as well as future, tests, and we would be required to expend additional time and resources to complying with the requirements of the IVDR.

If the FDA or foreign authorities were to require us to seek clearance, approval or certification for our existing tests or any of our future products for clinical use, we may not be able to obtain such approvals or certifications on a timely basis, or at all. While we believe our Afirma, Percepta, Envisia, Decipher Prostate Biopsy, Decipher Prostate RP and Decipher Bladder classifiers, as well as Immunoscore, would likely qualify for the “grandfathered” tests treatment, there can be no assurance of what the FDA might ultimately require if it issues a rule. If premarket reviews or certifications are required, our business could be negatively impacted if we are required to stop selling our products pending their clearance, approval or certification. In addition, the launch of any new products that we develop could be delayed by the implementation of future FDA or foreign regulations. The cost of complying with premarket review or certification requirements, including obtaining clinical data, could be significant. In addition, future regulation by the FDA or foreign authorities could subject our business to further regulatory risks and costs. Failure to comply with applicable regulatory requirements of the FDA or foreign authorities could result in enforcement action, including receiving untitled or warning letters, fines, injunctions, or civil or criminal penalties. Any such enforcement action would have a material adverse effect on our business, financial condition and operations. In addition, our sample collection containers are listed as Class I devices with the FDA. If the FDA were to determine that they are not Class I devices, we would be required to file 510(k) applications and obtain FDA clearance to use the containers, which could be time consuming and expensive.

Some of the materials we use for our tests and that we may use for future tests are labeled for research-use only, or RUO, or investigational-use only, or IUO. In November 2013, the FDA finalized guidance regarding the sale and use of products

labeled RUO or IUO. Among other things, the guidance advises that the FDA continues to be concerned about distribution of research or investigational-use only products intended for clinical diagnostic use and that the manufacturer's objective intent for the product's intended use will be determined by examining the totality of circumstances, including advertising, instructions for clinical interpretation, presentations that describe clinical use, and specialized technical support, surrounding the distribution of the product in question. The FDA has advised that if evidence demonstrates that a product is inappropriately labeled for research or investigational-use only, the device would be considered misbranded and adulterated within the meaning of the Federal Food, Drug and Cosmetic Act, or FDC Act. Some of the reagents, instruments, software or components obtained by us from suppliers for use in our products are currently labeled as RUO or IUO. If the FDA were to determine that any of these reagents, instruments, software or components are improperly labeled RUO or IUO and undertake enforcement actions, some of our suppliers might cease selling these reagents, instruments, software or components to us, and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations, including increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents, instruments, software or components necessary to perform testing.

Obtaining marketing authorization or certification by the FDA and foreign regulatory authorities for our diagnostic tests will take significant time and require significant research, development and clinical study expenditures and ultimately may not succeed.

Before we begin to label and market some of our products for use as clinical diagnostics in the United States, unless an exemption applies, we are required to obtain clearance from the FDA by submitting a premarket notification under section 510(k) of the FDC Act or 510(k), or approval from the FDA by submitting a premarket approval, or PMA. We may also be able to obtain marketing authorization through a *De Novo* classification process rather than through a PMA if the 510(k) pathway is not available. In September 2013, Prosigna obtained FDA 510(k) clearance as a prognostic indicator for distant recurrence-free survival at ten years in post-menopausal women with Stage I/II lymph node-negative or Stage II lymph node-positive (1-3 positive nodes), hormone receptor-positive breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors after they have undergone surgery in conjunction with locoregional treatment and consistent with the standard of care.

In August 2014, the FDA issued a final guidance document titled "In Vitro Companion Diagnostic Devices". In the guidance, the FDA defined an IVD companion diagnostic device as an in vitro diagnostic device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. The use of an IVD companion diagnostic device with a therapeutic product is stipulated in the instructions for use in the labeling of both the diagnostic device and the corresponding therapeutic product, including the labeling of any generic equivalents of the therapeutic product. The FDA stated that an IVD companion diagnostic should be submitted for review and approved or cleared through an appropriate device submission contemporaneously with the review and approval of the therapeutic product to facilitate concurrent review. The FDA guidance also stated that while there may be cases when a companion diagnostic could come to market through the 510(k) pathway, the FDA expects that most companion diagnostics will be Class III devices. Class III devices generally require the approval of a PMA before they can be marketed. An IVD diagnostic device that is not a companion diagnostic device because it is not essential for the safe and effective use of a corresponding therapeutic product, may still be beneficial for use with a therapeutic product but may not be identified in the labeling of the therapeutic product. It is possible that revenue from a cleared or approved beneficial or complementary IVD diagnostic device may be less than revenue from a cleared or approved IVD companion diagnostic device.

In July 2016, the FDA issued guidance pertaining to the co-development of companion diagnostic tests with a therapeutic product. The FDA explained that while it supports contemporaneous marketing authorizations, if there are any deficiencies in the submissions, the FDA may place a PMA review of a companion diagnostic on hold or request additional testing, which could potentially delay the approval of the corresponding new drug application or the marketing authorization of the companion diagnostic or otherwise complicate the review process. The FDA issued another draft guidance in December 2018 specific to oncology companion diagnostic tests, which it finalized in April 2020. The guidance explained that some oncology companion diagnostic tests can be developed in a way that results in labeling for a specific group of oncology therapeutic products, rather than a single therapeutic product. However, there is no assurance that we would be able to obtain clearance or approval for any of our diagnostic devices in development as a companion diagnostic device or that any such clearance or approval will occur without significant delay.

Any marketing authorization we obtain for any future device product would be subject to regulatory requirements that would affect how we are able to market and sell the device. The FDC Act and FDA regulations place considerable requirements on our products, including, but not limited to, compliance with the quality system regulations, or QSR, establishment registration and product listing with the FDA, and compliance with labeling, marketing, complaint handling, medical device reporting requirements, and reporting certain corrections and removals. Obtaining FDA clearance or approval for diagnostics

can be expensive and uncertain, generally may take several months to several years, and generally requires detailed and comprehensive scientific and clinical data, as well as compliance with FDA regulations for investigational devices. In addition, we have limited experience in obtaining PMA approval from the FDA and are therefore supplementing our operational capabilities to manage the more complex processes needed to obtain and maintain PMAs. Notwithstanding the expense, these efforts may never result in FDA clearance or approval. Even if we were to obtain marketing authorization, it may not be for the uses we believe are important or commercially attractive, in which case we would not market our product for those uses.

Sales of our diagnostic products outside the United States are subject to foreign regulatory requirements governing clinical studies, vigilance reporting, marketing approval, manufacturing, regulatory inspections, product licensing, pricing and reimbursement. These regulatory requirements vary greatly from country to country. As a result, the time required to obtain approvals or certifications outside the United States may differ from that required to obtain FDA marketing authorization, and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Marketing authorization from the FDA does not ensure approval or certification by regulatory authorities in other countries, and approval or certification by any foreign regulatory authority does not ensure marketing authorization or certifications by regulatory authorities in other countries or by the FDA. Foreign regulatory authorities could require additional testing beyond what the FDA requires. In addition, the FDC Act imposes requirements on the export of medical devices, such as labeling requirements, and foreign governments impose requirements on the import of medical devices from the United States. Failure to comply with these regulatory requirements or to obtain required approvals, clearances, and export certifications could impair our ability to commercialize our diagnostic products outside of the United States.

For instance, in order to sell our products in the EU, our products must comply with the essential requirements of the IVDD. Compliance with these requirements is a prerequisite to be able to affix the European Conformity, or CE, mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the essential requirements laid down in Annex I to the IVDD including the requirement that an in vitro diagnostic medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration of conformity of in vitro diagnostic medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence.

Except for (general) in vitro diagnostic medical devices, where the manufacturer can self-declare the conformity of its products with the essential requirements of the IVDD, a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. The notified body would typically audit and examine the product's technical file and the manufacturer's quality system (notified body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485:2016 for Quality Management Systems – conform to these requirements). If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE Mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to remain in compliance with applicable EU laws and directives, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EU and European Economic Area, or EEA (which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland).

The EU regulatory landscape concerning medical devices is evolving and a new regulation governing in vitro diagnostic medical devices will become applicable on May 26, 2022 the new requirements of which may have a significant effect on the way we conduct our business in the EU and the EEA.

On January 1, 2021 onwards, the Medicines and Healthcare Products Regulatory Agency, or MHRA became the sovereign regulatory authority responsible for the Great Britain (i.e. England, Wales and Scotland) medical device market according to the requirements provided in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) that sought to give effect to the three pre-existing EU directives governing active implantable medical devices, general medical devices and in vitro diagnostic medical devices whereas Northern Ireland continues to be governed by EU rules according to the Northern Ireland Protocol. Following the end of the Brexit transitional period on January 1, 2021, new regulations require medical devices to be registered with the MHRA (but manufacturers will be given a grace period of four to 12 months to comply with

the new registration process) before being placed on Great Britain market. The MHRA will only register devices where the manufacturer or their United Kingdom Responsible Person has a registered place of business in the United Kingdom. Manufacturers based outside the United Kingdom will need to appoint a U.K. Responsible Person that has a registered place of business in the United Kingdom to register devices with the MHRA in line with the grace periods. By July 1, 2023, in Great Britain, all medical devices will require a UK Conformity Assessed, or UKCA, mark but CE marks issued by EU notified bodies will remain valid until this time. Manufacturers may choose to use the UKCA mark on a voluntary basis until June 30, 2023. However, UKCA marking will not be recognized in the EU. The rules for placing medical devices on the market in Northern Ireland, which is part of the United Kingdom, differ from those in the rest of the United Kingdom. Compliance with this legislation is a prerequisite to be able to affix the UKCA mark to our products, without which they cannot be sold or marketed in Great Britain.

Under the terms of the Northern Ireland Protocol, Northern Ireland will follow EU rules on medical devices and devices marketed in Northern Ireland will require assessment according to the EU regulatory regime. Such assessment may be conducted by an EU notified body, in which case a CE mark will be required before placing the device on the market in the EU or Northern Ireland. Alternatively, if a UK notified body conducts such assessment, a 'UKNI' mark will be applied and the device may only be placed on the market in Northern Ireland and not the EU.

If we are unable to obtain marketing authorizations or certifications, approvals, clearances or certifications to market Prosigna or our other assays on the nCounter Analysis System in additional countries or if regulatory limitations are placed on our diagnostic kit products, our business and growth will be harmed.

The FDA cleared the Prosigna test for marketing in the United States. Prosigna is CE marked which permits us to market the test in the EU and Prosigna received marketing authorizations in selected other jurisdictions. We intend to seek regulatory authorizations or certifications for Prosigna in other jurisdictions and, potentially, for other indications.

On April 5, 2017, the IVDR, was adopted to establish a modernized and more robust EU legislative framework, with the aim of ensuring better protection of public health and patient safety. Unlike directives, the IVDR does not need to be transposed into national law and therefore reduces the risk of discrepancies in interpretation across the different European markets. The IVDR increases the regulatory requirements applicable to in vitro diagnostics in the EU and would require that we re-classify and obtain new certificates of conformity for our existing CE-marked IVD products by May 25, 2022 unless a transitional provision applies to our current certificates.

The EU-UK Trade and Cooperation Agreement, or TCA, came into effect on January 1, 2021. The TCA does not specifically refer to medical devices. However, as a result of Brexit, the EU Medical Devices Regulation will not be implemented in the UK, and previous legislation that mirrored the EU Medical Devices Regulation in the UK law has been revoked. The regulatory regime for medical devices in Great Britain (England, Scotland and Wales) will continue to be based on the requirements derived from current EU legislation, and the UK may choose to retain regulatory flexibility or align with the EU Medical Devices Regulation going forward. CE markings will continue to be recognized in the UK, and certificates issued by EU-recognized notified bodies will be valid in the UK, until June 30, 2023. For medical devices placed on the market in Great Britain after this period, the UKCA, marking will be mandatory. In contrast, UKCA marking and certificates issued by UK notified bodies will not be recognized on the EU market. The TCA does provide for cooperation and exchange of information in the area of product safety and compliance, including market surveillance, enforcement activities and measures, standardization related activities, exchanges of officials, and coordinated product recalls (or other similar actions). For medical devices that are locally manufactured but use components from other countries, the "rules of origin" criteria will need to be reviewed. Depending on in which countries products will ultimately be sold, manufacturers may start seeking alternative sources for components if this would allow them to benefit from no tariffs. The rules for placing medical devices on the Northern Ireland market will differ from those in Great Britain. These modifications may have an effect on the way we intend to conduct our business in these countries.

In addition, pursuant to our collaborations with pharmaceutical companies for the development of companion diagnostic tests for use with their drugs, we are responsible for obtaining regulatory authorizations or certifications to use the companion diagnostic tests in clinical trials as well as the marketing authorizations or certifications to sell the companion diagnostic tests following completion of such trials. Some of the compensation we expect to receive pursuant to these collaborations is based on the receipt of marketing authorizations or certifications. Any failure to obtain marketing authorizations or certifications for our diagnostic kits in a particular jurisdiction may also reduce sales of the nCounter Analysis System for clinical use in that jurisdiction, as the lack of a robust menu of available diagnostic tests would make those systems less attractive to testing laboratories.

In the EU, there is currently no legal definition or classification system for companion diagnostics. Companion diagnostics are deemed to be in vitro diagnostic medical devices, governed by the IVDD, and are required to conform with the essential requirements of the IVDD. The conformity assessment varies according to the type of in vitro diagnostic medical device. As there is currently no classification system for companion diagnostics, the conformity assessment will vary depending on the companion diagnostics' characteristics and they will be either subject to a conformity assessment by a notified body or to a self-assessment by the manufacturer (without the intervention of a notified body).The regulation of companion diagnostics will be subject to further requirements once the IVDR will become applicable on May 26, 2022. The IVDR introduces a new classification system for companion diagnostics which are now specifically defined as diagnostic tests that support the safe and effective use of a specific medicinal product, by identifying patients that are suitable or unsuitable for treatment. Companion diagnostics will have to undergo a conformity assessment by a notified body. Before it can issue a certificate of conformity, the notified body will have to seek a scientific opinion from the European Medicines Agency on the suitability of the companion diagnostic to the medicinal product concerned if the medicinal product falls exclusively within the scope of the centralized procedure for the authorization of medicines, the medicinal product is already authorized through the centralized procedure, or a marketing authorization application for the medicinal product has been submitted through the centralized procedure. For other substances, the notified body can seek the opinion from a national competent authority or the European Medicines Agency.

We cannot assure investors that we will be successful in obtaining or maintaining regulatory clearances, certifications, approvals, or marketing authorizations. If we do not obtain or maintain regulatory clearances, certifications, approvals, or marketing authorizations for future diagnostic kit products or expand future indications for diagnostic purposes, if additional regulatory limitations are placed on our diagnostic kit products or if we fail to successfully commercialize such products, the market potential for our diagnostic kit products would be constrained, and our business and growth prospects would be adversely affected.

We are subject to ongoing and extensive regulatory requirements, and our failure to comply with these requirements could substantially harm our business.

Certain of our products are regulated as in vitro diagnostic medical devices, including Prosigna and the nCounter Analysis System. Accordingly, we and certain of our contract manufacturers are subject to ongoing International Organization for Standardization, or ISO, obligations as well as requirements under the FDC Act and device regulations enforced by the FDA and other statutory and regulatory requirements enforced by other government authorities. These may include routine inspections by notified bodies, FDA, and other health authorities, of our manufacturing facilities and our records for compliance with standards such as ISO 13485 and QSR regulations, which establish extensive requirements for quality assurance and control as well as manufacturing and change control procedures, among other things. These inspections may include the manufacturing facilities of any suppliers. In the event that a supplier fails to maintain compliance with regulatory or our quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result. We are also subject to other regulatory obligations, such as registration of our company offices and facilities and the listing of our devices with the FDA; continued adverse event and malfunction reporting; reporting certain corrections and removals; and labeling and promotional requirements.

Other regulatory bodies may also issue guidelines and regulations that could impact the development of our products, including companion diagnostic tests. For example, the European Medicines Agency, the EU agency which is responsible for the scientific evaluation of medicines centrally approved in the EU, recently launched an initiative to determine guidelines for the use of genomic biomarkers in the development and lifecycle of drugs. The guidelines may impose greater requirements for demonstrating the clinical validity and utility of our biomarker-based tests and may interfere with our ability to develop companion diagnostics or otherwise obtain or maintain marketing authorization or certifications for our diagnostic tests.

The IVDR increases the regulatory requirements applicable to in vitro diagnostics in the EU and would require that we re-classify and obtain new certificates of conformity for our existing CE-marked IVD products by May 25, 2022 unless a transitional provision applies to our current certificates.

The IVDR will become applicable five years after publication (on May 26, 2022) and once applicable, the IVDR will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- establish explicit provisions on importers' and distributors' obligations and responsibilities;

- impose an obligation to identify a responsible person who is ultimately responsible for all aspects of compliance with the requirements of the new regulation;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through the introduction of a unique identification number, to increase the ability of manufacturers and regulatory authorities to trace specific devices through the supply chain and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk;
- set up a central database (Eudamed) to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices that may have to undergo an additional check by experts before they are placed on the market.

Due to a severe shortage of capacity of the European notified bodies designated for IVDR certification to assess all IVD devices that will require notified body certification under IVDR, it is widely recognized that not all applications for assessment will be approved before the deadline. Failure to secure these re-certifications in time will halt our ability to commercialize our products in relevant countries. Currently our tests that require recertification are Prosigna and Immunoscore. Moreover, complying with the stricter regulatory requirements of the IVDR, including with respect to clinical evaluation requirements, quality systems, and post-market surveillance, may require us to incur significant expenditures. Failure to meet these requirements could adversely impact our business in the EU and EEA and other regions that tie their product registrations or regulations to the EU requirements.

The TCA does not specifically refer to medical devices. However, as a result of Brexit, the EU Medical Devices Regulation will not be implemented in the UK, and previous legislation that mirrored the EU Medical Devices Regulation in the UK law has been revoked. The regulatory regime for medical devices in Great Britain (England, Scotland and Wales) will continue to be based on the requirements derived from current EU legislation, and the UK may choose to retain regulatory flexibility or align with the EU Medical Devices Regulation going forward. CE markings will continue to be recognized in the UK, and certificates issued by EU-recognized notified bodies will be valid in the UK, until June 30, 2023. For medical devices placed on the market in Great Britain after this period, the UKCA, marking will be mandatory. In contrast, UKCA marking and certificates issued by UK notified bodies will not be recognized on the EU market. The TCA does provide for cooperation and exchange of information in the area of product safety and compliance, including market surveillance, enforcement activities and measures, standardization related activities, exchanges of officials, and coordinated product recalls (or other similar actions). For medical devices that are locally manufactured but use components from other countries, the “rules of origin” criteria will need to be reviewed. Depending on in which countries products will ultimately be sold, manufacturers may start seeking alternative sources for components if this would allow them to benefit from no tariffs. The rules for placing medical devices on the Northern Ireland market will differ from those in Great Britain. These modifications may have an effect on the way we intend to conduct our business in these countries.

We may also be subject to additional FDA or foreign regulatory authority post-marketing obligations or requirements by the FDA or foreign regulatory authority to change our current product classifications which would impose additional regulatory obligations on us. The promotional claims we can make for Prosigna are limited to the indications for use in the United States as cleared by the FDA or outside the United States as authorized or certified by the applicable regulatory authority. If we are not able to maintain regulatory compliance, we may not be permitted to market our medical device products and/or may be subject to enforcement actions by the FDA or other governmental authorities such as the issuance of warning or untitled letters, fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions; and criminal prosecution. In addition, we may be subject to similar regulatory regimes of foreign jurisdictions as we continue to commercialize our products in new markets outside of the United States and Europe. Adverse notified body, EU Competent Authority or FDA or global regulatory authority action in any of these areas could significantly increase our expenses and limit our revenue and profitability.

If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability.

Our principal competition for our tests comes from traditional methods used by physicians to diagnose and manage patient care decisions. For example, with our Afirma genomic classifier, practice guidelines in the United States have historically recommended that patients with indeterminate diagnoses from cytopathology results be considered for surgery to remove all or part of the thyroid to rule out cancer. This practice has been the standard of care in the United States for many years, and we need to continue to educate physicians about the benefits of the Afirma genomic classifier to change clinical practice.

We also face competition from companies and academic institutions that use next generation sequencing technology or other methods to measure mutational markers such as BRAF and KRAS, along with numerous other mutations. These organizations include Interpace Diagnostics Group, Inc., CBLPath, Inc./University of Pittsburgh Medical Center and others

who are developing new products or technologies that may compete with our tests. In the future, we may also face competition from companies developing new products or technologies.

We believe our primary competition in pulmonology with our Percepta and Envisia classifiers will similarly come from traditional methods used by physicians to diagnose the related diseases. For the Percepta test, we expect competition from companies focused on lung cancer such as Biodesix, Inc. We believe our principal competitor in the breast cancer diagnostics market is Exact Sciences, Inc., which currently commands a substantial majority of the market. Other competitors in the breast cancer diagnostics market include Myriad Genetics, Inc. and Agendia, Inc. As we expand our portfolio of tests to address clinical questions across the clinical care continuum, we may also face competition from companies focused on screening at-risk patients for cancer or companies informing treatment decisions such as Guardant Health or Foundation Medicine, Inc. Competition could also emerge from competitors, including GRAIL, Inc. (which was acquired by our supplier Illumina Inc. in August 2021), using alternative samples, such as blood, urine or sputum. However, such "liquid biopsies" are currently being used to gauge risk of recurrence or response to treatment in patients already diagnosed with lung cancer.

In general, we also face competition from commercial laboratories, such as Laboratory Corporation of America Holdings and Sonic Healthcare USA, with strong infrastructure to support the commercialization of diagnostic services. We face potential competition from companies such as Illumina, Inc. and Thermo Fisher Scientific Inc., both of which have entered the clinical diagnostics market. Other potential competitors include companies that develop diagnostic products, such as Roche Diagnostics, a division of Roche Holding Ltd, Siemens AG and Qiagen N.V.

In addition, competitors may develop their own versions of our solutions in countries we may seek to enter where we do not have patents or where our intellectual property rights are not recognized and compete with us in those countries, including encouraging the use of their solutions by physicians in other countries.

To compete successfully, we must be able to demonstrate, among other things, that our diagnostic test results are accurate and cost effective, and we must secure a meaningful level of reimbursement for our products.

Many of our potential competitors have widespread brand recognition and substantially greater financial, technical and research and development resources, and selling and marketing capabilities than we do. Others may develop products with prices lower than ours that could be viewed by physicians and payers as functionally equivalent to our solutions, or offer solutions at prices designed to promote market penetration, which could force us to lower the list price of our solutions and affect our ability to achieve profitability. If we are unable to change clinical practice in a meaningful way or compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our products, which could prevent us from increasing our revenue or achieving profitability and could cause the market price of our common stock to decline. As we add new tests and services, we will face many of these same competitive risks for these new tests.

We have experienced significant changes in our senior management team, the loss of one or more of our executive officers, or any inability to attract and retain highly-skilled employees and other key personnel could adversely affect our business.

Our success depends in part on the skills, experience and performance of key members of our executive management team and others in key management positions. We have in the past and may in the future experience changes in our executive management, which may be disruptive to our business. For example, effective June 1, 2021, Marc Stapley assumed the role of Chief Executive Officer and Bonnie H. Anderson, our former Chairman and Chief Executive Officer, transitioned to the role of Executive Chair. In addition, effective July 19, 2021, Rebecca Chambers assumed the role of Chief Financial Officer, following the service of Jane Alley as Acting Chief Financial Officer since May 15, 2021. Executive transitions may impact our ability to implement our business strategy and could have a material adverse effect on our business. Although we believe our new executive management team will bring significant added strength and valuable experience to our company, the potential benefits of hiring new executives may not be immediately realized.

In addition, our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses. Our success in the development and commercialization of advanced diagnostics requires a significant medical and clinical staff to conduct studies and educate physicians and payers on the merits of our tests in order to achieve adoption and reimbursement. We are in a highly competitive industry to attract and retain this talent. Additionally, our success depends on our ability to attract and retain qualified sales-people. We recently significantly expanded our sales force as we invest in our multi-product sales strategy, which includes assignment of a single contact to successfully develop and implement relationships with our customers. There can be no assurance that we will be successful in maintaining and growing our business. Additionally, as we increase our sales channels

for new tests we commercialize, including the Percepta, Envisia, Decipher Prostate, Decipher Bladder and Immunoscore tests, as well as Prosigna, we may have difficulties recruiting and training additional sales personnel or retaining qualified sales-people, which could cause a delay or decline in the rate of adoption of our tests. Finally, our business requires specialized capabilities in reimbursement, billing, and other areas and there may be a shortage of qualified individuals. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to support our research and development, clinical laboratory, sales and reimbursement, billing and finance efforts. All of our employees are at will, which means that either we or the employee may terminate their employment at any time. We do not carry key man insurance for any of our employees.

Billing for our diagnostic tests is complex, and we must dedicate substantial time and resources to the billing process to be paid.

Billing for clinical laboratory testing services is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payers, including Medicare, insurance companies and patients, all of which have different billing requirements. We generally bill third-party payers for our diagnostic tests and pursue reimbursement on a case-by-case basis where pricing contracts are not in place. To the extent laws or contracts require us to bill patient co-payments or co-insurance, we must also comply with these requirements. We may also face increased risk in our collection efforts, including potential write-offs of accounts receivable and long collection cycles, which could adversely affect our business, results of operations and financial condition.

Several factors make the billing process complex, including:

- differences between the list price for our tests and the reimbursement rates of payers;
- compliance with complex federal and state regulations related to billing government payers, such as Medicare and Medicaid, including requirements to have an active CLIA certificate;
- risk of government audits related to billing Medicare and other government payers;
- disputes among payers as to which party is responsible for payment;
- differences in coverage and in information and billing requirements among payers, including the need for prior authorization and/or advanced notification;
- the effect of patient co-payments or co-insurance;
- changes to billing codes used for our tests;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

We use standard industry billing codes, known as CPT codes, to bill for cytopathology. Through December 31, 2020, we used the CPT code 81545 to bill for our Afirma classifier. Effective January 1, 2021, we will use the new CPT code 81546 to bill for our Afirma classifier, and code 81545 is being retired. Effective October 1, 2020, we are using the new CPT code 0204U to bill for Afirma Xpression Atlas, and the new CPT code 0208U to bill for Afirma MTC. Effective January 1, 2021, we are using the new CPT code 81554 to bill for our Envisia classifier. Effective January 1, 2020, we are using the new CPT code 81542 to bill for Decipher Prostate Biopsy and Decipher Prostate RP tests. Effective October 1, 2020, we are using the new CPT code 0016M to bill for our Decipher Bladder test. Effective October 1, 2021, we are using the new CPT code 0261U to bill for the Immunoscore test. There is no CPT code for our Percepta classifier. Therefore, until such time that we are assigned and are able to use a designated CPT code specific to Percepta, we use “unlisted” codes for claim submissions, which can lead to delays in payers adjudicating our claims or denying payment altogether.

CPT codes can change over time. When codes change, there is a risk of an error being made in the claim adjudication process. These errors can occur with claims submission, third-party transmission or in the processing of the claim by the payer. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment received. Coding changes, therefore, may have an adverse effect on our revenues. Even when we receive a designated CPT code specific to our tests, there can be no assurance that payers will recognize these codes in a timely manner or that the process of

transitioning to such a code and updating their billing systems and ours will not result in errors, delays in payments and a related increase in accounts receivable balances.

As we introduce new tests, we will need to add new codes to our billing process as well as our financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect our collection rates, revenue and cost of collecting.

Correct coding is subject to the coding policies of the American Medical Association CPT Editorial Panel, or AMA CPT. With respect to claims submitted to Medicare and Medicaid, it is also subject to coding policies developed through the National Correct Coding Initiative, or NCCI. Other payers may develop their own payer-specific coding policies. The broader coding policies of the AMA CPT, NCCI, and other payers are subject to change. For instance, the NCCI adopted an update to its Coding Policy Manual effective January 1, 2019, to limit instances when multiple codes may be billed for molecular pathology testing. Although the NCCI appears to have moderated this change in its updates effective January 1, 2020, such coding policy changes may negatively affect our revenues and cash flow.

Additionally, our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, challenge coverage and payment denials, assist patients in appealing claims, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Payers also conduct external audits to evaluate payments, which adds further complexity to the billing process. If the payer makes an overpayment determination, there is a risk that we may be required to return some portion of prior payments we have received. Additionally, the ACA established a requirement for providers and suppliers to report and return any overpayments received from government payers under the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws. These billing complexities, and the related uncertainty in obtaining payment for our tests, could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

We rely on a third-party provider to transmit claims to payers, and any delay in transmitting claims could have an adverse effect on our revenue.

While we manage the overall processing of claims, we rely on a third-party provider to transmit the actual claims to payers based on the specific payer billing format. We have previously experienced delays in claims processing when our third-party provider made changes to its invoicing system, and again when it did not submit claims to payers within the timeframe we require. Additionally, coding for diagnostic tests may change, and such changes may cause short-term billing errors that may take significant time to resolve. If claims are not submitted to payers on a timely basis or are erroneously submitted, or if we are required to switch to a different provider to handle claim submissions, we may experience delays in our ability to process these claims and receipt of payments from payers, or possibly denial of claims for lack of timely submission, which would have an adverse effect on our revenue and our business.

If our internal sales force is less successful than anticipated, our business expansion plans could suffer and our ability to generate revenues could be diminished. In addition, we have limited history selling our molecular diagnostics tests on a direct basis and our limited history makes forecasting difficult.

If our internal sales force is not successful or new additions to our sales team fail to gain traction among our customers, we may not be able to increase market awareness and sales of our molecular diagnostic tests. If we fail to establish our molecular diagnostic tests in the marketplace, it could have a negative effect on our ability to sell subsequent molecular diagnostic tests and hinder the desired expansion of our business. We have growing, however limited, historical experience forecasting the direct sales of our molecular diagnostics products. Our ability to produce test volumes that meet customer demand is dependent upon our ability to forecast accurately and plan production capacities accordingly.

Developing new products involves a lengthy and complex process, and if we do not achieve our projected development and commercialization goals in the time frames we announce and expect, our business will suffer and our stock price may decline.

From time to time, we expect to estimate and publicly announce the anticipated timing of the accomplishment of various clinical and other product development goals. The actual timing of accomplishment of these targets could vary dramatically compared to our estimates, in some cases for reasons beyond our control, including the impact of the COVID-19 pandemic. We cannot be certain that we will meet our projected targets and if we do not meet these targets as publicly announced, the commercialization of our diagnostic solutions may be delayed or may not occur at all and, as a result, our business will suffer and our stock price may decline.

We continually seek to develop enhancements to our current test offerings and additional diagnostic solutions that requires us to devote considerable resources to research and development. There can be no assurance that we will be able to identify other diseases that can be effectively addressed with our molecular cytology platform. In addition, if we identify such diseases, we may not be able to develop products with the diagnostic accuracy necessary to be clinically useful and commercially successful. We may face challenges obtaining sufficient numbers of samples to validate a genomic signature for a molecular diagnostic product. After launching new products, we still must complete studies that meet the clinical evidence required to obtain reimbursement. Moreover, we may experience delays in the development and introduction of new products due to the effects of the current COVID-19 outbreak.

In order to develop and commercialize diagnostic tests, we need to:

- expend significant funds to conduct substantial research and development;
- conduct successful analytical and clinical studies;
- scale our laboratory processes to accommodate new tests; and
- build the commercial infrastructure to market and sell new products.

Our product development process involves a high degree of risk and may take several years. Our product development efforts may fail for many reasons, including:

- failure to identify a genomic signature in biomarker discovery;
- inability to secure sufficient numbers of samples at an acceptable cost and on an acceptable timeframe to conduct analytical and clinical studies; or
- failure of clinical validation studies to support the effectiveness of the test.

Typically, few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical studies, which would adversely affect the timing for generating potential revenue from a new product and our ability to invest in other products in our pipeline. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study or if we fail to sufficiently demonstrate analytical validity, we might choose to abandon the development of the product, which could harm our business. In addition, competitors may develop and commercialize competing products or technologies faster than us or at a lower cost.

If we cannot enter into new clinical study collaborations, our product development and subsequent commercialization could be delayed.

In the past, we have entered into clinical study collaborations, and our success in the future depends in part on our ability to enter into additional collaborations with highly regarded institutions. This can be difficult due to internal and external constraints placed on these organizations. Some organizations may limit the number of collaborations they have with any one company so as to not be perceived as biased or conflicted. Organizations may also have insufficient administrative and related infrastructure to enable collaboration with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration. Moreover, it may take longer to obtain the samples we need which could delay our trials, publications, and product launches and reimbursement. Additionally, organizations often insist on retaining the rights to publish the clinical data resulting from the collaboration. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for our diagnostic tests, and our inability to control when and if results are published may delay or limit our ability to derive sufficient revenue from them.

If we are unable to develop products to keep pace with rapid technological, medical and scientific change, our operating results and competitive position could be harmed.

In recent years, there have been numerous advances in technologies relating to diagnostics, particularly diagnostics that are based on genomic information. These advances require us to continuously develop our technology and to work to develop new solutions to keep pace with evolving standards of care. Our solutions could become obsolete unless we continually innovate and expand our product offerings to include new clinical applications. If we are unable to develop new products or to demonstrate the applicability of our products for other diseases, our sales could decline and our competitive position could be harmed.

Our Loan and Security Agreement provides our lenders with a first-priority lien against substantially all of our assets, excluding our intellectual property, and contains financial covenants and other restrictions on our actions, which could limit our operational flexibility and otherwise adversely affect our financial condition.

Our Loan and Security Agreement restricts our ability to, among other things, incur liens, make investments, incur indebtedness, merge with or acquire other entities, dispose of assets, make dividends or other distributions to holders of its equity interests, engage in any new line of business, or enter into certain transactions with affiliates, in each case subject to certain exceptions. It also requires us to achieve certain revenue levels tested quarterly on a trailing twelve-month basis. However, failure to maintain the revenue levels will not be considered a default if the sum of our unrestricted cash and cash equivalents maintained with Silicon Valley Bank and amount available under the Revolving Line of Credit is at least $40.0 million. Our ability to comply with these and other covenants is dependent upon a number of factors, some of which are beyond our control.

Our failure to comply with the financial covenants, or the occurrence of other events specified in our Loan and Security Agreement, could result in an event of default under the Loan and Security Agreement, which would give our lenders the right to terminate their commitments to provide additional loans under the Loan and Security Agreement and to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. In addition, we have granted our lenders a first-priority lien against all of our assets, excluding our intellectual property, as collateral. Failure to comply with the covenants or other restrictions in the Loan and Security Agreement could result in a default. If the debt under our Loan and Security Agreement was to be accelerated, we may not have sufficient cash on hand or be able to sell sufficient collateral to repay it, which would have an immediate adverse effect on our business and operating results. This could potentially cause us to cease operations and result in a complete loss of your investment in our common stock.

Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Our operations are subject to other extensive federal, state, local, and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among others:

- the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions, and amendments made in 2013 to HIPAA under the Health Information Technology for Economic and Clinical Health Act, or HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general, and impose requirements for breach notification;

- Medicare billing and payment regulations applicable to clinical laboratories, including requirements to have an active CLIA certificate;

- the Federal Anti-kickback Statute (and state equivalents), which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal healthcare program;

- the Eliminating Kickbacks in Recovery Act of 2018, which prohibits the solicitation, receipt, payment or offering of any remuneration in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory for services covered by both government and private payers;

- the Federal Stark physician self-referral law (and state equivalents), which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, unless the financial relationship falls within an applicable exception to the prohibition;

- the Federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state health care program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;

- the Federal False Claims Act, which imposes liability on any person or entity who knowingly presents, or causes to be presented, a false, fictitious, or fraudulent claim for payment to the federal government;

- the Physician Payments Sunshine Act, enacted as part of the ACA, which imposes annual reporting requirements on manufacturers of certain devices, drugs and biologics for certain payments and transfers of value by them and in some cases their distributors to physicians, as defined by such law, and teaching hospitals;

- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, prohibitions on the provision of products at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payer, including private insurers;

- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;

- the Protecting Access to Medicare Act of 2014, which requires us to report private payer rates and test volumes for specific CPT codes on a triennial basis and imposes penalties for failures to report, omissions, or misrepresentations;

- the No Surprises Act and its implementing regulations (effective January 1, 2022), which prohibit an out-of-network provider from billing a patient at an amount in excess of the in-network cost sharing for services furnished with respect to a visit at certain in-network health care facilities, as well as various state laws restricting balance billing of patients;

- the rules regarding billing for diagnostic tests reimbursable by the Medicare program, which prohibit a physician or other supplier from marking up the price of the technical component or professional component of a diagnostic test ordered by the physician or other supplier and supervised or performed by a physician who does not “share a practice” with the billing physician or supplier;

- state laws that prohibit other specified practices related to billing such as billing physicians for testing that they order, waiving co-insurance, co-payments, deductibles, and other amounts owed by patients, and billing a state Medicaid program at a price that is higher than what is charged to other payers;

- the Foreign Corrupt Practices Act of 1977, and other similar laws, which apply to our international activities;

- unclaimed property (escheat) laws and regulations, which may require us to turn over to governmental authorities the property of others held by us that has been unclaimed for a specified period of time;

- enforcing our intellectual property rights; and

- foreign laws and regulations equivalent to the above.

We have adopted policies and procedures designed to comply with applicable laws and regulations. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance with some of these laws and regulations is also subject to governmental review. The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. We believe that we are in material compliance with all statutory and regulatory requirements, but there is a risk that one or more government agencies could take a contrary position.

In recent years U.S. Attorneys’ Offices have increased scrutiny of the healthcare industry, as have Congress, the Department of Justice, the Department of Health and Human Services’ Office of the Inspector General and the Department of Defense. These bodies have all issued subpoenas and other requests for information to conduct investigations of, and commenced civil and criminal litigation against, healthcare companies based on financial arrangements with health care providers, regulatory compliance, product promotional practices and documentation, and coding and billing practices. Whistleblowers have filed numerous qui tam lawsuits against healthcare companies under the federal and state False Claims Acts in recent years, in part because the whistleblower can receive a portion of the government’s recovery under such suits.

Many member states in the EU have adopted specific anti-gift statutes that further limit commercial practices for medical devices (including in vitro diagnostic medical devices), in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities. In addition, many EU member states have adopted national “Sunshine Acts” which impose reporting

and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers.

These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. If one or more such agencies alleges that we may be in violation of any of these requirements, regardless of the outcome, it could damage our reputation and adversely affect important business relationships with third parties, including managed care organizations and other commercial third-party payers. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

If we use hazardous materials in a manner that causes contamination or injury, we could be liable for resulting damages.

We are subject to federal, state and local laws, rules and regulations governing the use, discharge, storage, handling and disposal of biological material, chemicals and waste. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, remediation costs and any related penalties or fines, and any liability could exceed our resources or any applicable insurance coverage we may have. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could negatively affect our operating results.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our business strategy includes international expansion in select countries, and may include developing and maintaining physician outreach and education capabilities outside of the United States, establishing agreements with laboratories, and expanding our relationships with international payers. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain regulatory approvals or certifications where required for the use of our solutions in various countries;
- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- logistics and regulations associated with shipping tissue samples, including infrastructure conditions and transportation delays;
- challenges associated with establishing laboratory partners, including proper sample collection techniques, management of supplies, sample logistics, billing and promotional activities;
- limits on our ability to penetrate international markets if we are not able to process tests locally;
- financial risks, such as longer payment cycles, difficulty in collecting from payers, the effect of local and regional financial crises, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, including COVID-19, boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the Foreign Corrupt Practices Act of 1977, including both its books and records provisions and its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations.

Our reliance on distributors for sales of our products outside of the United States, and on clinical laboratories for delivery of Prosigna testing services, could limit or prevent us from selling our products and impact our revenue.

We have established distribution agreements for the nCounter Analysis System for diagnostic use and related diagnostic kit products in certain countries where we do not sell directly. We intend to continue to grow our business internationally, and to do so we must attract additional distributors and retain existing distributors to maximize the commercial opportunity for our products. There is no guarantee that we will be successful in attracting or retaining desirable sales and distribution partners or that we will be able to enter into such arrangements on favorable terms. Distributors may not commit the necessary resources to market and sell our products to the level of our expectations or may choose to favor marketing the products of our competitors. If current or future distributors do not perform adequately, or we are unable to enter into effective arrangements with distributors in particular geographic areas, we may not realize long-term international revenue growth.

Similarly, we or our distributors have entered into agreements with clinical laboratories globally to provide Prosigna testing services. We do not provide testing services directly and, thus, we are reliant on these clinical laboratories to actively promote and sell Prosigna testing services. These clinical laboratories may take longer than anticipated to begin offering Prosigna testing services and may not commit the necessary resources to market and sell Prosigna testing services to the level of our expectations. Furthermore, we intend to contract with additional clinical laboratories to offer Prosigna testing services, including physician-owned laboratories, and we may be unsuccessful in attracting and contracting with new clinical laboratory providers. If current or future Prosigna testing service providers do not perform adequately, or we are unable to enter into contracts with additional clinical laboratories to provide Prosigna testing services, we may not be successful selling Prosigna and our future revenue prospects may be adversely affected.

If we are sued for product liability or errors and omissions liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our current or future tests could lead to product liability claims if someone were to allege that the tests failed to perform as they were designed. We may also be subject to liability for errors in the results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. Our Afirma classifiers are performed on FNA samples that are diagnosed as indeterminate by standard cytopathology review. We report results as benign or suspicious to the prescribing physician. Under certain circumstances, we might report a result as benign that later proves to have been malignant. This could be the result of the physician having poor nodule sampling in collecting the FNA, performing the FNA on a different nodule than the one that is malignant or failure of the classifier to perform as intended. We may also be subject to similar types of claims related to our Percepta, Envisia, Prosigna, Decipher urology tests and Immunoscore, as well as tests we may develop or acquire in the future. A product liability or errors and omissions liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we maintain product liability and errors and omissions insurance, we cannot assure you that our insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or errors and omissions liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation or cause us to suspend sales of our products and solutions. The occurrence of any of these events could have an adverse effect on our business and results of operations.

Our business is subject to the risk of disruptions caused by pandemics, political events, war, terrorism, earthquakes, fire, power outages, floods, and other catastrophic events.

War, terrorism, geopolitical uncertainties, trade restrictions, public health issues, natural disasters and other catastrophic events may cause damage or disruption to the economy and commerce on a global, regional or country-specific basis, and could disrupt supply or delivery of, or demand for, our products. For example, the COVID-19 outbreak has had, and we expect will continue to have, a negative effect on consumer confidence and spending, and other impacts, which could adversely affect our business.

If a catastrophe strikes any of our laboratories or if any of our laboratories becomes inoperable for any other reason, we will be unable to perform our testing services and our business will be harmed.

We perform all of the Afirma, Percepta and Envisia genomic classifier testing at our laboratory in South San Francisco, California, near major earthquake faults known for seismic activity and in a region affected by wildfires. We perform our urology tests in our laboratory in San Diego, California. Our laboratory in Austin, Texas accepts and stores the majority of our Afirma FNA samples pending transfer to our California laboratory for genomic test processing. The laboratories and equipment

we use to perform our tests would be costly to replace and could require substantial lead time to replace and qualify for use if they became inoperable. Either of our facilities may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our testing services for some period of time or to receive and store samples. The inability to perform our tests for even a short period of time may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we maintain insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new solutions and technologies and expand our operations.

We expect continued capital expenditures and operating losses over the next few years as we expand our infrastructure, commercial operations and research and development activities. We may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. Our Loan and Security Agreement imposes restrictions on our operations, increases our fixed payment obligations, and has restrictive covenants. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third-party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. The trading prices for our common stock and other biotechnology companies have been highly volatile as a result of the COVID-19 pandemic, which may reduce our ability to access capital on favorable terms or at all. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our products or development programs, which could lower the economic value of those programs to our company.

Security breaches, loss of data and other disruptions to us or our third-party service providers could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we and our third-party service providers collect and store sensitive data, including legally protected health information, personally identifiable information about our patients, credit card information, intellectual property, and our proprietary business and financial information. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. We face a number of risks related to our protection of, and our service providers' protection of, this critical information, including loss of access, inappropriate disclosure and inappropriate access, as well as risks associated with our ability to identify and audit such events. System failures or outages, including any potential disruptions due to significantly increased global demand on certain cloud based systems during the COVID-19 pandemic, could compromise our ability to perform these functions in a timely manner, which could harm our ability to conduct business or delay our financial reporting. Such failures could materially adversely affect our operating results and financial condition.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. While we are not aware of any such attack or breach, if such event would occur and cause interruptions in our operations, our networks would be compromised and the information we store on those networks could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under federal, state, and international laws that protect the privacy of personal information, such as HIPAA and the EU General Data Protection Regulation, or GDPR, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to process tests, provide test results, bill payers or patients, process claims and appeals,

provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

In addition, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Certain health-related and data protection requirements have been modified during the Public Health Emergency, or PHE, under section 319 of the Public Health Service Act first declared January 31, 2020, which was most recently extended effective July 20, 2021. We cannot predict when the PHE declaration will be lifted. In addition, we are subject to various state laws, including the California Consumer Privacy Act, or CCPA, which was enacted in California in 2018 and components of which went into effect on January 1, 2020. The CCPA, among other things, requires covered companies to provide disclosures to California consumers concerning the collection and sale of personal information, and gives such consumers the right to opt-out of certain sales of personal information. Amendments to the CCPA have been made since its enactment, and it remains unclear what, if any, further amendments will be made to this legislation or how it will be interpreted. We cannot yet predict the impact of the CCPA on our business or operations, but it may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

Risks associated with data privacy issues, including evolving laws, regulations and associated compliance efforts, may adversely impact our business and financial results.

Legislation in various countries around the world with regard to cybersecurity, privacy and data protection is rapidly expanding and creating a complex compliance environment. We are subject to many federal, state, and foreign laws and regulations, including those related to privacy, rights of publicity, data protection, content regulation, intellectual property, health and safety, competition, protection of minors, consumer protection, employment, and taxation.

Recent developments in Europe have created compliance uncertainty regarding the processing of personal data from Europe. For example, the GDPR, which became effective in the EU on May 25, 2018, applies to our activities conducted from an establishment in the EU or related to products and services that we offer to EU users. The GDPR creates new compliance obligations applicable to our business, including accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects how their personal data is to be used; imposes limitations on retention of personal data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. These obligations could cause us to change our business practices, and increases financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher) for the most serious infringements). In addition, the GDPR prohibits the transfer of personal data from the EEA to the United States and other jurisdictions that the European Commission does not recognize as having “adequate” data protection laws unless a data transfer mechanism has been put in place. On July 16, 2020, the Court of Justice of the European Union, or CJEU, issued a decision invalidating outright the EU-US Privacy Shield framework which companies rely on to transfer data from the EU to the United States. As a result, we may need to modify the way we treat such information.

While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the standard contractual clauses cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer. The European Commission has published revised standard contractual clauses for data transfers from the EEA: the revised clauses must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. We will be required to implement the revised standard contractual clauses, in relation to relevant existing contracts and certain additional contracts and arrangements, within the relevant time frames. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR.

Following the United Kingdom's withdrawal from the EEA and the EU, and the expiry of the transition period, companies have to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision, and remains under review by the Commission during this period. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. These changes will lead to additional costs and increase our overall risk exposure.

These recent developments are likely to require us to review and amend the legal mechanisms by which we make and/ or receive personal data transfers to/in the United States and other countries outside of the EEA. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services and/or the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

If we cannot license rights to use technologies on reasonable terms, we may not be able to commercialize new products in the future.

In the future, we may license third-party technology to develop or commercialize new products. In return for the use of a third-party's technology, we may agree to pay the licensor royalties based on sales of our solutions. Royalties are a component of cost of revenue and affect the margins on our solutions. We may also need to negotiate licenses to patents and patent applications after introducing a commercial product. Our business may suffer if we are unable to enter into the necessary licenses on acceptable terms, or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable.

If we are unable to protect our intellectual property effectively, our business would be harmed.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

We apply for and in-license patents covering our products and technologies and uses thereof, as we deem appropriate, however we may fail to apply for patents on important products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. Our issued patents expire between 2021 and 2038 and are related to methods used in thyroid diagnostics, lung diagnostics, breast cancer diagnostics, urological diagnostics, colorectal cancer diagnostics and the nCounter Analysis System.

It is possible that none of our pending patent applications will result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties. It is possible that others will design around our current or future patented technologies. We may not be successful in defending any challenges made against our patents or patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents and increased competition to our business. The outcome of patent litigation can be uncertain and any attempt by us to enforce our patent rights against others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business.

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions in the biotechnology field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing or comparing nucleic acids.

In particular, the patent positions of companies engaged in the development and commercialization of genomic diagnostic tests are particularly uncertain. Various courts, including the U.S. Supreme Court, have rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to certain diagnostic tests and related methods. These decisions state, among other things, that patent claims that recite laws of nature (for example, the relationship between blood levels of certain metabolites and the likelihood that a dosage of a specific drug will be ineffective or cause harm) are not themselves patentable. What constitutes a law of nature is uncertain, and it is possible that certain aspects of genomic diagnostics tests would be considered natural laws. Accordingly, the evolving case law in the United States may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned and licensed patents.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties protecting and defending such rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. We may not develop additional proprietary products, methods and technologies that are patentable.

In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, academic institutions, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. If we are required to assert our rights against such party, it could result in significant cost and distraction.

Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third-party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

We may also be subject to claims that our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights and face increased competition to our business. A loss of key research personnel work product could hamper or prevent our ability to commercialize potential products, which could harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Further, competitors could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. Others may independently develop similar or alternative products and technologies or replicate any of our products and technologies. If our intellectual property does not adequately protect us against competitors' products and methods, our competitive position could be adversely affected, as could our business.

We have not registered certain of our trademarks in all of our potential geographic markets. If we apply to register these trademarks, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. If some other business in one of these markets already owns a trademark that is confusingly similar to one of our trademarks, we may be prohibited from entering that market under our trademark unless we re-brand our product in that location. Similarly, if we develop a new product line, there is no guarantee that one of our existing trademarks will be available as the brand for that new product line. Under those circumstances, we may incur the cost of developing a new trademark for this new product line.

To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property does not provide adequate coverage of our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

We may be involved in litigation related to intellectual property, which could be time-intensive and costly and may adversely affect our business, operating results or financial condition.

We may receive notices of claims of direct or indirect infringement or misappropriation or misuse of other parties' proprietary rights from time to time. Some of these claims may lead to litigation. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or other rights, or the validity of our patents, trademarks or other rights, will not be asserted or prosecuted against us.

We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings, or other post-grant proceedings declared by the U.S. Patent and Trademark Office that could result in substantial cost to us. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, recent changes to the patent laws of the United States allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction.

Litigation may be necessary for us to enforce our patent and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require on acceptable terms or at all. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products. In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on our business, operating results or financial condition.

As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others may now and, in the future, have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in our existing and targeted markets and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into or growth in those markets. Third parties may assert that we are employing their proprietary technology without authorization. In addition, our competitors and others may have patents or may in the future obtain patents and claim that making, having made, using, selling, offering to sell or importing our products infringes these patents. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses on acceptable terms, if at all. We could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our financial results. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing products, and the prohibition of sale of any of our products could materially affect our business and our ability to gain market acceptance for our products. With respect to trademarks, infringement litigation or threats of infringement litigation may require us to re-brand our product in order to enter into the new mark.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, our agreements with some of our customers, suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

Our ability to use our net operating loss carryforwards may be limited and may result in increased future tax liability to us.

We have incurred net losses since our inception and may never achieve profitability. As of December 31, 2020, we had net operating loss, or NOL, carryforwards of approximately $282.9 million, $63.0 million and $72.2 million available to reduce future taxable income, if any, for federal, California and other state income tax purposes, respectively. With the acquisition of Decipher Biosciences, Inc in March 2021, we acquired additional federal, California and other state NOL carryforwards of approximately $94.8 million, $25.5 million and $29.8 million, respectively. The U.S. federal NOL carryforwards will begin to expire in 2026 while for state purposes, the NOL carryforwards begin to expire in 2028. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Acts, or Tax Act, which was enacted in December 2017, federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. We may be limited in the portion of NOL carryforwards that we can use in the future to offset taxable income for U.S. federal and state income tax purposes, and federal tax credits to offset federal tax liabilities. Sections 382 and 383 of Internal Revenue Code limit the use of NOLs and tax credits after a cumulative change in corporate ownership of more than 50% occurs within a three-year period. The limitation could prevent a corporation from using some or all its NOL and tax credits before they expire within their normal 20-year lifespan, as it places a formula limit of how much NOL and tax credits a loss corporation can use in a tax year. In the event we have undergone an ownership change under Section 382 of the Internal Revenue Code, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us.

On March 27, 2020, the CARES Act was signed into law. The CARES Act changes certain provisions of the 2017 Tax Act. Under the CARES Act, NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, the CARES Act eliminates the limitation on the deduction of NOLs to 80% of current year taxable income for taxable years beginning before January 1, 2021, and increases the amount of interest expense that may be deducted to 50% of adjusted taxable income for taxable years beginning in 2019 or 2020. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act, as modified by the CARES Act, is uncertain and our business, financial conditions, results of operations and growth prospects could be materially and adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, as modified by the CARES Act. The impact of the Tax Act, as modified by the CARES Act, on holders of our common stock is also uncertain and could be adverse.

Impairment in the value of our goodwill or other intangible assets could have a material adverse effect on our operating results and financial condition.

We record goodwill and intangible assets at fair value upon the acquisition of a business. Goodwill represents the excess of amounts paid for acquiring businesses over the fair value of the net assets acquired. Goodwill and indefinite-lived intangible assets are evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with definite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, divestitures, sustained market declines and other factors that impact the fair value of our reporting unit could result in an impairment of goodwill or

intangible assets and, in turn, a charge to net income. Any such charges could have a material adverse effect on our results of operations or financial condition.

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

We are subject to income taxes in the United States and various foreign jurisdictions. Our effective tax rate may be lower or higher than experienced in the past due to numerous factors, including a change in the mix of our revenue from country to country, the establishment or release of valuation allowances against our deferred tax assets, and changes in tax laws. In addition, we have recorded gross unrecognized tax benefits in our financial statements that, if recognized, would impact our effective tax rate. We are subject to tax audits in various jurisdictions, including the United States, and tax authorities may disagree with certain positions we have taken and assess additional taxes. There can be no assurance that we will accurately predict the outcomes of these audits, and the actual outcomes could have a material impact on our net income or financial condition. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could have an adverse effect on our business and results of operations. The recognition of deferred tax assets is reduced by a valuation allowance if it is more likely than not that the tax benefits will not be realized. We regularly review our deferred tax assets for recoverability and establish a valuation allowance based on historical income, projected future income, the expected timing of the reversals of existing temporary differences, and the implementation of tax-planning strategies.

Changes in financial accounting standards or practices may cause adverse, unexpected financial reporting fluctuations and affect our reported operating results.

U.S. GAAP is subject to interpretation by the Financial Accounting Standards Board, the Securities and Exchange Commission, or the SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business.

Our condensed consolidated financial statements are subject to change and if our estimates or judgments relating to our critical accounting policies prove to be incorrect, our operating results could be adversely affected.

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our condensed consolidated financial statements and related notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as provided in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Quarterly Report on Form 10-Q. The results of these estimates form the basis for making judgments about the carrying values of assets, liabilities, and equity, and the amount of revenue and expenses that are not readily apparent from other sources. In addition, when we acquire businesses, we make judgments about how best to account for their revenue, assets and liabilities in our condensed consolidated financial statements. These judgments may be based on limited information, estimates and various assumptions, which we may revisit as we more fully integrate such businesses into our company. Critical accounting policies and estimates used in preparing our consolidated financial statements include those related to: revenue recognition; write-down of supplies; the useful lives of property and equipment; the recoverability of long-lived assets; the incremental borrowing rate for leases; the estimation of the fair value of intangible assets and contingent consideration; variable interest entity assessment; impairment of equity investment, at cost; stock options; income tax uncertainties, including a valuation allowance for deferred tax assets; reserve on accounts receivable and contingencies. Our operating results may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in the price of our common stock.

Risks Related to our Recent Acquisitions

The recently completed acquisitions of HalioDx and Decipher Biosciences presents risks and we must successfully integrate the HalioDx and Decipher Biosciences businesses to realize the financial goals that we currently anticipate.

Risks we face in connection with the recently completed acquisition and ongoing integration of HalioDx and Decipher Biosciences include:

- We may not realize the benefits we expect to receive from these transactions, such as anticipated synergies;
- We may have difficulties managing acquired products and tests or retaining key personnel from the acquired businesses;
- We may not successfully integrate the acquired businesses as planned, there could be unanticipated adverse impacts on the acquired businesses, or we may otherwise not realize the expected return on our investments, which could adversely affect our business or operating results and potentially cause impairment to assets that we record as a part of an acquisition including intangible assets and goodwill;
- The Decipher Biosciences Merger Agreement does not provide for post-closing indemnification protection related to pre-closing Decipher Biosciences operations and, therefore, we may incur unforeseen costs as a result of Decipher Biosciences' pre-closing activities, over which we have limited control, including Decipher Biosciences' breach of the covenants contained in the Merger Agreement;
- Our operating results or financial condition may be adversely impacted by (i) claims or liabilities related to the acquired businesses including, among others, claims from U.S. or international regulatory or other governmental agencies, terminated employees, current or former customers or business partners, or other third parties; (ii) pre-existing contractual relationships of the acquired businesses that we would not have otherwise entered into, the termination or modification of which may be costly or disruptive to our business; (iii) unfavorable accounting treatment as a result of the acquired businesses' practices; and (iv) intellectual property claims or disputes;
- Neither HalioDx nor Decipher Biosciences was required to maintain an internal control infrastructure that would meet the standards of a public company, including the requirements of the Sarbanes-Oxley Act of 2002. The costs that we may incur to implement such controls and procedures may be substantial and we could encounter unexpected delays and challenges in this implementation. In addition, we may discover significant deficiencies or material weaknesses in the quality of HalioDx's or Decipher Biosciences' respective financial and disclosure controls and procedures;
- We may experience a failure of development activities on behalf of a HalioDx customer where HalioDx bears development risk resulting in a refund of development fees;
- We may fail to transition manufacturing of the test kits for the nCounter, currently produced by NanoString, to HalioDx's manufacturing facility in Marseille, France in a timely manner or at all, or we may experience manufacturing irregularities or challenges in connection with the transition;
- We may not realize the anticipated accretion to our gross margins as a result of transitioning manufacturing of test kits to HalioDx;
- We may experience disagreements with the employee French work council;
- Decipher Biosciences operates in segments of the diagnostic market that we have less experience with, including urology, and our further expansion of operations into these areas could present various integration challenges and result in increased costs and other unforeseen challenges; and
- We may have failed to identify or assess the magnitude of certain liabilities, shortcomings or other circumstances prior to acquiring either of the acquired businesses, which could result in unexpected litigation or regulatory exposure, unfavorable accounting treatment, a diversion of management's attention and resources, and other adverse effects on our business, financial condition, and operating results.

Doing business internationally at the scale of HalioDx creates operational risk for our business.

Conducting and launching operations on an international scale requires close coordination of activities across multiple jurisdictions and consumes significant management resources. If we fail to coordinate and manage these activities effectively

for any reason, including the risks noted below, our business, financial condition, or results of operations could be adversely affected.

The Acquisition increases the following risks and challenges associated with conducting business outside the U.S., where we expect a growing proportion of our operations and revenue to be located:

- longer payment cycles and difficulties in collecting accounts receivable outside of the United States;
- longer sales cycles due to the volume of transactions taking place through public tenders;
- challenges in staffing and managing foreign operations;
- lack of consistency, and unexpected changes, in legislative or regulatory requirements of foreign countries into which we sell our products;
- increased risk of governmental and regulatory scrutiny and investigations;
- the burden of complying with a wide variety of foreign laws, regulations, and legal standards;
- import and export requirements, tariffs, taxes, and other trade barriers;
- possible enactment of laws regarding the management of and access to data and public networks and websites;
- potential negative impact of a global health crisis, such as the outbreak of a serious infectious disease, to our commercial or manufacturing operations, including the loss of productivity from our own workforce and consequences of any restrictions on the movement of people or materials;
- possible future limitations on foreign-owned businesses;
- significant taxes; and
- other factors beyond our control, including political, social and economic instability, and security concerns in general.

Additionally, we must comply with complex foreign and U.S. laws and regulations, such as the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act, and other local laws prohibiting corrupt payments to governmental officials, anti-competition regulations and sanctions imposed by the U.S. Office of Foreign Assets Control and other similar laws and regulations. Violations of these laws and regulations could result in fines and penalties, criminal sanctions, restrictions on our business conduct and on our ability to offer our products in one or more countries, and could also materially affect our brand, our ability to attract and retain employees, our international operations, our business and our operating results. Although we have implemented policies and procedures designed to ensure compliance with these laws and regulations, there can be no assurance that our employees, contractors, or agents will not violate our policies, or that our policies will be adopted or enforceable in all jurisdictions.

As we continue to expand our business into multiple international markets, our success will depend, in large part, on our ability to anticipate and effectively manage these and other risks associated with our international operations. Any of these risks could harm our international operations and negatively impact our sales, adversely affecting our business, results of operations, financial condition and growth prospects.

We are exposed to risks associated with transactions denominated in foreign currency.

Changes in the value of the relevant currencies may affect the cost of certain items required in our operations and contractual agreements. Changes in currency exchange rates may also affect the relative prices at which we are able to sell products in the same market. Our revenues from international customers may be negatively impacted as increases in the U.S. dollar relative to our international customers local currency could make our products more expensive, impacting our ability to compete. Our costs of materials from international suppliers may increase if, in order to continue doing business with us, they raise their prices as the value of the U.S. dollar decreases relative to their local currency. Foreign policies and actions regarding currency valuation could result in actions by the United States and other countries to offset the effects of such fluctuations. Recent global financial conditions have led to a high level of volatility in foreign currency exchange rates and that level of volatility may continue, which could adversely affect our business, financial condition, or results of operations.

Risks Related to Being a Public Company

We will continue to incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we will continue to incur significant legal, accounting, consulting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. In addition, the

Sarbanes-Oxley Act of 2002 and the Dodd-Frank Act of 2010, as well as rules implemented by the SEC, and The Nasdaq Stock Market LLC, impose a number of requirements on public companies, including with respect to corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. Moreover, these rules and regulations have and will continue to increase our legal, accounting and financial compliance costs and make some activities more complex, time-consuming and costly. We also expect that it will continue to be expensive for us to maintain director and officer liability insurance.

If we are unable to implement and maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal controls on an annual basis. If we have material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our consolidated financial statements may be materially misstated. We will need to maintain and enhance the systems, processes and documentation necessary to comply with Section 404 of the Sarbanes-Oxley Act as we grow, and we will require additional management and staff resources to do so. Additionally, even if we conclude our internal controls are effective for a given period, we may in the future identify one or more material weaknesses in our internal controls, in which case our management will be unable to conclude that our internal control over financial reporting is effective. We are also required to include an attestation report from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting annually. Further, our recent acquisitions of Decipher Biosciences and HalioDx, both of which were previously private companies and were not subject to audits of internal controls, require or will require us to incorporate additional controls to such businesses, which may be difficult, costly and time-consuming. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

If we are unable to conclude that our internal control over financial reporting is effective, or if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our reported operating results and harm our reputation. Internal control deficiencies could also result in a restatement of our financial results.

Risks Related to Our Common Stock

Our stock price may be volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated variations in our and our competitors' results of operations;
- the global macroeconomic impact of the current COVID-19 outbreak;
- announcements by us or our competitors of new products, commercial relationships or capital commitments;
- changes in reimbursement by current or potential payers, including governmental payers;
- issuance of new securities analysts' reports or changed recommendations for our stock;
- fluctuations in our revenue, due in part to the way in which we recognize revenue;
- actual or anticipated changes in regulatory oversight of our products;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;

- announced or completed acquisitions of businesses or technologies by us or our competitors, including the effect of additional equity we or our competitors issue as consideration for such acquisitions;
- any major change in our management; and
- general economic conditions and slow or negative growth of our markets.

In addition, the stock market in general, and the market for stock of life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may cause the trading volume of our stock to decrease. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us, our business and our competitors. We do not control these analysts or the content and opinions or financial models included in their reports. Securities analysts may elect not to provide research coverage of our company, and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

Anti-takeover provisions in our charter documents and under Delaware law could discourage, delay or prevent a change in control and may affect the trading price of our common stock.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 5.0 million shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, our chairman of the board, or our chief executive officer;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may, except as otherwise required by law, be filled only by a majority of directors then in office, even if less than a quorum;
- provide that the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended;
- specify that no stockholder is permitted to cumulate votes at any election of directors; and

- require a super-majority of votes to amend certain of the above-mentioned provisions.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. Section 203 generally prohibits us from engaging in a business combination with an interested stockholder subject to certain exceptions.

We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. In addition, our Loan and Security Agreement restricts our ability to pay cash dividends on our common stock and we may also enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

ITEM 6. EXHIBITS

Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.1	Amended and Restated Offer Letter, dated August 15, 2021, between the Registrant and Rebecca Chambers					X
10.2	Change in Control and Severance Agreement, effective July 19, 2021 between Rebecca Chambers and the Registrant					X
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. § 1350 (Section 906 of the Sarbanes-Oxley Act of 2002)					X
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. § 1350 (Section 906 of the Sarbanes-Oxley Act of 2002)					X
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL					X
101.SCH	Inline XBRL Taxonomy Extension Schema					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101)					X

* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Exchange Act or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act except to the extent that the registrant specifically incorporates it by reference.

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.

Date: November 9, 2021

VERACYTE, INC.

By: /s/ Rebecca Chambers

Rebecca Chambers
Chief Financial Officer

08/15/2021

Note: This Offer Letter amends and replaces the Offer Letter dated 6/24/21

Rebecca Chambers 4233 Ridgeway Drive San Diego, CA
92116

Dear Rebecca Chambers:

We're delighted to confirm our offer of employment as Veracyte's Chief Financial Officer. In this role, you will report to Marc Stapley, Chief Executive Officer. (You should note that the Company may modify job titles and reporting relationships from time to time as it deems necessary.)

The terms of this offer are as follows:

1. You will receive a base salary of $450,000 per year, less all applicable taxes and withholdings, paid in accordance with Veracyte's established payroll schedule, presently semi-monthly.

   In addition, you will be eligible to participate in the Company's 2021 Bonus Plan. Your target bonus for 2021 will be 55% of eligible annual earnings. Payout is dependent on company and individual performance and is not guaranteed.

2. The Company's Board of Directors has agreed to offer equity participation to you. You will be granted the option to purchase 67,000 shares of Veracyte Common Stock. The price per share will be equal to the fair market value of the Common Stock on the date of grant (your hire date). The vesting schedule will be 1/4 of the shares vesting on the first anniversary of your employment, and then 1/48 of the shares vesting each month for the next 36 months.

   In addition, you will be granted 34,000 restricted stock units (RSUs) of Veracyte's common stock as recommended and approved by the Company's Board of Directors following commencement of your full-time employment with Veracyte. Your RSUs will vest over four years, with the first 1/4th vesting on September 2, 2022 and your remaining RSUs vesting 1/16th per quarter thereafter on the company's RSU vesting schedule.

   The Company has also granted you 13,600 Performance Stock Units (PSUs). The PSUs will be subject to the same terms and conditions, including performance metrics and vesting requirements, as the PSUs granted to certain of the Company's executive officers in February 2021. The PSU will be further subject to the terms and conditions set forth in the applicable award agreement between you and the Company, the Company's 2013 Stock Incentive Plan and the Company's Change of Control and Severance Agreement.

3. Veracyte will provide you a sign-on bonus of $100,000 (less applicable taxes and withholdings) contingent upon starting by July 19, 2021. It will be included in your first paycheck. If you voluntarily resign within 12 months of your start date, you will be required to repay Veracyte.

4. You also will be eligible for medical, dental, vision and life insurance benefits, and participation in the Company's 401(k) and Employee Stock Purchase Plans, which will be further detailed in a separate conversation with Human Resources.

Also, you will be eligible for paid time off and company paid holidays in accordance with Veracyte's established policies. These and other policies are explained fully in the Company's employee handbook.

5. In accordance with Federal immigration law, you will be required to provide the Company documentary evidence of your identity and eligibility for employment in the United States. This documentation must be provided to the Company within three (3) business days of your date of hire, or the Company may terminate its employment relationship with you.

6. In accordance with the law, employment with the Company is at-will, and may be terminated at any time by you or the Company, with or without cause and with or without notice. However, if employment is terminated by you, the Company requests that you provide as much notice as possible.

7. Employment with the Company is contingent upon your signature of, and compliance with, its At- Will Employment, Confidential Information and Invention Assignment and Arbitration Agreement. This requires, among other provisions, the assignment of patent rights to any invention made during your employment with the Company, as well as non-disclosure of Company proprietary information. There is also a requirement for resolution by binding arbitration of any dispute arising out of our employment relationship. The arbitration requirement is described in detail in the agreement, a copy of which is enclosed with this offer. Kindly send a signed copy of this agreement to Geraldine Yamaguchi (geraldine@veracyte.com) prior to your first day of employment.

8. This offer is contingent upon a successfully completed background report.

To accept the Company's offer, please sign and date this letter in the space provided below. Your target start date is July 19, 2021. This letter, together with any agreements relating to proprietary rights as herein described, sets forth the terms of your employment with the Company, and supersedes any prior representations or agreements including, but not limited to, any representations made during your recruitment, interviews or pre-employment negotiations, whether written or oral. This letter including, but not limited to, its at-will employment provision, may not be modified or amended except by written agreement signed by an Officer of the Company and you.

We're all keenly looking forward to welcoming you aboard! If you have any questions about this offer or its terms, please feel free to contact Jennifer Harvey, HR Director, directly at 650-243-6328.

Sincerely,

/s/ Marc Stapley
Marc Stapley
Chief Executive Officer

Agreed to and accepted:

Signature: /s/ Rebecca Chambers

Printed Name: Rebecca Chambers

Date: 8/16/2021

VERACYTE, INC.

CHANGE OF CONTROL AND SEVERANCE AGREEMENT

This Change of Control and Severance Agreement (the "***Agreement"***) is made and entered into by and between Rebecca Chambers ("***Executive***") and Veracyte, Inc., a Delaware corporation (the "***Company***"), effective as of July 19, 2021 (the "***Effective Date***").

RECITALS

1. The Board of Directors of the Company (the "***Board"***) believes that it is in the best interests of the Company and its stockholders (i) to assure that the Company will have the continued dedication and objectivity of Executive, notwithstanding the possibility, threat, or occurrence of a Change of Control and (ii) to provide Executive with an incentive to continue Executive's employment Lea to a Change of Control and to motivate Executive to maximize the value of the Company upon a Change of Control for the benefit of its stockholders.

2. The Board believes that it is imperative to provide Executive with certain severance benefits upon Executive's termination of employment under certain circumstances. These benefits will provide Executive with enhanced financial security and incentive and encouragement to remain with the Company notwithstanding the possibility of a Change of Control.

3. Certain capitalized terms used in the Agreement are defined in Section 6 below.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual covenants contained herein, the parties hereto agree as follows:

1. Term of Agreement. This Agreement will have an initial term of four (4) years commencing on the Effective Date (the "***Initial Term***"). On the fourth anniversary of the Effective Date, this Agreement will renew automatically for additional one (1) year terms (each an "***Additional Term***"), unless either party provides the other party with written notice of non-renewal at least sixty (60) days prior to the date of automatic renewal. Notwithstanding the foregoing provisions of this paragraph, if a Change of Control occurs when there are fewer than twelve (12) months remaining during the Initial Term or an Additional Term, the term of this Agreement will extend automatically through the date that is twelve (12) months following the effective date of the Change of Control. If Executive becomes entitled to benefits under Section 3 during the term of this Agreement, the Agreement will not terminate until all of the obligations of the parties hereto with respect to this Agreement have been satisfied.

2. At-Will Employment. The Company and Executive acknowledge that Executive's employment is and will continue to be at-will, as defined under applicable law. As an at-will employee, either the Company or the Executive may terminate the employment relationship at any time, with or without Cause.

3. Severance Benefits.

(a) Termination without Cause or Resignation for Good Reason Unrelated to a Change of Control. If the Company terminates Executive's employment with the Company without Cause (excluding death or Disability) or if Executive resigns from such employment for Good Reason, and such

termination occurs outside of the Change of Control Period, then subject to Section 4, Executive will receive the following:

(i) Accrued Compensation. The Company will pay Executive all accrued but unpaid vacation, expense reimbursements, wages, and other benefits due to Executive under any Company-provided plans, policies, and arrangements.

(ii) Continuing Severance Payments. Executive will be paid continuing payments of severance pay at a rate equal to Executive's base salary rate, as then in effect, for six (6) months from the date of such termination of employment to be paid periodically in accordance with the Company's normal payroll policies.

(iii) Continuation Coverage. If Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ***("COBRA")*** within the time period prescribed pursuant to COBRA for Executive and Executive's eligible dependents, then the Company will reimburse Executive for the COBRA premiums for such coverage (at the coverage levels in effect immediately prior to Executive's termination) until the earlier of (A) a period of six (6) months from the date of termination or (B) the date upon which Executive and/or Executive's eligible dependents become covered under similar plans. The reimbursements will be made by the Company to Executive consistent with the Company's normal expense reimbursement policy. Notwithstanding the first sentence of this Section 3(a)(iii), if the Company determines in its sole discretion that it cannot provide the foregoing benefit without potentially violating, or being subject to an excise tax under, applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company will in lieu thereof provide to Executive a taxable monthly payment, payable on the last day of a given month, in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's group health coverage in effect on the termination of employment date (which amount will be based on the premium for the first month of COBRA coverage), which payments will be made regardless of whether Executive elects COBRA continuation coverage and will commence on the month following Executive's termination of employment and will end on the earlier of (x) the date upon which Executive obtains other employment or (y) the date the Company has paid an amount equal to six (6) payments. For the avoidance of doubt, the taxable payments in lieu of COBRA reimbursements may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to all applicable tax withholdings.

(b) Termination without Cause or Resignation for Good Reason in Connection with a Change of Control. If the Company terminates Executive's employment with the Company without Cause (excluding death or Disability) or if Executive resigns from such employment for Good Reason, and, in each case, such termination occurs during the Change of Control Period, then subject to Section 4, Executive will receive the following:

(i) Accrued Compensation. The Company will pay Executive all accrued but unpaid vacation, expense reimbursements, wages, and other benefits due to Executive under any Company-provided plans, policies, and arrangements.

(ii) Severance Payment. Executive will receive a lump-sum payment (less applicable withholding taxes) equal to eighteen (18) months of Executive's annual base salary as in effect immediately prior to Executive's termination date or, if greater, at the level in effect immediately prior to the Change of Control. For the avoidance of doubt, if (x) Executive incurred a termination prior to a Change of Control that qualifies Executive for severance payments under Section 3(a)(ii); and (y) a

Change of Control occurs within the two (2)-month period following Executive's termination of employment that qualifies Executive for the superior benefits under this Section 3(b)(ii), then Executive shall be entitled to a lump-sum payment of the amount calculated under this Section 3(b)(ii), less amounts already paid under Section 3(a)(ii) and such amount lump-sum amount shall be payable upon the later of: (A) the Change of Control, (B) the date the Release (as defined below) is effective and irrevocable; or (C) such later date required by Section 4(c).

(iii) Bonus Payment. Executive will receive a lump-sum payment equal to one hundred fifty percent (150%) of the higher of (A) the greater of (x) Executive's target bonus for the fiscal year in which the Change of Control occurs (as in effect immediately prior to the Change of Control) or (y) Executive's target bonus as in effect for the fiscal year in which Executive's termination of employment occurs, or (B) Executive's actual bonus for performance during the calendar year prior to the calendar year during which the termination of employment occurs. For avoidance of doubt, the amount paid to Executive pursuant to this Section 3(b)(iii) will not be prorated based on the actual amount of time Executive is employed by the Company during the fiscal year (or the relevant performance period if something different than a fiscal year) during which the termination occurs.

(iv) Continuation Coverage. If Executive elects continuation coverage pursuant to COBRA within the time period prescribed pursuant to COBRA for Executive and Executive's eligible dependents, then the Company will reimburse Executive for the COBRA premiums for such coverage (at the coverage levels in effect immediately prior to Executive's termination) until the earlier of(A) a period of eighteen (18) months from the date of termination or (B) the date upon which Executive and/or Executive's eligible dependents become covered under similar plans. The reimbursements will be made by the Company to Executive consistent with the Company's normal expense reimbursement policy. Notwithstanding the first sentence of this Section 3(b)(iv), if the Company determines in its sole discretion that it cannot provide the foregoing benefit without potentially violating, or being subject to an excise tax under, applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company will in lieu thereof provide to Executive a taxable monthly payment, payable on the last day of a given month, in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's group health coverage in effect on the termination of employment date (which amount will be based on the premium for the first month of COBRA coverage), which payments will be made regardless of whether Executive elects COBRA continuation coverage and will commence on the month following Executive's termination of employment and will end on the earlier of (x) the date upon which Executive obtains other employment or (y) the date the Company has paid an amount equal to eighteen (18)payments. For the avoidance of doubt, the taxable payments in lieu of COBRA reimbursements may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to all applicable tax withholdings.

(v) Accelerated Vesting of Equity Awards. One hundred percent (100%) of Executive's then-outstanding and unvested Equity Awards will become vested in full. If, however, an outstanding Equity Award is to vest and/or the amount of the award to vest is to be determined based on the achievement of performance criteria, then the Equity Award will vest as to one hundred percent (100%) of the amount of the Equity Award assuming the performance criteria had been achieved at target levels for the relevant performance period(s).

(c) Voluntary Resignation; Termination for Cause. If Executive's employment with the Company terminates (i) voluntarily by Executive (other than for Good Reason) or (ii) for Cause by the Company, then Executive will not be entitled to receive severance or other benefits except for those (if

any) as may then be established under the Company's then existing severance and benefits plans and practices or pursuant to other written agreements with the Company.

(d) Disability; Death. If the Company terminates Executive's employment as a result of Executive's Disability, or Executive's employment terminates due to Executive's death, then Executive will not be entitled to receive any other severance or other benefits, except for those (if any) as may then be established under the Company's then existing written severance and benefits plans and practices or pursuant to other written agreements with the Company.

(e) Exclusive Remedy. In the event of a termination of Executive's employment as set forth in Section 3(a) or (b) of this Agreement, the provisions of Section 3 are intended to be and are exclusive and in lieu of any other rights or remedies to which Executive or the Company otherwise may be entitled, whether at law, tort or contract, in equity, or under this Agreement (other than the payment of accrued but unpaid wages, as required by law, and any unreimbursed reimbursable expenses). Executive will be entitled to no benefits, compensation or other payments or rights upon a termination of employment other than those benefits expressly set forth in Section 3 of this Agreement.

4. Conditions to Receipt of Severance

(a) Release of Claims Agreement. The receipt of any severance payments or benefits (other than the accrued benefits set forth in either Sections 3(a)(i) or 3(b)(i)) pursuant to this Agreement is subject to Executive signing and not revoking a separation agreement and release of claims in substantially the form attached hereto as Exhibit A (the "***Release***"), which must become effective and irrevocable no later than the sixtieth (60th) day following Executive's termination of employment (the "***Release Deadline***"). If the Release does not become effective and irrevocable by the Release Deadline, Executive will forfeit any right to severance payments or benefits under this Agreement. In no event will severance payments or benefits be paid or provided until the Release actually becomes effective and irrevocable.

(b) Confidential Information and Invention Assignment Agreements. Executive's receipt of any payments or benefits under Section 3 (other than the accrued benefits set forth in either Sections 3(a)(i) or 3(b)(i)) will be subject to Executive continuing to comply with the terms of the Confidentiality Agreement, dated on or about September 12, 2011, between the Company and Executive, as such agreement may be amended from time to time.

(c) Section 409A.

(i) Notwithstanding anything to the contrary in this Agreement, no severance pay or benefits to be paid or provided to Executive, if any, pursuant to this Agreement that, when considered together with any other severance payments or separation benefits, are considered deferred compensation under Section 409A of the Code, and the final regulations and any guidance promulgated thereunder ("***Section 409A***") (together, the "***Deferred Payments***") will be paid or otherwise provided until Executive has a "separation from service" within the meaning of Section 409A. Similarly, no severance payable to Executive, if any, pursuant to this Agreement that otherwise would be exempt from Section 409A pursuant to Treasury Regulation Section 1.409A-1(b)(9) will be payable until Executive has a "separation from service" within the meaning of Section 409A.

(ii) It is intended that none of the severance payments under this Agreement will constitute Deferred Payments but rather will be exempt from Section 409A as a payment that would fall within the "short-term deferral period" as described in Section 4(c)(iv) below or resulting from an

involuntary separation from service as described in Section 4(c)(v) below. Any severance payments or benefits under this Agreement will be paid on, or, in the case of installments, will commence on, the sixty-first (61st) day following Executive's separation from service, or, if later, such time as required by Section 4(c)(iii). Except as required by Section 4(c)(iii), any installment payments that would have been made to Executive during the sixty (60) day period immediately following Executive's separation from service but for the preceding sentence will be paid to Executive on the sixty-first (61st) day following Executive's separation from service and the remaining payments will be made as provided in this Agreement.

(iii) Notwithstanding anything to the contrary in this Agreement, if Executive is a "specified employee" within the meaning of Section 409A at the time of Executive's termination (other than due to death), then the Deferred Payments, if any, that are payable within the first six (6) months following Executive's separation from service, will become payable on the first payroll date that occurs on or after the date six (6) months and one (I) day following the date of Executive's separation from service. All subsequent Deferred Payments, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if Executive dies following Executive's separation from service, but before the six (6) month anniversary of the separation from service, then any payments delayed in accordance with this paragraph will be payable in a lump sum as soon as administratively practicable after the date of Executive's death and all other Deferred Payments will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment and benefit payable under this Agreement is intended to constitute a separate payment under Section 1.409A-2(b)(2) of the Treasury Regulations.

(iv) Any amount paid under this Agreement that satisfies the requirements of the "short-term deferral" rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations will not constitute Deferred Payments for purposes of clause (i) above.

(v) Any amount paid under this Agreement that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section 1.409A-1(b)(9)(iii) of the Treasury Regulations that does not exceed the Section 409A Limit (as defined below) will not constitute Deferred Payments for purposes of clause (i) above.

(vi) The foregoing provisions are intended to comply with the requirements of Section 409A so that none of the severance payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be interpreted to so comply. The Company and Executive agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition before actual payment to Executive under Section 409A.

5. Limitation on Payments. In the event that the severance and other benefits provided for in this Agreement or otherwise payable to Executive (i) constitute "parachute payments" within the meaning of Section 280G of the Code, and (ii) but for this Section 5, would be subject to the excise tax imposed by Section 4999 of the Code, then Executive's benefits under Section 3 will be either:

(a) delivered in full, or

(b) delivered as to such lesser extent which would result in no portion of such benefits being subject to excise tax under Section 4999 of the Code,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, results in the receipt by Executive on an after-tax basis, of the greatest amount of benefits, notwithstanding that all or some portion of such benefits may be taxable under Section 4999 of the Code. If a reduction in severance and other benefits constituting "parachute payments" is necessary so that benefits are delivered to a lesser extent, reduction will occur in the following order: (i) reduction of cash payments; (ii) cancellation of awards granted "contingent on a change in ownership or control" (within the meaning of Code Section 280G), (iii) cancellation of accelerated vesting of equity awards; (iv) reduction of employee benefits. In the event that acceleration of vesting of equity award compensation is to be reduced, such acceleration of vesting will be cancelled in the reverse order of the date of grant of Executive's equity awards.

Unless the Company and Executive otherwise agree in writing, any determination required under this Section 5 will be made in writing by the Company's independent public accountants immediately prior to a Change of Control or such other person or entity to which the parties mutually agree (the "***Firm***"), whose determination will be conclusive and binding upon Executive and the Company. For purposes of making the calculations required by this Section 5, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and Executive will furnish to the Firm such information and documents as the Firm may reasonably request in order to make a determination under this Section. The Company will bear all costs the Firm may incur in connection with any calculations contemplated by this Section 5.

6. Definition of Terms. The following terms referred to in this Agreement will have the following meanings:

(a) Cause. "***Cause***" will mean:

(i) The willful or grossly negligent failure of the Executive to substantially perform his or her duties as an employee of the Company;

(ii) Executive's commission of a gross misconduct which is injurious to the Company;

(iii) Executive's breach of a material provision of any agreement between Executive and the Company;

(iv) Executive's material and willful violation of a federal or state law or regulation applicable to the business of the Company;

(v) Executive's misappropriation or embezzlement of Company funds or Executive's act of fraud or dishonesty upon the Company; or

(vi) Executive's conviction of, or plea of nolo contendere, to a felony (other than motor vehicle offenses the effect of which do not materially impair Executive's performance of Executive's duties for the Company).

The Company will not terminate Executive's employment for Cause without first providing Executive with written notice specifically identifying the acts or omissions constituting the grounds for a Cause termination and, with respect to clauses (i), (iii) and (iv), a reasonable opportunity to cure (to the extent curable) for a period of not less than ten (10) business days following such notice.

The determination as to whether Executive is being terminated for Cause will be made in good faith by the Board and will be final and binding on Executive. The foregoing definition does not in any way limit the Company's ability to terminate Executive's employment relationship at any time as provided in Section 2 above, and the term "Company" will be interpreted to include any subsidiary, parent, affiliate or successor thereto, if applicable.

(b) Change of Control. "***Change of Control***" means the occurrence of any of the following events:

(i) A change in the ownership of the Company which occurs on the date that any one person, or more than one person acting as a group ("***Person***"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than fifty percent (50%) of the total voting power of the stock of the Company; provided, however, that for purposes of this subsection, the acquisition of additional stock by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the stock of the Company will not be considered a Change of Control; or

(ii) A change in the effective control of the Company which occurs on the date that a majority of members of the Board is replaced during any twelve (12) month period by Directors whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this clause (ii), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Change of Control; or

(iii) A change in the ownership of a substantial portion of the Company's assets which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions; provided, however, that for purposes of this subsection (iii), the following will not constitute a change in the ownership of a substantial portion of the Company's assets: (A) a transfer to an entity that is controlled by the Company's stockholders immediately after the transfer, or (B) a transfer of assets by the Company to: (1) a stockholder of the Company (immediately before the asset transfer) in exchange for or with respect to the Company's stock, (2) an entity, fifty percent (50%) or more of the total value or voting power of which is owned, directly or indirectly, by the Company, (3) a Person, that owns, directly or indirectly, fifty percent (50%) or more of the total value or voting power of all the outstanding stock of the Company, or (4) an entity, at least fifty percent (50%) of the total value or voting power of which is owned, directly or indirectly, by a Person described in this subsection (iii)(B)(3). For purposes of this subsection (iii), gross fair market value means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

For purposes of this definition, persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company.

Notwithstanding the foregoing, a transaction will not be deemed a Change of Control unless the transaction qualifies as a change in control event within the meaning of Code Section 409A, as it has been and may be amended from time to time, and any proposed or final Treasury Regulations and Internal

Revenue Service guidance that has been promulgated or may be promulgated thereunder from time to time.

Further and for the avoidance of doubt, a transaction will not constitute a Change of Control if: (i) its sole purpose is to change the state of the Company's incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

(c) Change of Control Period. "***Change of Control Period***" will mean the period beginning two (2) months prior to, and ending twelve (12) months following, a Change of Control.

(d) Code. "***Code***" will mean the Internal Revenue Code of 1986, as amended.

(e) Disability. "***Disability***" will mean that Executive has been unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months. Alternatively, Executive will be deemed disabled if determined to be totally disabled by the Social Security Administration. Termination resulting from Disability may only be effected after at least thirty (30) days' written notice by the Company of its intention to terminate Executive's employment. In the event that Executive resumes the performance of substantially all of Executive's duties hereunder before the termination of Executive's employment becomes effective, the notice of intent to terminate based on Disability will automatically be deemed to have been revoked.

(f) Equity Awards. "***Equity Awards***" will mean Executive's outstanding stock options, stock appreciation rights, restricted stock units, performance shares, performance stock units and any other Company equity compensation awards.

(g) Good Reason. "***Good Reason***" will mean termination of employment within forty-five (45) days following the expiration of any cure period (discussed below) following the occurrence of one or more of the following, without Executive's express written consent:

(i) a material reduction of Executive's authorities, duties or responsibilities relative to Executive's authorities, duties or responsibilities in effect immediately prior to such reduction;

(ii) a material reduction in Executive's base salary and/or target bonus opportunity, other than a reduction applicable to similarly situated employees generally that does not adversely affect Executive to a greater extent than other similarly situated employees;

(iii) the relocation of Executive's principal place of performing his or her duties as an employee of the Company by more than fifty (50) miles; or

(iv) a successor of the Company as set forth in Section 7(a) hereof does not assume this Agreement.

In order for an event to qualify as Good Reason, Executive must not terminate employment with the Company without first providing the Company with written notice of the acts or omissions constituting the grounds for "Good Reason" within ninety (90) days of the initial existence of the grounds for "Good Reason' and a reasonable cure period of not less than thirty (30) days following the end of such notice.

For purposes of the "Good Reason" definition, the term "Company" will be interpreted to include any subsidiary, parent, affiliate or successor thereto, if applicable.

(h) Section 409A Limit. "***Section 409A Limit"*** will mean two (2) times the lesser of: Executive's annualized compensation based upon the annual rate of pay paid to Executive during the Executive's taxable year preceding the Executive's taxable year of Executive's termination of employment as determined under, and with such adjustments as are set forth in, Treasury Regulation 1.409A-1(b)(9)(iii)(A)(l) and any Internal Revenue Service guidance issued with respect thereto; or (ii) the maximum amount that may be taken into account under a qualified plan pursuant to Section 401(a)(17) of the Code for the year in which Executive's employment is terminated.

7. Successors.

(a) The Company's Successors. Any successor to the Company (whether direct or indirect and whether by purchase, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets will assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term "Company" will include any successor to the Company's business and/or assets which executes and delivers the assumption agreement described in this Section 7(a) or which becomes bound by the terms of this Agreement by operation of law.

(b) Executive's Successors. The terms of this Agreement and all rights of Executive hereunder will inure to the benefit of, and be enforceable by, Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

8. Notice.

(a) General. Notices and all other communications contemplated by this Agreement will be in writing and will be deemed to have been duly given when sent electronically or personally delivered when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid or when delivered by a private courier service such as UPS, DHL or Federal Express that has tracking capability. In the case of Executive, notices will be sent to the e-mail address or addressed to Executive at the home address, in either case which Executive most recently communicated to the Company in writing. In the case of the Company, electronic notices will be sent to the e-mail address of the Chief Executive Officer and the General Counsel and mailed notices will be addressed to its corporate headquarters, and all notices will be directed to the attention of its Chief Executive Officer and General Counsel.

(b) Notice of Termination. Any termination by the Company for Cause or by Executive for Good Reason will be communicated by a notice of termination to the other party hereto given in accordance with Section 8(a) of this Agreement. Such notice will indicate the specific termination provision in this Agreement relied upon, will set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination under the provision so indicated, and will specify the termination date (which will be not more than ninety (90) days after the giving of such notice).

9. Resignation. Upon the termination of Executive's employment for any reason, Executive will be deemed to have resigned from all officer and/or director positions held at the Company and its affiliates voluntarily, without any further required action by Executive, as of the end of Executive's

employment and Executive, at the Board's request, will execute any documents reasonably necessary to reflect Executive's resignation.

10. Arbitration.

(a) Arbitration. In consideration of Executive's employment with the Company, its promise to arbitrate all employment-related disputes, and Executive's receipt of the compensation, pay raises and other benefits paid to Executive by the Company, at present and in the future, Executive agrees that any and all controversies, claims, or disputes with anyone (including the Company and any employee, officer, director, stockholder or benefit plan of the Company in their capacity as such or otherwise) arising out of, relating to, or resulting from Executive's employment with the Company or termination thereof, including any breach of this Agreement, will be subject to binding arbitration under the Arbitration Rules set forth in California Code of Civil Procedure Section 1280 through 1294.2, including Section 1281.8 (the "***Act***"), and pursuant to California law . The Federal Arbitration Act will also apply with full force and effect, notwithstanding the application of procedural rules set forth under the Act.

(b) Dispute Resolution. Disputes that Executive agrees to arbitrate, and thereby agrees to waive any right to a trial by jury, include any statutory claims under local, state, or federal law, including, but not limited to, claims under Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act of 1990, the Age Discrimination in Employment Act of 1967, the Older Workers Benefit Protection Act, the Sarbanes Oxley Act, the Worker Adjustment and Retraining Notification Act, the California Fair Employment and Housing Act, the Family and Medical Leave Act, the California Family Rights Act, the California Labor Code, claims of harassment, discrimination, and wrongful termination, and any statutory or common law claims. Executive further understands that this Agreement to arbitrate also applies to any disputes that the Company may have with Executive.

(c) Procedure. Executive agrees that any arbitration will be administered by the Judicial Arbitration & Mediation Services, Inc. ("***JAMS***"), pursuant to its Employment Arbitration Rules & Procedures (the "***JAMS Rules***"). The arbitrator will have the power to decide any motions brought by any party to the arbitration, including motions for summary judgment and/or adjudication, motions to dismiss and demurrers, and motions for class certification, prior to any arbitration hearing. The arbitrator will have the power to award any remedies available under applicable law, and the arbitrator will award attorneys' fees and costs to the prevailing party, except as prohibited by law. The Company will pay for any administrative or hearing fees charged by the administrator or JAMS, and all arbitrator's fees, except that Executive will pay any filing fees associated with any arbitration that Executive initiates, but only so much of the filing fee as Executive would have instead paid had Executive filed a complaint in a court of law. Executive agrees that the arbitrator will administer and conduct any arbitration in accordance with California law, including the California Code of Civil Procedure and the California Evidence Code, and that the arbitrator will apply substantive and procedural California law to any dispute or claim, without reference to the rules of conflict of law. To the extent that the JAMS Rules conflict with California law, California law will take precedence. The decision of the arbitrator will be in writing. Any arbitration under this Agreement will be conducted in San Mateo County, California.

(d) Remedy. Except as provided by the Act, arbitration will be the sole, exclusive, and final remedy for any dispute between Executive and the Company. Accordingly, except as provided by the Act and this Agreement, neither Executive nor the Company will be permitted to pursue court action regarding claims that are subject to arbitration. Notwithstanding, the arbitrator will not have the authority to disregard or refuse to enforce any lawful Company policy, and the arbitrator will not order or

require the Company to adopt a policy not otherwise required by law which the Company has not adopted.

(e) Administrative Relief. Executive is not prohibited from pursuing an administrative claim with a local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, including, but not limited to, the Department of Fair Employment and Housing, the Equal Employment Opportunity Commission, the National Labor Relations Board, or the Workers' Compensation Board. However, Executive may not pursue court action regarding any such claim, except as permitted by law.

(f) Voluntary Nature of Agreement. Executive acknowledges and agrees that Executive is executing this Agreement voluntarily and without any duress or undue influence by the Company or anyone else. Executive further acknowledges and agrees that Executive has carefully read this Agreement and that Executive has asked any questions needed for Executive to understand the terms, consequences and binding effect of this Agreement and fully understands it, including that ***EXECUTIVE IS WAIVING EXECUTIVE'S RIGHT TO A JURY TRIAL***. Finally, Executive agrees that Executive has been provided an opportunity to seek the advice of an attorney of Executive's choice before signing this Agreement.

11. Miscellaneous Provisions.

(a) No Duty to Mitigate. Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any such payment be reduced by any earnings that Executive may receive from any other source.

(b) Waiver. No provision of this Agreement will be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party will be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

(d) Entire Agreement. This Agreement constitutes the entire agreement of the parties hereto and supersedes in their entirety all prior representations, understandings, undertakings or agreements (whether oral or written and whether expressed or implied) of the parties with respect to the subject matter hereof. No waiver, alteration, or modification of any of the provisions of this Agreement will be binding unless in writing and signed by duly authorized representatives of the parties hereto and which specifically mention this Agreement.

(e) Choice of Law. The validity, interpretation, construction and performance of this Agreement will be governed by the laws of the State of California (with the exception of its conflict of laws provisions). Any claims or legal actions by one party against the other arising out of the relationship between the parties contemplated herein (whether or not arising under this Agreement) will be commenced or maintained in any state or federal court located in the jurisdiction where Executive -resides, and Executive and the Company hereby submit to the jurisdiction and venue of any such court.

(f) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement will not affect the validity or enforceability of any other provision hereof, which will remain in full force and effect.

(g) Withholding. All payments made pursuant to this Agreement will be subject to withholding of applicable income, employment and other taxes.

(h) Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

[Signature Page to Follow]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year set forth below.

COMPANY	VERACYTE, INC.
	By: /s/ Marc Stapley
	Title: Chief Executive Officer
	Date: 7/1/2021
EXECUTIVE	By: /s/ Rebecca Chambers
	Title: Chief Financial Officer
	Date: 7/1/2021

[signature page of the Change of Control and Severance Agreement]

EXHIBIT A

FORM OF RELEASE OF CLAIMS

This release of claims (this "***Agreement'***) is made by and between Veracyte, Inc. (the "***Company***"), and Name ("***Executive***"). The Company and Executive are sometimes collectively referred to herein as the "***Parties***" and individually referred to as a "***Party***."

RECITALS

[**WHEREAS**, Executive signed a [Confidential Information and Invention Assignment Agreement] with the Company on Date (the "***Confidentiality Agreement***");]

WHEREAS, Executive signed a Change of Control and Severance Agreement with the company on _____ (the "***Severance Agreement***"), which, among other things, provides for certain severance benefits to be paid to Executive by the Company upon the termination of Executive's employment;

WHEREAS, Executive was employed by the Company until _____, when Executive's employment was terminated ("***Termination Date***");

WHEREAS, in accordance with Section 4 of the Severance Agreement between the Company and Executive, Executive has agreed to enter into and not revoke a standard release of claims in favor of the Company as a condition to receiving the severance benefits described in the Severance Agreement; and

WHEREAS, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions and demands that Executive may have against the Company and any of the Releasees (as defined below), including, but not limited to, any and all claims arising out of or in any way related to Executive's employment relationship with the Company and the termination of that relationship.

NOW THEREFORE, for good and valuable consideration, including the mutual promises and covenants made herein, the Company and Executive hereby agree as follows:

COVENANTS

1. Termination. Executive's employment with the Company terminated on the Termination Date.

2. Payment of Salary and Receipt of All Benefits. Executive acknowledges and represents that, other than the consideration to be paid in accordance with the terms and conditions of the Severance Agreement, the Company has paid or provided all salary, wages, bonuses, accrued vacation/paid time off, premiums, leaves, housing allowances, relocation costs, interest, severance, outplacement costs, fees, reimbursable expenses, commissions, draws, stock, stock options or other equity awards (including restricted stock unit awards), vesting, and any and all other benefits and compensation due to Executive and that no other reimbursements or compensation are owed to Executive.

3. Release of Claims. Executive agrees that the consideration to be paid in accordance with the terms and conditions of the Severance Agreement represents settlement in full of all outstanding

obligations owed to Executive by the Company and its current and former officers, directors, employees, agents, investors, attorneys, stockholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries, and predecessor and successor corporations and assigns (collectively, the "***Releasees***"). Executive, on Executive's own behalf and on behalf of Executive's respective heirs, family members, executors, agents, and assigns, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, demand, or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the Effective Date of this Agreement, including, without limitation the following:

(a) any and all claims relating to or arising from Executive's employment relationship with the Company and the termination of that relationship;

(b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of shares of stock of the Company, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state corporate law, and securities fraud under any state or federal law;

(c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

(d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standards Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; the Sarbanes-Oxley Act of2002; [the California Family Rights Act]; [the California Labor Code]; [the California Workers' Compensation Act]; and [the California Fair Employment and Housing Act];[1]

(e) any and all claims for violation of the federal, or any state, constitution;

(f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

(g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non- withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement; and

(h) any and all claims for attorneys' fees and costs.

[1] References to California statutes will only be included in this Agreement if Executive resides in California at the time Executive's employment relationship is terminated. Otherwise, statutes specific to the state in which Executive resides at the time of termination will be substituted.

Executive agrees that the release set forth in this Section 3 (the "***Release***") will be and remain in effect in all respects as a complete general release as to the matters released. The Release does not extend to any severance obligations due Executive under the Severance Agreement. The Release does not release claims that cannot be released as a matter of law. Executive represents that Executive has made no assignment or transfer of any right, claim, complaint, charge, duty, obligation, demand, cause of action, or other matter waived or released by this Section 3. Nothing in this Agreement waives Executive's rights to indemnification or any payments under any fiduciary insurance policy, if any, provided by any act or agreement of the Company, state or federal law or policy of insurance.

4. Protected Rights. Executive understands that nothing in Section 3 above, or otherwise in this Agreement, limits Executive's ability to file a charge or complaint with the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal, state or local government agency or commission ("***Government Agencies***"). Executive further understands that this Agreement does not limit Executive's ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. This Agreement does not limit Executive's right to receive an award for information provided to any Government Agencies.

5. [Acknowledgment of Waiver of Claims under ADEA. Executive acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("***ADEA***") and that this waiver and release is knowing and voluntary. Executive agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the Effective Date of this Agreement. Executive acknowledges that the consideration given for this waiver and release Agreement is in addition to anything of value to which Executive was already entitled. Executive further acknowledges that Executive has been advised by this writing that (a) Executive should consult with an attorney ***prior*** to executing this Agreement; (b) Executive has at least 21 days within which to consider this Agreement; (c) Executive has 7 days following the execution of this Agreement by the parties to revoke the Agreement; (d) this Agreement will not be effective until the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and delivers it to the Company in less than the 21-day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement. Executive acknowledges and understands that revocation must be accomplished by a written notification to the Chief Executive Officer of the Company that is received prior to the Effective Date.][2]

6. [California Civil Code Section 1542. Executive acknowledges that Executive has been advised to consult with legal counsel and is familiar with the provisions of California Civil Code Section 1542, a statute that otherwise prohibits the release of unknown claims, which provides as follows:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM OR

[2] This provision will only be included in this Agreement if Executive is age 40 or older at the time Executive's employment relationship is terminated.

HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.

Executive, being aware of California Civil Code Section 1542, agrees to expressly waive any rights Executive may have thereunder, as well as under any other statute or common law principles of similar effect.

OR

Unknown Claims. Executive acknowledges that Executive has been advised to consult with legal counsel and that Executive is familiar with the principle that a general release does not extend to claims that the releaser does not know or suspect to exist in his or her favor at the time of executing the release, which, if known by him or her, must have materially affected his or her settlement with the releasee. Executive, being aware of this principle, agrees to expressly waive any rights Executive may have to that effect, as well as under any other statute or common law principles of similar effect.][3]

7. No Pending or Future Lawsuits. Executive represents that Executive has no lawsuits, claims, or actions pending in Executive's name, or on behalf of any other person or entity, against the Company or any of the other Releasees. Executive also represents that Executive does not intend to bring any claims on Executive's own behalf or on behalf of any other person or entity against the Company or any of the other Releasees.

8. Sufficiency of Consideration. Executive hereby acknowledges and agrees that Executive has received good and sufficient consideration for every promise, duty, release, obligation, agreement and right contained in this Release.

9. Confidential Information. Executive reaffirms and agrees to observe and abide by the terms of the Confidentiality Agreement, specifically including the provisions therein regarding nondisclosure of the Company's trade secrets and confidential and proprietary information, which agreement will continue in force; *provided, however*, that: (a) as to any provisions regarding competition contained in the Confidentiality Agreement that conflict with the provisions regarding competition contained in the Severance Agreement, the provisions of the Severance Agreement will control; (b) as to any provisions regarding solicitation of employees contained in the Confidentiality Agreement that conflict with the provisions regarding solicitation of employees contained in this Agreement, the provisions of this Agreement will control.

10. Return of Company Property; Passwords and Password-protected Documents. Executive confirms that Executive has returned to the Company in good working order all keys, files, records (and copies thereof), equipment (including, but not limited to, computer hardware, software and printers, wireless handheld devices, cellular phones and pagers), access or credit cards, Company identification, and any other Company-owned property in Executive's possession or control. Executive further confirms that Executive has cancelled all accounts for Executive's benefit, if any, in the Company's name, including, but not limited to, credit cards, telephone charge cards, cellular phone and/or pager accounts and computer accounts. Executive also confirms that Executive has delivered all passwords in use by Executive at the time of Executive's termination, a list of any documents that Executive created or of

[3] If Executive resides in California at the time Executive's employment relationship is terminated, the first provision - "*California Civil Code Section 1542*" - will be included in this Agreement, otherwise the second provision - "*Unknown Claims*" - will be used.

which Executive is otherwise aware that are password-protected, along with the password(s) necessary to access such password-protected documents.

11. No Cooperation. Executive agrees that Executive will not knowingly encourage, counsel, or assist any attorneys or their clients in the presentation or prosecution of any disputes, differences, grievances, claims, charges, or complaints by any third party against any of the Releasees, unless under a subpoena or other court order to do so or as related directly to the ADEA waiver in this Agreement. If approached by anyone for counsel or assistance in the presentation or prosecution of any disputes, differences, grievances, claims, charges, or complaints against any of the Releasees, Executive will state no more than that Executive cannot provide any such counsel or assistance.

12. Nondisparagement. Executive agrees that Executive will not in any way, directly or indirectly, do or say anything at any time which disparages the Company, its business interests or reputation, or that of any of the other Released Parties.

13. No Admission of Liability. Executive understands and acknowledges that this Agreement constitutes a compromise and settlement of any and all actual or potential disputed claims by Executive. No action taken by the Company hereto, either previously or in connection with this Agreement, will be deemed or construed to be (a) an admission of the truth or falsity of any actual or potential claims or (b) an acknowledgment or admission by the Company of any fault or liability whatsoever to Executive or to any third party.

14. Solicitation of Employees. Executive agrees that for a period of 12 months immediately following the Effective Date of this Agreement, Executive will not directly or indirectly (a) solicit, induce, recruit or encourage any of the Company's employees to leave their employment at the Company or (b) attempt to solicit, induce, recruit or encourage, either for Executive or for any other person or entity, any of the Company's employees to leave their employment.

15. Costs. The Parties will each bear their own costs, attorneys' fees and other fees incurred in connection with the preparation of this Agreement.

16. Arbitration. THE PARTIES AGREE THAT ANY AND ALL DISPUTES ARISING OUT OF THE TERMS OF THIS AGREEMENT, THEIR INTERPRETATION, AND ANY OF THE MATTERS HEREIN RELEASED, WILL BE SUBJECT TO ARBITRATION IN SAN MATEO COUNTY, BEFORE JUDICIAL ARBITRATION & MEDIATION SERVICES ("***JAMS***"), PURSUANT TO ITS EMPLOYMENT ARBITRATION RULES & PROCEDURES ("***JAMS RULES***"). THE ARBITRATOR MAY GRANT INJUNCTIONS AND OTHER RELIEF IN SUCH DISPUTES. THE ARBITRATOR WILL ADMINISTER AND CONDUCT ANY ARBITRATION IN ACCORDANCE WITH CALIFORNIA LAW, INCLUDING THE CALIFORNIA CODE OF CIVIL PROCEDURE, AND THE ARBITRATOR WILL APPLY SUBSTANTIVE AND PROCEDURAL CALIFORNIA LAW TO ANY DISPUTE OR CLAIM, WITHOUT REFERENCE TO ANY CONFLICT-OF-LAW PROVISIONS OF ANY JURISDICTION. TO THE EXTENT THAT THE JAMS RULES CONFLICT WITH CALIFORNIA LAW, CALIFORNIA LAW WILL TAKE PRECEDENCE. THE DECISION OF THE ARBITRATOR WILL BE FINAL, CONCLUSIVE, AND BINDING ON THE PARTIES TO THE ARBITRATION. THE PARTIES AGREE THAT THE PREVAILING PARTY IN ANY ARBITRATION WILL BE ENTITLED TO INJUNCTIVE RELIEF IN ANY COURT OF COMPETENT JURISDICTION TO ENFORCE THE ARBITRATION AWARD. THE PARTIES TO THE ARBITRATION WILL EACH PAY AN EQUAL SHARE OF THE COSTS AND EXPENSES OF SUCH ARBITRATION, AND EACH PARTY WILL SEPARATELY PAY FOR ITS RESPECTIVE

COUNSEL FEES AND EXPENSES; PROVIDED, HOWEVER, THAT THE ARBITRATOR WILL AWARD ATTORNEYS' FEES AND COSTS TO THE PREVAILING PARTY, EXCEPT AS PROHIBITED BY LAW. THE PARTIES HEREBY AGREE TO WAIVE THEIR RIGHT TO HAVE ANY DISPUTE BETWEEN THEM RESOLVED IN A COURT OF LAW BY A JUDGE OR JURY. NOTWITHSTANDING THE FOREGOING, THIS SECTION WILL NOT PREVENT EITHER PARTY FROM SEEKING INJUNCTIVE RELIEF (OR ANY OTHER PROVISIONAL REMEDY) FROM ANY COURT HAVING JURISDICTION OVER THE PARTIES AND THE SUBJECT MATTER OF THEIR DISPUTE RELATING TO THIS AGREEMENT AND THE AGREEMENTS INCORPORATED HEREIN BY REFERENCE. SHOULD ANY PART OF THE ARBITRATION AGREEMENT CONTAINED IN THIS PARAGRAPH CONFLICT WITH ANY OTHER ARBITRATION AGREEMENT BETWEEN THE PARTIES, THE PARTIES AGREE THAT THIS ARBITRATION AGREEMENT WILL GOVERN. [4]

17. Authority. The Company represents and warrants that the undersigned has the authority to act on behalf of the Company and to bind the Company and all who may claim through it to the terms and conditions of this Agreement. Executive represents and warrants that Executive has the capacity to act on Executive's own behalf and on behalf of all who might claim through Executive to bind them to the terms and conditions of this Agreement. Each Party warrants and represents that there are no liens or claims of lien or assignments in law or equity or otherwise of or against any of the claims or causes of action released herein.

18. No Representations. Executive represents that Executive has had the opportunity to consult with an attorney, and has carefully read and understands the scope and effect of the provisions of this Agreement. Executive has relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement.

19. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement will continue in full force and effect without said provision or portion of provision.

20. Entire Agreement. This Agreement represents the entire agreement and understanding between the Company and Executive concerning the subject matter of this Agreement and Executive's employment with and separation from the Company and the events leading thereto and associated therewith, and supersedes and replaces any and all prior agreements and understandings concerning the subject matter of this Agreement and Executive's relationship with the Company, with the exception of the Severance Agreement, the Confidentiality Agreement, and Executive's written equity compensation agreements with the Company.

21. No Oral Modification. This Agreement may only be amended in writing signed by Executive and the Chairman of the Board of Directors of the Company.

[4] References to California will only be included in this Agreement if Executive resides in California at the time Executive's employment relationship is terminated.

22. Governing Law. This Agreement will be governed by the laws of the State of California, without regard for choice-of-law provisions. Executive consents to personal and exclusive jurisdiction and venue in the State of California. [5]

23. Effective Date. [Executive understands that this Agreement will be null and void if not executed by Executive within 21 days. Each Party has seven days after that Party signs this Agreement to revoke it. This Agreement will become effective on the eighth (8th) day after Executive signed this Agreement, so long as it has been signed by the Parties and has not been revoked by either Party before that date (the "***Effective Date***").][6] ***OR*** [This Agreement will be effective after it has been signed or executed by both Parties (the "***Effective Date***")][7]

24. Counterparts. This Agreement may be executed in counterparts and by facsimile, and each counterpart and facsimile will have the same force and effect as an original and will constitute an effective, binding agreement on the part of each of the undersigned.

25. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive expressly acknowledges that:

(a) Executive has read this Agreement;

(b) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel;

(c) Executive understands the terms and consequences of this Agreement and of the releases it contains; and

(d) Executive is fully aware of the legal and binding effect of this Agreement.

* * * * *

[Signature page to follow]

[5] References to California will only be included in this Agreement if Executive resides in California at the time Executive's employment relationship is terminated.
[6] This provision will only be included in this Agreement if Executive is age 40 or older at the time Executive's employment relationship is terminated.
[7] This provision will only be included in this Agreement if Executive is under the age of 40 at the time Executive's employment relationship is terminated.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

COMPANY	**VERACYTE, INC.**
	By: __
	Name: __
	Title:
	Date: __
EXECUTIVE	By: ____ (Signature)
	Name: __
	Date: __

Exhibit 31.1

PRINCIPAL EXECUTIVE OFFICER'S CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Marc Stapley, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Veracyte, Inc. for the quarter ended September 30, 2021;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: November 9, 2021

/s/ Marc Stapley

Marc Stapley
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

PRINCIPAL FINANCIAL OFFICER'S CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Rebecca Chambers, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Veracyte, Inc. for the quarter ended September 30, 2021;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: November 9, 2021

/s/ Rebecca Chambers

Rebecca Chambers
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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 Veracyte, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

(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.

Date: November 9, 2021

/s/ Marc Stapley
Marc Stapley
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 Veracyte, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

(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.

Date: November 9, 2021

/s/ Rebecca Chambers
Rebecca Chambers
Chief Financial Officer
(Principal Financial Officer)