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, 2022
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 October 28, 2022, there were 71,752,896 shares of common stock, par value $0.001 per share, outstanding.

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VERACYTE, INC.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Quarterly Report on Form 10-Q other than statements of historical fact, including statements concerning our business strategy and plans, future operating results and financial position, as well as our objectives and expectations for our future operations, are forward-looking statements.

In some cases, you can identify forward-looking statements by such terminology as “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “expect” and similar expressions that convey uncertainty of future events or outcomes, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements about:

- our expectations regarding total revenue and total test volume;
- 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 economy;
- our ability to continue to successfully integrate HalioDx, Decipher Biosciences, and the assets acquired from NanoString Technologies, Inc. into our business;
- our ability to deploy the nCounter Analysis System successfully and run our tests on this platform worldwide;
- our expectations regarding our biopharma partnerships and agreements;
- our anticipated cash needs and our estimates regarding our capital requirements and profitability;
- the impact of the conflict in Ukraine, supply chain disruptions, inflation and foreign exchange fluctuations, and market volatility resulting from the above, on our business;
- our ability to maintain Medicare and commercial payer coverage for each of our tests;
- our sales, marketing and distribution capabilities and strategy;
- our intellectual property position;
- the impact of government laws and regulations; and
- our competitive position.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations, prospects, and financial needs. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. We disclaim any intention or obligation to publicly update or revise any forward-looking statements for any reason or to conform such statements to actual results or revised expectations, except as required by law.

PART I. — FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements-(Unaudited)

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

	September 30, 2022	December 31, 2021 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 170,112	$ 173,197
Short-term investments	—	3,964
Accounts receivable	40,068	41,461
Supplies and inventory	13,798	11,225
Prepaid expenses and other current assets	14,538	13,255
Total current assets	238,516	243,102
Property and equipment, net	17,237	15,098
Right-of-use assets, operating leases	13,885	16,043
Intangible assets, net	176,542	202,731
Goodwill	676,885	707,904
Restricted cash	749	749
Other assets	2,143	2,198
Total assets	$ 1,125,957	$ 1,187,825
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 11,114	$ 12,360
Accrued liabilities	32,137	39,475
Current portion of long-term debt	1,187	1,127
Current portion of deferred revenue	3,863	4,646
Current portion of acquisition-related contingent consideration	5,913	2,682
Current portion of operating lease liabilities	3,958	3,630
Current portion of other liabilities	180	231
Total current liabilities	58,352	64,151
Deferred revenue, net of current portion	—	343
Deferred tax liabilities	4,342	5,592
Acquisition-related contingent consideration, net of current portion	2,411	5,722
Operating lease liabilities, net of current portion	11,527	14,096
Other liabilities	1,148	1,407
Total liabilities	77,780	91,311
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding as of September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 125,000,000 shares authorized, 71,741,517 and 71,123,108 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	72	71
Additional paid-in capital	1,492,044	1,468,683
Accumulated deficit	(389,873)	(357,157)
Accumulated other comprehensive loss	(54,066)	(15,083)
Total stockholders' equity	1,048,177	1,096,514
Total liabilities and stockholders' equity	$ 1,125,957	$ 1,187,825

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,	
	2022	2021	2022	2021
Revenue:				
Testing revenue	$ 64,577	$ 50,897	$ 180,275	$ 134,768
Product revenue	3,314	2,959	9,401	8,706
Biopharmaceutical and other revenue	7,701	6,514	26,563	8,704
Total revenue	75,592	60,370	216,239	152,178
Operating expenses:				
Cost of testing revenue	19,816	16,073	55,923	42,494
Cost of product revenue	1,981	1,491	5,202	4,304
Cost of biopharmaceutical and other revenue	4,211	4,079	13,626	4,720
Research and development	10,773	8,006	29,316	19,591
Selling and marketing	25,678	21,670	73,433	57,628
General and administrative	17,600	20,749	58,310	82,504
Intangible asset amortization	5,213	4,983	16,090	10,507
Total operating expenses	85,272	77,051	251,900	221,748
Loss from operations	(9,680)	(16,681)	(35,661)	(69,570)
Other income (loss), net	805	1,202	2,675	(762)
Loss before income taxes	(8,875)	(15,479)	(32,986)	(70,332)
Income tax benefit	(152)	(1,350)	(270)	(5,297)
Net loss	$ (8,723)	$ (14,129)	$ (32,716)	$ (65,035)
Net loss per common share, basic and diluted	$ (0.12)	$ (0.20)	$ (0.46)	$ (0.97)
Shares used to compute net loss per common share, basic and diluted	71,656,694	69,743,733	71,456,008	66,820,654

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,	
	2022	**2021**	**2022**	**2021**
Net loss	$ (8,723)	$ (14,129)	$ (32,716)	$ (65,035)
Other comprehensive loss:				
Change in currency translation adjustments	(16,016)	(8,140)	(38,983)	(8,140)
Net comprehensive loss	$ (24,739)	$ (22,269)	$ (71,699)	$ (73,175)

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, 2022	71,559	$ 72	$ 1,483,279	$ (381,150)	$ (38,050)	$ 1,064,151
Issuance of common stock on exercise of stock options and vesting of restricted stock units	110	—	623	—	—	623
Issuance of common stock under employee stock purchase plan (ESPP)	73	—	1,633	—	—	1,633
Tax portion of vested restricted stock units	—	—	(773)	—	—	(773)
Stock-based compensation expense (employee)	—	—	6,815	—	—	6,815
Stock-based compensation expense (ESPP)	—	—	467	—	—	467
Net loss	—	—	—	(8,723)	—	(8,723)
Comprehensive loss	—	—	—	—	(16,016)	(16,016)
Balance at September 30, 2022	71,742	$ 72	$ 1,492,044	$ (389,873)	$ (54,066)	$ 1,048,177
Balance at December 31, 2021	71,123	$ 71	$ 1,468,683	$ (357,157)	$ (15,083)	$ 1,096,514
Issuance of common stock upon exercise of stock options and vesting of restricted stock units	464	1	2,385	—	—	2,386
Issuance of common stock under ESPP	155	—	3,748	—	—	3,748
Tax portion of vested restricted stock units	—	—	(2,639)	—	—	(2,639)
Stock-based compensation expense (employee)	—	—	18,459	—	—	18,459
Stock-based compensation expense (non-employee)	—	—	11	—	—	11
Stock-based compensation expense (ESPP)	—	—	1,397	—	—	1,397
Net loss	—	—	—	(32,716)	—	(32,716)
Comprehensive loss	—	—	—	—	(38,983)	(38,983)
Balance at September 30, 2022	71,742	$ 72	$ 1,492,044	$ (389,873)	$ (54,066)	$ 1,048,177

	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 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 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 Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2022	2021
Operating activities		
Net loss	$ (32,716)	$ (65,035)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	19,372	13,189
Loss on disposal of property and equipment	72	—
Stock-based compensation	19,867	15,787
Benefit from income taxes	(270)	(5,297)
Interest on end-of-term debt obligation	161	161
Noncash lease expense	2,487	1,566
Revaluation of acquisition-related contingent consideration	(80)	303
Effect of foreign currency on operations	1,563	1,601
Impairment of intangible assets	3,318	—
Changes in operating assets and liabilities:		
Accounts receivable	(4,356)	(6,285)
Supplies and inventory	(2,841)	4
Prepaid expenses and other current assets	(25)	(1,905)
Other assets	160	353
Operating lease liabilities	(2,570)	(1,710)
Accounts payable	(325)	3,872
Accrued liabilities and deferred revenue	(6,026)	3,329
Net cash used in operating activities	(2,209)	(40,067)
Investing activities		
Acquisition of Decipher Biosciences, net of cash acquired	—	(574,411)
Acquisition of HalioDx, net of cash acquired	—	(163,645)
Purchase of short-term investments	(8,972)	—
Proceeds from maturity of short-term investments	12,696	—
Proceeds from sale of equity securities	—	3,000
Purchases of property and equipment	(6,677)	(4,535)
Net cash used in investing activities	(2,953)	(739,591)
Financing activities		
Proceeds from the issuance of common stock in a public offering, net of issuance costs	—	593,821
Payment of long-term debt	(94)	—
Payment of taxes on vested restricted stock units	(2,639)	(8,307)
Proceeds from the exercise of common stock options and employee stock purchases	6,134	10,633
Net cash provided by financing activities	3,401	596,147
Decrease in cash, cash equivalents and restricted cash	(1,761)	(183,511)
Effect of foreign currency on cash, cash equivalents and restricted cash	(1,324)	(1,678)
Net decrease in cash, cash equivalents and restricted cash	(3,085)	(185,189)
Cash, cash equivalents and restricted cash at beginning of period	173,946	349,967
Cash, cash equivalents and restricted cash at end of period	$ 170,861	$ 164,778
Supplementary cash flow information:		
Purchases of property and equipment included in accounts payable and accrued liability	$ 15	$ 31
Interest paid on debt	$ —	$ 9
Cash paid for tax	$ 430	$ —
Issuance of common stock for acquisition of HalioDx	$ —	$ 147,089

Cash, Cash Equivalents and Restricted Cash:

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 170,112	$ 173,197
Restricted cash	749	749
Total cash, cash equivalents and restricted cash	$ 170,861	$ 173,946

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

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 menu of tests leverage advances in genomic science and machine learning technology to influence 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 diagnostic access to the nCounter Analysis System positions the company to deliver tests to patients worldwide through laboratories and hospitals that can perform them locally.

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 South San Francisco, California, and it also has operations in San Diego, California; Austin, Texas; Richmond, Virginia; 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, and Richmond.

Veracyte's foundational approach for its tests 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 their ability to influence care. This approach has enabled the Company to obtain Medicare reimbursement for many of its commercially available tests. 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 thyroid cancer (Afirma); prostate and bladder cancers (Decipher); breast cancer (Prosigna); lung cancer (Percepta); and interstitial lung diseases, or ILD, including idiopathic pulmonary fibrosis, or IPF (Envisia). The Company's commercially available tests in each of these indications are covered by Medicare.

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 Technologies, Inc. or NanoString, 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.

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

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, 2022, the condensed consolidated statements of operations for the three and nine months ended September 30, 2022 and 2021, the condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2022 and 2021, the condensed consolidated statements of stockholders' equity for the three and nine months ended September 30, 2022 and 2021, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2022 and 2021 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, 2021 has been derived from audited financial statements. The results for the three and nine months ended September 30, 2022 are not 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, 2021.

Reclassifications

Certain prior period balances have been reclassified to conform to current period presentation of the Company's condensed consolidated financial statements and accompanying notes. Such reclassifications have no effect on previously reported results of operations, accumulated deficit, subtotals of operating, investing or financing cash flows or consolidated balance sheet totals; however, for the period December 31, 2021, the Company reclassified $4.0 million of prepaid expenses and other current assets to short-term investments in the condensed consolidated balance sheets.

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. Significant items subject to such estimates include: revenue recognition; 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 based compensation; income tax uncertainties, including a valuation allowance for deferred tax assets; credit related losses on investments; and 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.

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, revenue, 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, the Company 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, 2022, most of the Company's revenue has been derived from the sale of Decipher and Afirma testing. To date, Decipher and Afirma 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 other revenue based on collection history, current developments and credit worthiness of the customer. The estimate of credit losses is not material at September 30, 2022.

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,	
	2022	2021	2022	2021
Medicare	31 %	31 %	31 %	31 %
UnitedHealthcare	10 %	9 %	10 %	10 %
	41 %	40 %	41 %	41 %

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, 2022	December 31, 2021
Medicare	14 %	12 %
UnitedHealthcare	10 %	9 %

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.

Short-Term Investments

The Company's short-term investments consist of U.S. treasury securities and time deposits with a bank with maturities at the time of purchase that were between 90 days and one year. The Company classifies these investments as held-to-maturity debt securities, which are reported at amortized cost. Discounts or premiums from the purchase of the securities are recognized as a component of interest income in other income (loss), net in the condensed consolidated statements of operations. Investments are initially recorded net of an allowance for expected credit losses, if any, which are remeasured each period and any impairments are recognized as an expense. Unrealized gains and losses are not recognized in income. As of both September 30, 2022 and December 31, 2021, no allowances for expected credit losses had been recorded and there have been no impairment or credit losses on the Company's short term investments.

Restricted Cash

The Company had deposits of $0.7 million included in long-term assets as of both September 30, 2022 and December 31, 2021, 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

The Company recognizes revenue in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers*, or ASC 606. 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 completed a service or transferred control of a product to the customer.

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

Testing Revenue

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.

The Company has changed its revenue estimates due to actual and anticipated cash collections for tests delivered in prior quarters and recognized immaterial changes in revenue, loss from operations and basic and diluted net loss per share for the three and nine months ended September 30, 2022 and 2021.

Product Revenue

The Company's products consist of the Prosigna breast cancer assay, the nCounter Analysis System and related diagnostic kits. Product revenue from diagnostic kits is generally recognized upon shipment. Product revenue from instruments is generally recognized when the instrument is ready for use by the end customer. Shipping and handling costs incurred for product shipments are included in product revenue. Revenue is presented net of the taxes that are collected from customers and remitted to governmental authorities.

Biopharmaceutical and Other Revenue

The Company enters into arrangements for biopharmaceutical research and development, commercialization, contract manufacturing and development, and testing services, which are classified under biopharmaceutical and other revenue. Such arrangements may require the Company to deliver various rights, manufactured diagnostic test kits, services and/or samples, including intellectual property rights/licenses, biopharmaceutical research and development services, and/or commercialization services. The Company receives consideration in the form of upfront license fees; payments on delivery of data, test results or manufactured products; costs of service plus margin; and development and commercial performance milestone payments.

The Company develops 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. The estimation of the stand-alone selling price may include independent evidence of market price, forecasted revenue or costs, development timelines, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation to determine if the obligation 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. 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. 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.

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. 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 revenue and earnings in the period of adjustment. Revisions to the Company's estimate of the transaction price may also result in negative revenue and earnings in the period of adjustment. One collaboration arrangement with milestone payments falls under the scope of ASC Topic 808, *Collaborative Arrangements*, or ASC 808. These milestone payments are recognized in the same manner as milestone payments from customers and are classified under biopharmaceutical and other revenue.

Accounts receivable from biopharmaceutical and other revenue was $7.7 million at September 30, 2022 and $11.6 million at December 31, 2021. There was $3.9 million and $5.0 million of deferred revenue related to these agreements at September 30, 2022 and December 31, 2021, respectively. Revenue included in biopharmaceutical and other revenue for the three and nine months ended September 30, 2022 and 2021 was as follows (in thousands of dollars):

	Three Months Ended September 30,		**Nine Months Ended September 30**	
	2022	**2021**	**2022**	**2021**
Biopharmaceutical revenue	$ 6,368	$ 5,241	$ 20,820	$
Contract manufacturing and testing	1,333	1,273	5,743	
Total	$ 7,701	$ 6,514	$ 26,563	$

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, 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, and our internal labor expenses. In addition, cost of product includes royalty costs for licensed technologies included in the Company's products. 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 biopharmaceutical research and development, commercialization, contract manufacturing and contract testing services on behalf of a customer.

Pension Liability

The Company offers a defined benefit pension plan to certain non-U.S. employees of its Veracyte SAS subsidiary. As of September 30, 2022 and December 31, 2021, the total pension obligation was $0.9 million and $1.1 million, respectively, and is included in other liabilities on the condensed consolidated balance sheets.

Recent Accounting Pronouncements

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, which requires entities to recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with ASC 2014-09, Revenue from Contracts with Customers (Topic 606). The update will generally result in an entity recognizing contract assets and contract liabilities at amounts consistent with those recorded by the acquiree immediately before the acquisition date rather than at fair value. The

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new standard is effective on a prospective basis for fiscal years beginning after December 15, 2022, with early adoption permitted. The Company does not expect to have a material impact on its consolidated financial statements and related disclosures from the adoption of this guidance.

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,	
	2022	2021	2022	2021
Shares of common stock subject to outstanding options	4,043,274	3,668,179	3,902,116	3,817,351
Employee stock purchase plan	39,177	14,445	40,094	16,686
Restricted stock units	2,114,223	1,246,888	1,929,696	1,011,466
Total common stock equivalents	6,196,674	4,929,512	5,871,906	4,845,503

3. Balance Sheet Components

Goodwill

Goodwill was $676.9 million and $707.9 million as of September 30, 2022 and December 31, 2021, respectively. The changes in the carrying amounts of goodwill during the nine months ended September 30, 2022 were due to foreign currency translation and measurement period adjustments. The Company has not recorded any impairment related to goodwill.

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, 2022			December 31, 2021			Weighted Avera Remaining Amortization Period (Years)
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	
Percepta product technology	$ 16,000	$ (8,000)	$ 8,000	$ 16,000	$ (7,200)	$ 8,800	7
Prosigna product technology	4,120	(778)	3,342	4,120	(572)	3,548	11
Prosigna customer relationships	2,430	(1,377)	1,053	2,430	(1,013)	1,417	1
nCounter Dx license	46,880	(8,855)	38,025	46,880	(6,511)	40,369	11
LymphMark product technology	990	(401)	589	990	(295)	695	4
Decipher product technology	90,000	(13,984)	76,016	90,000	(7,234)	82,766	8
Decipher trade names	4,000	(1,243)	2,757	4,000	(643)	3,357	3
HalioDx developed technology	36,367	(4,500)	31,867	45,640	(1,877)	43,763	9
HalioDx customer relationships	4,213	(861)	3,352	4,870	(352)	4,518	6
HalioDx customer backlog	5,976	(1,735)	4,241	6,908	(710)	6,198	2
Total finite-lived intangibles	210,976	(41,734)	169,242	221,838	(26,407)	195,431	8.9
In-process research and development	7,300	—	7,300	7,300	—	7,300	
Total intangible assets	$ 218,276	$ (41,734)	$ 176,542	$ 229,138	$ (26,407)	$ 202,731	

During the three months ended June 30, 2022, the Company concluded it had a triggering event requiring assessment of impairment for certain of its long-lived assets in conjunction with management's decision to cease commercialization efforts related to the Company's stand-alone Immunoscore Colon Dx commercial offering. As a result, the Company reviewed the long-lived assets for impairment and recorded a $3.3 million impairment charge associated with its HalioDx Immunoscore Colon Dx developed technology finite-lived intangible asset. The impairment is recorded within general and administrative expense on the condensed consolidated statement of operations for the nine months ended September 30, 2022. The impairment was assessed under an income approach estimating forecasted discounted cash flows. This method is consistent with the methods the Company employed in prior periods to value other long-lived assets.

Amortization of the finite-lived intangible assets is recognized on a straight-line basis. Amortization expense of $5.2 million and $5.0 million was recognized for the three months ended September 30, 2022 and 2021, respectively, and expense of $16.1 million and $10.5 million was recognized for the nine months ended September 30, 2022 and 2021, respectively.

The estimated future aggregate amortization expense as of September 30, 2022 is as follows (in thousands of dollars):

Year Ending December 31,	Amounts
2022 remainder of year	$ 5,184
2023	20,735
2024	20,695
2025	19,635
2026	17,899
Thereafter	85,094
Total	$ 169,242

Supplies and Inventory

As of September 30, 2022 and December 31, 2021, supplies and inventory consisted of $10.5 million and $8.2 million, respectively, of lab supplies and reagents consumed in the performance of testing services, and $3.3 million and $3.0 million, respectively, of inventory related to raw materials consumed in contract manufacturing process as well as finished diagnostic kits sourced from third parties related to product sales.

Accrued Liabilities

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

	September 30, 2022	December 31, 2021
Accrued compensation expenses	$ 25,732	$ 30,792
Accrued other	6,405	8,683
Total accrued liabilities	$ 32,137	$ 39,475

4. Business Combinations

HalioDx

On August 2, 2021, the Company acquired 100% of the equity interests, or 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. The HalioDx Acquisition gave the Company the capabilities and expertise to manufacture its own IVD test kits for use on the nCounter Analysis System. The acquisition also deepened the Company's scientific expertise and capabilities in the rapidly growing area of immuno-oncology, further strengthening its offerings for biopharmaceutical and other partners. The consideration to acquire HalioDx was $319.6 million, composed of $147.1 million in the form of 3.3 million shares of the

VERACYTE, INC.
Notes to Financial Statements
(unaudited)

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 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		9,298
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		92,303
Accounts payable		(2,645)
Accrued liabilities		(5,627)
Current portion of financing lease liability		(247)
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		(6,946)
Net identifiable assets acquired		69,794
Goodwill		249,846
Total purchase price	$	319,640

Since the acquisition, the Company has recorded certain measurement period adjustments due to new information becoming available pertaining to the valuation of accounts payable and certain other assets. These adjustments were recorded as net increases to goodwill totaling $0.2 million and did not impact the condensed consolidated statements of operations.

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, or the Decipher Acquisition.

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		(4,740)
Net identifiable assets acquired		126,428
Goodwill		468,266
Total purchase price	$	594,694

The measurement period concluded in March 2022, and no adjustments were recorded during the nine months ended September 30, 2022.

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 President of its CLIA US Business. Dr. Epstein continues to serve on Veracyte's board of directors.

5. Fair Value Measurements

The Company records certain of its financial assets and liabilities at fair value. The accounting guidance for fair value provides a framework for measuring fair value and clarifies the definition of fair value. 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 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 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 $108.7 million and $159.2 million as of September 30, 2022 and December 31, 2021, respectively, and are Level I assets as described above. The deposits for the leases, included in restricted cash, were $0.7 million as of both September 30, 2022 and December 31, 2021 and are a Level I assets as described above. There were no transfers between Levels 1, 2 or 3 for the three and nine months ended September 30, 2022 and 2021.

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 first achievement or occurrence, by or on behalf of Veracyte, of the commercial launch of the first, second and third diagnostic tests for use on the nCounter multiplex analysis system. 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, 2022 and December 31, 2021, this contingency was remeasured to $8.3 million and $8.4 million, respectively, with the corresponding changes included in general and administrative expense in the Company's condensed consolidated statements of operations. For the three months ended September 30, 2022 and 2021, expenses of zero and $0.1 million, respectively, were recorded in general and administrative expense for the changes in carrying value. For the nine months ended September 30, 2022 and 2021, a reversal of expense of $0.1 million and an expense of $0.3 million, respectively, were recorded. As of September 30, 2022, the achievement of two of the milestones is forecasted to occur within the next 12 months. As a result, $5.9 million of the contingent consideration is included in short term liabilities at September 30, 2022. 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, 2022 and December 31, 2021, 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, 2022**	**December 31, 2021**
Discount rate	8.9%	5.9%
Probability of achievement	80% - 100% (94%)	80% - 100% (94%)

Short-Term Investments Held-to-Maturity

The Company's short-term investments consist of time deposits with a bank with maturities at the time of purchase that were between 90 days and one year. The Company classifies these investments as held-to-maturity debt securities, which are reported at amortized cost, and are Level II assets as described above. As of September 30, 2022, the Company held no short-term investments and, as of December 31, 2021, short-term investments were recorded at amortized cost of $4.0 million and had a fair value of approximately $4.0 million. As of September 30, 2022 and December 31, 2021, gross unrealized losses on short-term investments were insignificant.

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 October 2030 and contain extension of lease terms and expansion options. The leases have a weighted average remaining lease term of 4.1 years as of September 30, 2022. The Company had deposits of $0.7 million included in long-term assets as of both September 30, 2022, and December 31, 2021 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 6.4% 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.

Future minimum lease payments under non-cancelable operating leases as of September 30, 2022 are as follows (in thousands of dollars):

Year Ending December 31,		**Amounts**
Remainder of 2022	$	1,149
2023		4,654
2024		4,423
2025		4,474
2026		1,389
Thereafter		1,524
Total future minimum lease payments		17,613
Less: amount representing interest		2,128
Present value of future lease payments		15,485
Less: short-term lease liabilities		3,958
Long-term lease liabilities	$	11,527

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,**			
	2022		**2021**		**2022**		**2021**	
Operating lease expense	$	1,105	$	982	$	3,271	$	2,460
Cash paid for amounts included in the measurement of lease liabilities	$	1,148	$	1,011	$	3,360	$	2,518

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 $0.4 million and $0.5 million, respectively, as of September 30, 2022, and are included in property and equipment, net and other liabilities in the accompanying condensed consolidated balance sheets. As of December 31, 2021, the total right-of-use assets and total financing lease liabilities for these financing leases were $0.7 million and $0.6 million, respectively.

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 at which time the Company will record a lease liability and a corresponding ROU asset. 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 allowed 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 Company had not drawn on the Revolving Line of Credit as of September 30, 2022. Borrowings under the Loan and Security Agreement matured on October 1, 2022. Amounts were 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 bore 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 bore interest at a variable rate equal to (i) LIBOR plus (ii) 3.50%, with a minimum rate of 4.70% per annum.

A final payment on the Term Loan Advance in the amount of $1.2 million was due upon the earlier of the maturity date of the Term Loan Advance or its payment in full. The Loan and Security Agreement contained customary representations, warranties, and events of default, as well as affirmative and negative covenants. As of September 30, 2022, the Company was in compliance with the loan covenants. The Company's obligations under the Loan and Security Agreement were 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, 2022	December 31, 2021
Debt principal	$ —	$ —
End-of-term debt obligation	1,187	1,026
Total debt obligation	$ 1,187	$ 1,026

As of September 30, 2022, the principal balance outstanding was one dollar. In October 2022, the Loan and Security Agreement matured, and the outstanding principal and final payment, totaling $1.2 million, was repaid in full.

The end-of-term debt obligation accreted over the term of the Loan and Security Agreement until maturity and is included in other income(loss), net 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, 2022	December 31, 2021
Stock options and restricted stock units issued and outstanding	6,502,656	4,892,164
Stock options and restricted stock units available for grant under stock option plans	5,189,164	4,418,364
Common stock available for the Employee Stock Purchase Plan	1,335,353	1,490,130
Total	13,027,173	10,800,658

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,	
	2022	2021	2022	2021
French research tax credits	$ 962	$ 419	$ 2,790	$ 419
Interest income	573	27	824	46
Interest expense	(61)	(61)	(193)	(177)
Loss on currency revaluation	(597)	708	(673)	(1,159)
Other	(72)	109	(73)	109
	$ 805	$ 1,202	$ 2,675	$ (762)

10. Income Taxes

The Company recorded income tax benefits of $0.2 million and $1.4 million for the three months ended September 30, 2022 and 2021, respectively, and $0.3 million and $5.3 million for the nine months ended September 30, 2022 and 2021, respectively. 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.

On August 16, 2022, the U.S. enacted the Inflation Reduction Act of 2022, which, among other things, implements a 15% minimum tax on book income of certain large corporations, a 1% excise tax on net stock repurchases and several tax incentives to promote clean energy. Based on its current analysis of the provisions, the Company does not believe this legislation will have a material impact on its consolidated financial statements.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q.

As discussed in the section titled "Special Note Regarding Forward Looking Statements," the following discussion and analysis contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth in the section titled "Risk Factors" under Part II, Item 1A.

When used in this report, all references to "Veracyte," the "company," "we," "our" and "us" refer to Veracyte, Inc., together with its consolidated subsidiaries, unless otherwise noted.

Veracyte, the Veracyte logo, HalioDx, Decipher, Decipher GRID, Afirma, Percepta, Envisia, Prosigna, LymphMark, Immunoscore, TMExplore, Brightplex, Immunosign, "Know by Design" and "More about You" are registered trademarks of Veracyte, Inc. and its subsidiaries in the U.S. and selected countries. nCounter is the registered trademark of NanoString Technologies, Inc., or NanoString, in the U.S. and selected countries and used by Veracyte under license.

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 leverages advances in molecular science and machine learning technology to improve care for patients, enabling them to avoid risky, costly procedures and interventions, and reduce time to appropriate treatment.

In addition to making our tests available in the United States through our central laboratories, our exclusive license for diagnostic rights to the nCounter Analysis System positions us to deliver our tests to patients worldwide through laboratories and hospitals that can perform the tests locally.

We develop tests that address significant unmet clinical needs in the diagnosis, prognosis and treatment of cancer and other diseases. We deploy a comprehensive strategic planning approach that broadly examines the clinical care spectrum in areas where our unique approach and expertise may potentially benefit physicians, patients and payers. In each disease area, our medical affairs and research teams focus intensely on understanding the patient journey and analyzing critical points of clinical decision-making, where having better information can impact what happens next for the patient.

Our extensive team of research, bioinformatics and clinical professionals rely on deep scientific expertise and an extensive network of practicing physicians and key opinion leaders, or KOLs, to help inform new product development. This includes determining what clinical question each test should answer, where it should be positioned in the patient work-up and what sample type and technology should be used. We develop our molecular tests using advanced scientific methods, such as RNA whole-transcriptome sequencing and machine learning. Veracyte's tests are purposefully designed to integrate easily into current physician protocols, delivering clinical utility and economic value to physicians, payers, and the healthcare system.

We currently offer tests in thyroid cancer (Afirma); prostate cancer (Decipher Prostate); breast cancer (Prosigna); lung cancer (Percepta); interstitial lung diseases (Envisia); and bladder cancer (Decipher Bladder). Our tests for kidney cancer and lymphoma are in development, the latter as a companion diagnostic.

We serve global markets with two complementary and inter-related models. In the United States, we offer laboratory developed tests, or LDTs, which we perform in our centralized, CLIA-certified laboratories in South San Francisco and San Diego, California, and Richmond, Virginia, supported by our cytopathology expertise in our Austin, Texas CLIA lab. In addition, outside of the United States, we intend to offer our tests as in vitro diagnostic, or IVD, tests that run on the nCounter Analysis System by laboratories that perform them for physicians and their patients locally. We believe our broad menu of advanced diagnostic tests, combined with our ability to deliver them globally, uniquely positions us in the diagnostics sector.

In the process of developing leading diagnostics across the oncology market, we have collected a significant number of patient samples and proprietary data related to various cancer types. We combine these assets with our robust machine learning core competency to further enhance our research and clinical development capabilities, as well as build opportunities with biopharmaceutical and other partners.

In March 2021, Veracyte acquired Decipher Biosciences, expanding our genomic testing menu into urologic cancers. The acquisition also provided Veracyte with Decipher GRID (Genomics Resource for Intelligent Discovery), a platform and database that helps drive biopharmaceutical partnerships, KOL engagement and pipeline development in urologic cancers.

In August 2021, we acquired HalioDx, giving us the capabilities and expertise to manufacture our own IVD test kits for use on the nCounter Analysis System. The acquisition also deepened our scientific expertise and capabilities in the rapidly growing area of immuno-oncology, further strengthening our offerings for biopharmaceutical and other partners.

COVID-19 and Macroeconomic Factors

We believe the COVID-19 outbreak, including its numerous variants, has impacted our total test volumes primarily during 2020 and 2021. Our customers, third-party contract manufacturers, carriers, 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 remained more accessible to patients and our sales reps. Our Afirma thyroid cancer test was impacted by COVID-19 in 2020 and portions of 2021 as a majority of our samples come from large institutions which are less accessible to patients and our reps. We believe our pulmonology business has been the most impacted since the bronchoscopy procedures used to collect samples for our Percepta and Envisia tests are considered elective procedures and are performed in hospital settings, which have been more restrictive, and these tests are ordered by pulmonologists who could be largely preoccupied with caring for COVID-19 patients.

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, develop alternative sources of supply and implement procedures to mitigate the impact on our supply chain and 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 total test volumes or levels of revenue.

In addition, ongoing interest rate increases and persistent inflation in the U.S. and other markets globally may increase the risk of an economic recession and volatility and dislocation in the capital or credit markets in the U.S. or globally. Moreover, the continued strengthening of the U.S. dollar compared to other currencies (including the Euro, in which a material portion of our European sales are denominated), has impacted and may continue to impact our results of operations. We intend to continue to monitor macroeconomic conditions closely and may determine to take certain financial or operational actions in response to such conditions as appropriate.

The extent of the impact of COVID-19 and other macroeconomic factors 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; the impact to our sales and renewal cycles; changes in central bank policies and interest rates; rates of inflation; and changes in foreign currency exchange rates. See Risk Factors for further discussion.

Factors Affecting Our Performance

Reported Total 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 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.

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. 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 and associated collections, 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 Advancing 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 Decipher Biosciences in March 2021 and HalioDx in August 2021 may impact our revenue and operating results as we integrate various functions.

Revenue growth from our biopharmaceutical and IVD contract manufacturing partners depends on our ability to deliver services, information and/or achieve milestones.

How We Recognize Revenue

We recognize revenue in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers*, or ASC 606. 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.

Testing Revenue

We bill for testing services at the time of test completion as defined by the delivery of test results. We recognize revenue 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 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.

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 determine accrual rates by calculating an average of reimbursement from all payers for tests performed over a four-quarter period as it reduces the effects of temporary volatility and seasonality. The periods selected to determine accrual rates are at least six months old because it takes a significant period of time to collect from some payers. We may also determine accrual rates based on other factors such as coverage decisions, contracts, or more recent reimbursement data as appropriate.

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

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. Revenue is presented net of the taxes that are collected from customers and remitted to governmental authorities.

Biopharmaceutical and Other Revenue

We enter into arrangements to license or provide access to our assets or services, including testing services, clinical services, research and development, contract manufacturing and development, as well as other services. Such arrangements may require us to deliver various rights, data, services, manufactured diagnostic test kits, access and/or testing services to partner biopharmaceutical companies. One such arrangement is a collaborative arrangement that falls under the scope of ASC Topic 808, *Collaborative Arrangements,* or ASC 808. 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 808, are recognized in the same manner as milestone payments from customers and are considered to be 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 delivered to a customer, 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 revenue generated from royalties or profit sharing as the underlying sales occur.

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 on activities to secure clinical trial results in support of our testing and product development portfolio and on-market tests, as well as clinical validation and utilization studies. The timing of these research and development activities is difficult to predict, as is the timing of clinical trial enrollments and 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, 2022, we had derived most of our revenue from the sale of Decipher and Afirma 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,	
	2022	2021	2022	2021
Medicare	31 %	31 %	31 %	31 %
UnitedHealthcare	10 %	9 %	10 %	10 %
	41 %	40 %	41 %	41 %

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 Testing 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, 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.

Cost of Product Revenue

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.

Cost of Biopharmaceutical and Other Revenue

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 development, and contract testing services on behalf of a customer. This cost is mainly composed 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 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 incurred a majority of our research and development expenses in support of our pipeline products in 2021 and in the nine months ended September 30, 2022. Going forward, we expect to incur significant expense as we invest in the development of our pipeline products, including required clinical studies, the development of current tests for the nCounter instrument and the transition of manufacturing to our Veracyte SAS facility.

Selling and Marketing

Selling and marketing expenses consist of compensation expenses, direct marketing expenses, professional fees, other expenses such as travel and communications costs, as well as 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, 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. General and administrative expenses include costs related to the acquisitions of Decipher Biosciences and HalioDx, which were included in general and administrative compensation expense and professional fees. We expect general and administrative expenses to continue to increase as we build our infrastructure to scale revenue, 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 $20.7 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 Income (Loss), Net

Other income (loss), net consists primarily of realized and unrealized gains and losses on foreign currency transactions, French research tax credits, interest expense on our debt and interest income from our cash held in interest bearing accounts. The French research tax credits (crédit d'impôt recherche or CIR) are generated by our wholly-owned subsidiary, Veracyte SAS, in connection with its research efforts performed in Marseille, France.

Foreign Currency Translation

The functional currency of our foreign subsidiary, Veracyte SAS, 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. Revenue 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 income (loss), net, on the condensed consolidated statements of operations.

Results of Operations

Comparison of the three and nine months ended September 30, 2022 and 2021 (in thousands of dollars, except percentages and test volume):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2022	2021	Change	%	2022	2021	Change	%
Revenue:								
Testing revenue	$ 64,577	$ 50,897	$ 13,680	27%	$ 180,275	$ 134,768	$ 45,507	34%
Product revenue	3,314	2,959	355	12%	9,401	8,706	695	8%
Biopharmaceutical and other revenue	7,701	6,514	1,187	18%	26,563	8,704	17,859	205%
Total revenue	75,592	60,370	15,222	25%	216,239	152,178	64,061	42%
Operating expense:								
Cost of testing revenue	19,816	16,073	3,743	23%	55,923	42,494	13,429	32%
Cost of product revenue	1,981	1,491	490	33%	5,202	4,304	898	21%
Cost of biopharmaceutical and other revenue	4,211	4,079	132	3%	13,626	4,720	8,906	189%
Research and development	10,773	8,006	2,767	35%	29,316	19,591	9,725	50%
Selling and marketing	25,678	21,670	4,008	18%	73,433	57,628	15,805	27%
General and administrative	17,600	20,749	(3,149)	(15)%	58,310	82,504	(24,194)	(29)%
Intangible asset amortization	5,213	4,983	230	5%	16,090	10,507	5,583	53%
Total operating expenses	85,272	77,051	8,221	11%	251,900	221,748	30,152	14%
Loss from operations	(9,680)	(16,681)	7,001	(42)%	(35,661)	(69,570)	33,909	(49)%
Other income (loss), net	805	1,202	(397)	(33)%	2,675	(762)	3,437	(451)%
Loss before income taxes	(8,875)	(15,479)	6,604	(43)%	(32,986)	(70,332)	37,346	(53)%
Income tax benefit	(152)	(1,350)	1,198	(89)%	(270)	(5,297)	5,027	(95)%
Net loss	$ (8,723)	$ (14,129)	$ 5,406	(38)%	$ (32,716)	$ (65,035)	$ 32,319	(50)%
Other Operating Data:								
Diagnostic tests reported	24,000	18,842	5,158	27%	67,661	50,127	17,534	35%
Product tests sold	2,374	2,130	244	11%	6,862	6,138	724	12%
Total test volume	26,374	20,972	5,402	26%	74,523	56,265	18,258	32%
Depreciation and amortization expense	$ 6,321	$ 6,138	$ 183	3%	$ 19,372	$ 13,189	$ 6,183	47%
Stock-based compensation expense	$ 7,442	$ 8,234	$ (792)	(10)%	$ 20,423	$ 16,154	$ 4,269	26%

Revenue

Revenue increased $15.2 million for the three months ended September 30, 2022 compared to the same period in 2021. This was primarily due to a $13.7 million increase in testing revenue driven by a 27% volume increase in our diagnostic tests, as well as a $1.2 million increase in our Biopharmaceutical and other revenue. Testing revenue and tests reported for the three months ended September 30, 2022 increased primarily due to continued adoption of our Decipher and Afirma tests. Product revenue increased $0.4 million for the three months ended September 30, 2022 compared to the same period in 2021, primarily due to an increase in product tests sold and sales of the nCounter Analysis System, partially offset by a decline in currency exchange rates. Biopharmaceutical and other revenue primarily increased for the three months ended September 30, 2022 driven primarily by the contribution of the HalioDx acquisition.

Revenue increased $64.1 million for the nine months ended September 30, 2022 compared to the same period in 2021. This was primarily due to a $45.5 million increase in testing revenue driven by a 35% volume increase in our diagnostic tests, as well as a $17.9 million increase in our Biopharmaceutical and other revenue. Testing revenue and tests reported for the nine months ended September 30, 2022 increased primarily due to the addition of the Decipher urology tests following our acquisition of Decipher Biosciences on March 12, 2021, which contributed $41.4 million to the increase in testing revenue during the nine months ended September 30, 2022. Product revenue increased $0.7 million for the nine months ended September 30, 2022 compared to the same period in 2021, primarily driven by an increase in product tests sold and sales of the nCounter Analysis System, partially offset by a decline in currency exchange rates. Biopharmaceutical and other revenue primarily increased for the nine months ended September 30, 2022 driven primarily by the contribution of the HalioDx acquisition.

Cost of revenue

Comparison of the three and nine months ended September 30, 2022 and 2021 is as follows (in thousands of dollars, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2022	2021	Change	%	2022	2021	Change	%
Cost of testing revenue:								
Laboratory costs	$ 9,492	$ 8,777	$ 715	8 %	$ 27,790	$ 23,489	$ 4,301	18 %
Sample collection costs	2,724	1,337	1,387	104 %	7,170	3,989	3,181	80 %
Compensation expense	4,522	3,111	1,411	45 %	12,738	8,381	4,357	52 %
License fees and royalties	26	332	(306)	(92)%	(1)	585	(586)	(100)%
Depreciation and amortization	280	291	(11)	(4)%	935	830	105	13 %
Other expenses	1,257	972	285	29 %	3,058	2,032	1,026	50 %
Allocations	1,515	1,253	262	21 %	4,233	3,188	1,045	33 %
Total	$ 19,816	$ 16,073	$ 3,743	23 %	$ 55,923	$ 42,494	$ 13,429	32 %
Cost of product revenue:								
Product costs	$ 1,460	$ 1,201	$ 259	22 %	$ 3,933	$ 3,459	$ 474	14 %
License fees and royalties	276	271	5	2 %	825	789	36	5 %
Depreciation and amortization	61	19	42	221 %	112	56	56	100 %
Other expenses	160	—	160	NM	281	—	281	NM
Allocations	24	—	24	NM	51	—	51	NM
Total	$ 1,981	$ 1,491	$ 490	33 %	$ 5,202	$ 4,304	$ 898	21 %
Cost of biopharmaceutical and other revenue:								
Compensation expense	$ 2,030	$ 1,770	$ 260	15 %	$ 6,907	$ 1,862	$ 5,045	271 %
License fees and royalties	13	6	7	117 %	84	6	78	1,300 %
Depreciation and amortization	96	84	12	14 %	271	84	187	223 %
Other expenses	2,001	2,219	(218)	(10)%	6,196	2,768	3,428	124 %
Allocations	71	—	71	NM	168	—	168	NM
Total	$ 4,211	$ 4,079	$ 132	3 %	$ 13,626	$ 4,720	$ 8,906	189 %

Cost of testing revenue increased $3.7 million for the three months ended September 30, 2022 compared to the same period in 2021. The increase for cost of testing is related to increased volume in testing, primarily related to Decipher.

Cost of testing revenue increased $13.4 million for the nine months ended September 30, 2022 compared to the same period in 2021. Following the acquisition of Decipher Biosciences in March 2021, its operations are included in cost of testing revenue. The remaining increase for cost of testing is related to increased volume in testing, primarily related to Afirma.

Cost of product revenue is related to sales of Prosigna. Cost of product revenue increased $0.5 million, or 33%, for the three months ended September 30, 2022 compared to the same period in 2021, primarily due to an increased volume of test and system sales.

Cost of product revenue increased $0.9 million, or 21%, for the nine months ended September 30, 2022 compared to the same period in 2021, primarily due to an increased volume of test and system sales.

Cost of biopharmaceutical and other revenue includes labor costs incurred by our employees working on customer projects, 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.

Research and development

Comparison of the three and nine months ended September 30, 2022 and 2021 is as follows (in thousands of dollars, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2022	2021	Change	%	2022	2021	Change	%
Research and development expense:								
Compensation expense	$ 6,647	$ 5,422	$ 1,225	23%	$ 20,341	$ 13,863	$ 6,478	47 %
Direct research and development expense	1,896	1,382	514	37%	3,944	2,840	1,104	39 %
Depreciation and amortization	126	285	(159)	(56)%	360	405	(45)	(11)%
Other expenses	1,330	323	1,007	312%	2,633	927	1,706	184 %
Allocations	774	594	180	30%	2,038	1,556	482	31 %
Total	$ 10,773	$ 8,006	$ 2,767	35%	$ 29,316	$ 19,591	$ 9,725	50 %

Research and development expense increased $2.8 million, or 35%, for the three months ended September 30, 2022 compared to the same period in 2021. The operations of HalioDx are included in research and development expense following our acquisition of it in August 2021. The remaining increase is primarily due to expense related to headcount and annual compensation increases.

Research and development expense increased $9.7 million, or 50%, for the nine months ended September 30, 2022 compared to the same period in 2021. The increase in compensation expense was primarily due to an increase in headcount, including the additions of new personnel from the acquisitions of Decipher Biosciences and HalioDx.

Selling and marketing

Comparison of the three and nine months ended September 30, 2022 and 2021 is as follows (in thousands of dollars, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2022	2021	Change	%	2022	2021	Change	%
Selling and marketing expense:								
Compensation expense	$ 19,102	$ 15,335	$ 3,767	25 %	$ 54,691	$ 40,951	$ 13,740	34 %
Direct marketing expense	1,650	1,629	21	1 %	4,671	5,683	(1,012)	(18)%
Other expenses	3,435	3,220	215	7 %	9,894	7,541	2,353	31 %
Allocations	1,491	1,486	5	— %	4,177	3,453	724	21 %
Total	$ 25,678	$ 21,670	$ 4,008	18 %	$ 73,433	$ 57,628	$ 15,805	27 %

Selling and marketing expense increased $4.0 million, or 18%, for the three months ended September 30, 2022 compared to the same period in 2021. The increase in compensation expense was primarily due to the addition of HalioDx employees in August 2021. The increase in other expenses was primarily due to increased travel and entertainment expense given limited travel in the prior year.

Selling and marketing expense increased $15.8 million, or 27%, for the nine months ended September 30, 2022 compared to the same period in 2021. The increase in compensation expense was primarily due to the addition of Decipher employees in March 2021, as well as HalioDx employees in August 2021. The increase in other expenses was primarily due to the addition of Decipher Biosciences, along with increased travel and entertainment.

General and administrative

Comparison of the three and nine months ended September 30, 2022 and 2021 is as follows (in thousands of dollars, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2022	2021	Change	%	2022	2021	Change	%
General and administrative expense:								
Compensation expense	$ 12,031	$ 12,135	$ (104)	(1)%	$ 38,721	$ 52,871	$ (14,150)	(27)%
Occupancy expenses	1,424	1,502	(78)	(5)%	4,416	3,622	794	22 %
Depreciation and amortization	547	476	71	15 %	1,598	1,307	291	22 %
Other expenses	7,473	9,969	(2,496)	(25)%	24,242	32,901	(8,659)	(26)%
Allocations	(3,875)	(3,333)	(542)	16 %	(10,667)	(8,197)	(2,470)	30 %
Total	$ 17,600	$ 20,749	$ (3,149)	(15)%	$ 58,310	$ 82,504	$ (24,194)	(29)%

General and administrative expense decreased by $3.1 million for the three months ended September 30, 2022, compared to the same period in 2021. This decrease is driven by expenses recognized in the three months ended September 30, 2021 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. The remaining increase was driven primarily in compensation related to the acquisition of HalioDx in August 2021, headcount additions and annual compensation adjustments. General and administrative expenses related to occupancy costs and information technology costs are allocated to general and administrative expense, selling and marketing expense, research and development expense, and cost of revenue based on the headcount and employee location.

General and administrative expense decreased by $24.2 million for the nine months ended September 30, 2022, compared to the same period in 2021. This decrease is driven by expenses recognized in the nine months ended September 30, 2021 related to the acquisition of Decipher Biosciences, including $27.0 million of stock-based compensation and $18.3 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 contributed to an increase in general and administrative expenses. Additionally, we recorded expense of $3.3 million in the nine months ended September 30, 2022 related to the impairment of an intangible asset. The remaining increase was primarily due to annual compensation adjustments and investments in infrastructure.

Other income (loss), net

Other income (loss), net, decreased $0.4 million for the three months ended September 30, 2022 compared to the same period in 2021, due to a decrease of $1.3 million of unrealized foreign currency loss partially offset by an increase of $0.5 million from operations in France related to the CIR during the period and an increase of $0.5 million from interest and dividend income. We recognize other income from the CIR over time based on when the research and development expenses are incurred.

Other income (loss), net, increased $3.4 million for the nine months ended September 30, 2022 compared to the same period in 2021, due to an increase of $2.4 million from operations in France related to the CIR during the period, an increase of $0.8 million from interest and dividend income and an increase of $0.5 million due to unrealized foreign currency loss.

Income tax benefit

We recorded income tax benefits of $0.2 million and $1.4 million for the three months ended September 30, 2022 and 2021, respectively, and $0.3 million and $5.3 million for the nine months ended September 30, 2022 and 2021, respectively. The income tax benefit for 2021 was primarily impacted by a discrete tax adjustment related to the release of certain valuation allowances on our deferred tax assets upon recording of the deferred tax liabilities for the acquisition of Decipher Biosciences.

Liquidity and Capital Resources

From inception through September 30, 2022, 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, 2022, we had a net loss of $32.7 million, and we expect to incur additional losses for the remainder of 2022 and potentially in future years. As of September 30, 2022, we had an accumulated deficit of $389.9 million.

We believe our existing cash and cash equivalents and short-term investments of $170.1 million as of September 30, 2022, 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, capital expenditures, lease obligations 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, 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 and other operating restrictions that could adversely affect our ability to conduct our business. 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.

Operating Leases

We lease office and laboratory facilities in South San Francisco and San Diego, California; Austin, Texas; Marseille, France; and Richmond, Virginia, and lease certain equipment under various non-cancelable lease agreements. The lease terms extend to October 2030 and contain extension of lease term and expansion options. As of September 30, 2022, the leases have a weighted average remaining lease term of 4.1 years and total future minimum lease payments of $17.6 million.

Veracyte SAS has signed 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 we currently expect to occur in the fourth quarter of 2023 at which time we will record a lease liability and a corresponding ROU asset. 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.

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. As of September 30, 2022, the principal balance outstanding was one dollar. In addition, a final payment on the Term Loan in the amount of $1.2 million is due upon the maturity date. In October 2022, the Loan and Security Agreement matured, and we repaid the outstanding principal and final payment totaling $1.2 million.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2022 and 2021 (in thousands of dollars):

	Nine Months Ended September 30,	
	2022	2021
Net cash used in operating activities	$ (2,209)	$ (40,067)
Net cash used in investing activities	(2,953)	(739,591)
Net cash provided by financing activities	3,401	596,147

Cash Flows from Operating Activities

Cash used in operating activities for the nine months ended September 30, 2022 was $2.2 million. The net loss of $32.7 million includes non-cash charges of $19.9 million of stock-based compensation expense, $19.4 million of depreciation and amortization, which includes $16.1 million of intangible asset amortization, $3.3 million of impairment of intangible asset and non-cash lease expense of $2.5 million. Cash used as a result of changes in operating assets and liabilities was $16.0 million, primarily comprising a decrease in accrued liabilities and deferred revenue of $6.0 million, an increase in accounts receivable of $4.4 million, an increase in supplies and inventory of $2.8 million, a decrease in operating lease liability of $2.6 million and a $0.1 million impact from other working capital accounts.

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 comprising 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 Flows from Investing Activities

Cash used in investing activities, for the nine months ended September 30, 2022, was $3.0 million for the purchase and maturity of short-term investments and purchase of property and equipment.

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 Flows from Financing Activities

Cash provided by financing activities, for the nine months ended September 30, 2022, was $3.4 million, consisting of $6.1 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 $2.6 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, 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 ESPP, partially offset by $8.3 million in tax payments during the period related to the vesting of restricted stock units granted to employees.

Recent Accounting Pronouncements

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, which requires entities to recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with ASC 2014-09, Revenue from Contracts with Customers (Topic 606). The update will generally result in an entity recognizing contract assets and contract liabilities at amounts consistent with those recorded by the acquiree immediately before the acquisition date rather than at fair value. The new standard is effective on a prospective basis for fiscal years beginning after December 15, 2022, with early adoption permitted. We do not expect to have a material impact on our consolidated financial statements and related disclosures from the adoption of this guidance.

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 $170.1 million as of September 30, 2022 which consisted of 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

As of September 30, 2022 we held $5.0 million of bank deposits and time 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. As of September 30, 2022 a hypothetical 10% appreciation or depreciation of the U.S. dollar relative to the Euro would have increased or decreased our net loss by $0.5 million for nine months ended September 30, 2022.

Inflation Risk

We are facing inflation headwinds in compensation, travel and supply costs, however we do not believe that inflation has had a material effect on our business, financial condition, or operating results.

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. 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, 2022, 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.

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.
- 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 our other diagnostic tests to grow our business.
- If we are unable to grow sales of our portfolio of tests including Prosigna, Envisia, and Decipher Bladder, or we are unable to launch or commercialize our new tests, 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.
- We have estimated the sizes of the markets for our current and future products and services, and these markets may be different than we estimate.
- 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.
- 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.
- 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 and manufacture select tests to be performed on the nCounter Analysis System.
- If we are not successful in advancing our biopharma collaborations, or if our general strategy of seeking growth through such collaborations is not successful, our prospects and financial condition will suffer.
- The COVID-19 pandemic has had, and may continue to have, 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.
- 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 or notified regulatory bodies 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 increasingly extensive regulatory requirements, which may be subject to change, 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 depend on our senior management team, and the loss of one or more of our executive officers, or the inability to attract and retain highly-skilled employees or 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 revenue could be diminished.
- 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.
- Aspects of our international business expose us to business, personnel, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States.
- Our operating results may be adversely affected by unfavorable economic and market conditions.
- Security breaches, loss of data and other disruptions to our or our third-party service providers' data systems 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.

Risks Related to our Recent Acquisitions

- The acquisitions of HalioDx and Decipher Biosciences each present risks and we must successfully integrate the HalioDx and Decipher Biosciences businesses to realize the financial goals that we currently anticipate.

Risks Related to Being a Public Company

- 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.

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.

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, 2022 and 2021, we had net losses of $33 million and $65 million, respectively. As of September 30, 2022, we had an accumulated deficit of $390 million. We expect to incur additional losses in the future, and we may never achieve revenue sufficient to offset our expenses. We have experienced and may continue to experience decreases in total test volume due to the impact of COVID-19, including as a result of additional COVID-19 variants. Additionally, in 2022, widespread inflationary pressures in the U.S. and across global economies resulted in higher costs for our raw materials, non-material costs, labor and other business costs, and significant increases in the future could adversely affect our results of operations. We expect to continue to devote substantially all of our resources to increase adoption of and reimbursement for our molecular diagnostic portfolio of 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 our other diagnostic tests 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. We also derive significant revenue from our Decipher urological tests. 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 Prosigna, Percepta, Envisia, and Immunoscore 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 tests 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, Decipher Prostate, Prosigna, Envisia, and Decipher Bladder tests, or develop and commercialize other tests, 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 Prosigna, Envisia, and Decipher Bladder, or we are unable to launch or commercialize our new tests, our business may suffer.

Although Prosigna, Envisia, and Decipher Bladder 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 new tests going forward as well. There can be no assurance that we will be successful in our launch or commercialization of new tests, nor that physicians will request our new tests be performed in sufficient volumes for our revenue to meet our projections. Additionally, we anticipate expanding the reach of our 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.

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.

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, 2022, compared with 31% and 10%, respectively, for the nine months ended September 30, 2021. 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.

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 payment rates made between January 1 and June 30, 2016, which we reported to the Centers for Medicare & Medicaid Services 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 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 for the payment rates based on 2017 reporting through December 31, 2022. In December 2021, through the Protecting Medicare and American Farmers from Sequester Cuts Act, Congress further delayed the next reporting period to 2023. 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. Since the Afirma GSC code 81546 was newly issued in 2021, the first PAMA data collection period for 81546 under the current triennial data collection and reporting process would be January 2023 through June 2023. There is no guarantee that the Afirma GSC Medicare rate will not be negatively impacted starting in 2027 based on the reported weighted median of private commercial payers.

New CPT Proprietary Laboratory Analyses, or PLA, codes were also 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 rate for 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 a new CPT code, for Afirma MTC as a stand-alone test. 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.

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.

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.

An LCD was issued for Prosigna by Palmetto GBA in August 2015, which has been in effect since October 1, 2015. There can be no assurance that the Afirma or Prosigna rates will not decrease during subsequent reporting cycles under PAMA.

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 submit claims to Medicare for Percepta using an unlisted code under the MolDX program and MolDX priced Percepta at $3,220. There is no assurance that MolDX won’t reprice Percepta in the future and the rate could be lower than $3,220.

Noridian Healthcare Solutions provided Medicare coverage for the Envisia Genomic Classifier on April 11, 2019.

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, 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.

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.

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 is currently not subject to a coverage policy from Medicare or any of the MACs. HalioDx's Immunoscore test has been assigned CPT code 0261U effective October 1, 2021. The Immunoscore code went through the national payment determination process, was crosswalked to CPT code 0108U and assigned a rate of $2,513.25 effective January 1, 2022. There is no assurance that the clinical laboratory fee schedule rate for Immunoscore will not decrease during a future reporting cycle under PAMA or that Medicare may require a coverage policy in the future.

Although we have entered into contracts with certain third-party payers that establish in-network allowable rates of reimbursement for many of our 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.

We have estimated the sizes of the markets for our current and future products and services, and these markets may be different than we estimate.

Our estimates of the annual addressable markets for our current tests, products and services and those under development are based on a number of internal and third-party estimates, including, without limitation, the number of patients who have developed one or more of a broad range of cancers and certain diseases, the number of individuals who are at a higher risk for developing one or more of broad range of cancers and certain diseases, the number of individuals with certain diseases we or our collaborators are able to detect through our tests, products and services, the proportion of patients in each market whose needs can be addressed by our or our collaborators' tests, products and services, the number of potential tests utilized per patient and the assumed prices at which we can sell our current and future tests, products and services for markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be as accurate as we initially intended and the conditions upon which our assumptions or estimates are based may change at any time. As a result, our estimates of the annual addressable market for our current or future tests, products and services may ultimately be incorrect. If the actual number of patients who would benefit from our tests, products or services, the price at which we can sell future tests, products and services or the annual addressable market for our tests, products or services is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

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 are an out-of-network provider with some commercial payers in the U.S. and thus, we do not have control over rates or terms of reimbursement. Without contracted rates 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 we are out-of-network, there is typically a greater patient cost-share responsibility which may result in further delays and/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, Decipher Prostate, Prosigna, Percepta, Envisia, Decipher Bladder, and Immunoscore 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 clinical utility 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.

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.

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, Decipher Prostate Biopsy, Decipher Prostate RP, Percepta, Envisia, 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.

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 conduct 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. We have received approval for the Afirma, Decipher Prostate, Percepta, Envisia and Decipher Bladder tests. 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, limitation or otherwise, 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, whether as a result of revocation, suspension, limitation or otherwise, 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, limitation or otherwise, 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.

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 conditions in the US and globally, 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; and
- seek and obtain regulatory clearances, approvals or certifications of our new solutions, as required by applicable regulatory bodies.

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 tests, or we may be required to expend considerable resources repeating clinical studies, which would adversely impact the timing for generating potential revenue from those new diagnostic tests. In addition, as we develop diagnostic tests, 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 study, 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. Furthermore, most of our European sales are denominated in Euros, and as the U.S. dollar has strengthened in recent periods relative to the Euro, our results of operations may be adversely affected even where our underlying business is performing as anticipated. 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 securities 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.

If a 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, we acquired the nCounter Analysis System and Prosigna test from NanoString, we also acquired Decipher Biosciences and 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 future success and international growth depends, in part, on our ability to adapt and manufacture 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 genetic tests 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 biopharma collaborations, 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.

The COVID-19 pandemic has had, and may continue to have, an adverse effect on our business, results of operations and financial condition.

The COVID-19 pandemic and the ongoing emergence of new variants has caused, and continues to cause, significant volatility in global financial markets. 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. The global COVID-19 pandemic continues to evolve. Certain jurisdictions have begun re-opening only to return to restrictions due to increases in new COVID-19 cases and the emergence of new variant strains of COVID-19. 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, timing to receive patient sample shipments and additional costs related to business continuity initiatives, that cannot be fully mitigated through succession planning, employees working remotely or teleconferencing technologies. To date, the FDA has approved several vaccines, certain of which are subject to an Emergency Use Authorization, or EUA, for certain uses. Although vaccines are increasingly available in the United States and Europe, and certain countries in South America, Asia and Oceania, 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:

- Inability of healthcare providers to deliver anticipated total test volumes due to temporary or permanent staff attrition.
- 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. 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 total 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.
- We may incur significant employee health care costs under our insurance programs.
- Inability or delay of regulatory bodies to conduct inspections/surveys, review or clear/approve our regulatory filings and submissions, and perform other activities necessary for us to conduct our business.

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 emergence of new variant strains of COVID-19, 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 and services 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. Periodically, as a result of the COVID-19 pandemic and other challenges to global supply chains, 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 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 tests to physicians or deliver patient reports and we may incur higher one-time switching costs. Carriers responsible for transporting samples to us are currently operating at lower than usual capacity because of COVID-19, causing delays in the timeliness of our receipt of samples. 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 total 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 total 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.

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 2031). 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. The Protecting Medicare and American Farmers from Sequester Cuts Act, enacted on December 10, 2021, extends the suspension through March 31, 2022, after which a 1.0% sequestration would apply for Medicare payments made between April 1, 2022 and June 30, 2022. The legislation also applies a 2.25% sequestration to Medicare payments made during the first six months of fiscal year 2030, and a 3% reduction to payments made during the last six months of fiscal year 2030.

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 revenue 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. In December 2021, through the

Protecting Medicare and American Farmers from Sequester Cuts Act, Congress further delayed the next reporting period to 2023. 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, Decipher Prostate Biopsy, Decipher Prostate RP, Percepta, 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. HHS, the Department of Labor, and the Department of the Treasury in 2021 implemented the No Surprises Act through Interim Final Rules issued on July 1, 2021 and 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, Decipher Prostate Biopsy, Decipher Prostate RP, Percepta, Envisia, 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, Decipher Prostate Biopsy, Decipher Prostate RP, Percepta, Envisia, 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 clinical diagnostic tests developed and run within a single CLIA-certified clinical laboratory (known as “laboratory developed tests” or “LDTs”), are not currently subject to regulation under the FDA's enforcement discretion policy. While the FDA maintains its authority to regulate LDTs, it continues to exercise enforcement discretion not to enforce the premarket review, quality system/current Good Manufacturing Practices regulations, and other applicable medical device requirements against most LDT developers and users. Certain reagents, instruments, software or components manufactured and sold by third parties and used by their customers to manufacture or perform diagnostic tests may be subject to regulation under certain circumstances. Further, FDA has raised concerns about companies who manufacture, and label finished clinical test kits or clinical testing components as “research use only”, or RUO, or “investigational use only”, or IUO, and either knowingly use them or sell them for use in patient care. We believe that the Afirma, Decipher Prostate Biopsy, Decipher Prostate RP, Percepta, Envisia, and Decipher Bladder classifiers, as well as Immunoscore, have been developed and are performed in a manner consistent with FDA’s enforcement discretion policy.

In October 2014, the FDA issued two draft guidance documents stating that the FDA intended to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the existing classification of medical devices. Although the FDA halted finalization of the guidance in November 2016 to allow for further public discussion on an appropriate oversight approach to LDTs and to give Congressional authorizing committees the opportunity to develop a legislative solution, it is unclear if Congress or the FDA will modify the current approach to the regulation of LDTs in a way that would subject our current or future services marketed as LDTs to the enforcement of FDA regulatory requirements. The FDA Commissioner and the Director of the Center for Devices and Radiological Health, or CDRH, have expressed significant concerns regarding disparities between some LDTs and in vitro diagnostics that have been reviewed, cleared, authorized or approved by the FDA. If the FDA were to determine that Afirma, Decipher Prostate Biopsy, Decipher Prostate RP, Percepta, Envisia, and Decipher Bladder classifiers, as well as Immunoscore, offered as LDTs are not within the scope of FDA's enforcement discretion policy for LDTs for any reason, including new rules, policies or guidance, or due to changes in statute, our tests may become subject to extensive FDA requirements, or our business may otherwise be adversely affected. If the FDA were to disagree with our LDT status or modify its approach to regulating LDTs, we could experience reduced revenue or increased costs, which could adversely affect our business, prospects, results of operations and financial condition.

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, with an updated discussion draft proposed by the Senate on May 18, 2022 as part of the Food and Drug Administration (FDA) Safety and Landmark Advancements Act (FDASLA). 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.

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. The EU Regulation (EU) 2017/746 of April 5, 2017, repealing the IVDD, referred to as the IVD Medical Devices Regulation, or IVDR, became applicable on May 26, 2022 (subject to certain transition provisions). Under the IVDR, the general safety and performance requirements set out in Annex I are also applicable to devices that are not placed on the market but used in the context of a commercial activity. 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. Following Brexit, the IVDR will not be applicable in Great

Britain (although it will apply in Northern Ireland), but the UK government is currently undertaking a consultation on the regime applicable to in vitro diagnostics in the UK, and it is anticipated that similar provisions will be introduced as under the IVDR.

If the FDA or foreign authorities were to require us to seek clearance, approval or certification for our existing tests that are not currently cleared, approved, or certified or any of our future products for clinical use, we may not be able to obtain such clearances, approvals or certifications on a timely basis, or at all. While we believe our Afirma, Decipher Prostate Biopsy, Decipher Prostate RP, Percepta, Envisia, 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 or if legislative reforms are enacted. 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 kits are listed as Class I devices with the FDA. If the FDA were to determine that they are not Class I devices or otherwise not exempt from 510(k) clearance requirements, we would be required to file 510(k) premarket notifications and obtain FDA clearance to use the containers, which could be time consuming and expensive.

The FDA has taken the position that if evidence demonstrates that a product which otherwise meets the definition of a regulated medical device is inappropriately labeled RUO or IUO, distribution, sale, or use of the product could violate the misbranding or adulteration provisions of the Federal Food, Drug, and Cosmetic Act, or the FDC Act. In the EU, under the IVDD, RUO products which are intended to be used for research purposes, without any medical objective, are not regarded as devices for performance evaluation used in diagnostic procedures. More importantly, the IVDR expressly provides that products intended for RUO are excluded from the scope of the regulation. A material intended for RUO, without any medical purpose or objective, is therefore not considered as an IVD MD and is not subject to compliance with the IVD MDs requirements. Depending on the product in question, other regulations may be applicable to the RUO products. Some of the reagents, instruments, software or components obtained by us from suppliers for use in our products are currently labeled by those suppliers as “RUO” or “IUO”. If the FDA or foreign bodies 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 or be forced to recall them, 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. Such actions could also lead FDA to investigate our purchase and use of supplier products and for the Agency to question whether or not Veracyte has violated the FDC Act.

Obtaining marketing authorization or certification by the FDA and foreign regulatory authorities or notified regulatory bodies 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, we obtained FDA 510(k) clearance for Prosigna 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.

The FDA issued guidance titled "In Vitro Companion Diagnostic Devices" that 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 cleared or approved 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. 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.

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 regulation, 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 tests 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 some of our products in the EU, those products must comply with the General Safety and Performance Requirements of the IVDR. Compliance with these requirements is a prerequisite to place IVD products on the EU market. All medical devices placed on the market in the EU must meet the General Safety and Performance Requirements laid down in Annex I to the IVDR, including the requirement that an IVD MD 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 General Safety and Performance 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 IVD MDs 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.

The EU regulatory landscape concerning medical devices has significantly changed, and the new IVDR governing IVD MDs became applicable on May 26, 2022 (subject to certain transitional provisions meaning that were such transitional provisions apply, the products can continue to be placed on the market under the IVDD for a certain period of time). The new requirements in the IVDR have a significant effect on the way we conduct our business in the EU and the EEA. In particularly, substantially more IVDs require the involvement of a notified body to be able to affix a CE Mark to the product, which may lead to delay in being able to place such products on the market.

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 IVD MDs in the EU and would require that we re-classify and obtain new certificates of conformity for our existing CE-marked IVD MDs by May 25, 2022, unless a transitional provision applies to the product, meaning that where such transitional provisions apply, the products can continue to be placed on the market under the IVDD for a certain period of time. For most IVD MDs, the manufacturer used to self-declare the conformity of its products with the essential requirements of the IVDD. Under the IVDR, the majority of IVD MDs require now the intervention of a notified body for conformity assessment. 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 audits and examines the product’s technical documentation and the manufacturer’s quality system. If satisfied that the relevant product conforms to the General Safety and Performance Requirements, the notified body issues a certificate 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 IVDR will not be implemented in Great Britain, and since January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, has become 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). The UK regulation implemented the three pre-existing EU directives, including the IVDD. Following the end of the Brexit transitional period on January 1, 2021, new regulations require medical devices to be registered with the MHRA before being placed on the Great Britain market. The MHRA only registers devices where the manufacturer or their United Kingdom, or UK, Responsible Person has a registered place of business in the UK. Manufacturers based outside the UK need to appoint a UK Responsible Person that has a registered place of business in the UK to register devices with the MHRA. 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 regulatory bodies will remain valid until this time. Manufacturers may choose to use the UKCA mark on a voluntary basis until June 30, 2023.

For the time being, the regulatory regime for medical devices and IVD MDs in Great Britain (England, Scotland and Wales) continues to be based on the requirements derived from current EU legislation. An MHRA public consultation was opened until end of November 2021 on the post-Brexit regulatory framework for medical devices and diagnostics. The MHRA seeks to amend the UK Medical Devices Regulations 2002, in particular to create a new access pathway to support innovation, create an innovative framework for regulating software and artificial intelligence as medical devices, reform IVD MD regulation, and foster sustainability through the reuse and remanufacture of medical devices. The regime is expected to come into force in July 2023, coinciding with the end of the acceptance period for EU CE marks in Great Britain, subject to appropriate transitional arrangements. The consultation indicated that the MHRA will publish guidance in relation to the changes to the regulatory framework and may rely more heavily on guidance to add flexibility to the regime.

Subject to the outcome of the MHRA public consultation on the post-Brexit regulatory framework for medical devices and diagnostics, the UK may choose to retain regulatory flexibility or align with the EU Medical Devices Regulation and the IVDR going forward. EU CE markings will continue to be recognized in the UK, and certificates issued by EU-registered notified regulatory bodies will be valid in the UK, until June 30, 2023. For medical devices, including IVD MDs, 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 regulatory bodies are not recognized on the EU market.

The rules for placing medical devices on the Northern Ireland market differ from those in Great Britain, and the IVDR will apply in Northern Ireland. Under the terms of the Northern Ireland Protocol of the Withdrawal Agreement between the EU and UK, Northern Ireland follows EU rules on medical devices, including the IVDR when applicable. Therefore, 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 is 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 is applied and the device may only be placed on the market in Northern Ireland and not the EU.

A mutual recognition agreement (MRA) aligning in vitro diagnostic (IVD) regulations between the European Union and Switzerland has officially expired following the In Vitro Diagnostic Medical Devices Regulation’s (IVDR) May 26, 2022 date of application, impacting certification and authorized representation requirements for manufacturers. The Swiss government has issued its own Ordinance on In Vitro Diagnostic Medical Devices (IvDO). The Swiss regulation aligns closely with the IVDR in terms of requirements for manufacturers, and follows the IVDR's transitional timelines regarding compliance deadlines according to IVD risk classifications as well as designations of Swiss Authorized Representatives.

These modifications may have an effect on the way we intend to conduct our business in these countries.

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.

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 studies as well as the authorizations or certifications to sell the companion diagnostic tests following completion of such studies. Some of the compensation we expect to receive pursuant to these collaborations is based on the receipt of authorizations or certifications. Any failure to obtain 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, the IVDR has introduced a new classification system for companion diagnostics which are now specifically defined as a device which is essential for the safe and effective use of a corresponding medicinal product to: (a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or (b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product. Companion diagnostics 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 or the relevant national competent authority on the suitability of the companion diagnostic to the medicinal product concerned.

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 increasingly extensive regulatory requirements, which may be subject to change, and our failure to comply with these requirements could substantially harm our business.

Certain of our products are regulated as IVD MDs, 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 CLIA and state laboratory quality statutes and regulations, the FDC Act and related FDA regulations, and other statutory and regulatory requirements enforced by other government authorities. These may include routine inspections by notified bodies, FDA, CMS, and other health authorities, of our manufacturing facilities and our records for compliance with standards such as ISO 13485 and the QSR, 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 (and similar listings and certifications in certain other countries); continued adverse event and malfunction reporting; reporting certain corrections and removals; and labeling and promotional requirements.

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 the product. 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 IVDR became applicable five years after publication (on May 26, 2022), subject to relevant transitional periods, and once applicable to a particular product, 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;
- establish recourse for damage caused by a defective device; 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.

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 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.

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. For example, FDA has issued a proposed rule to revise the QSR to more closely align with ISO 13485:2016 but that also includes proposed clarifications and additional definitions and requirements. 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 or diagnostic tests provided by other commercial and academic laboratories. For 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, for example, 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.

Our Decipher Prostate test faces competition from Myriad Genetics and Exact Sciences, which offer genomic testing for prognostic purposes within localized prostate cancer. Additionally, traditional methods used by pathologists and clinicians to estimate risk of disease progression pose competitive threats to our business. Companies combining these traditional methods with artificial intelligence could potentially emerge as competitors, but most of these technologies are currently in the research stage. In bladder cancer, we are not currently aware of a direct competitor offering genomic testing for prognostic purposes that match the intended use population for the Decipher Bladder test. However, DNA mutational analysis and traditional clinical methods and nomograms are currently in use by physicians for similar purposes.

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.

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 depend on our senior management team, and 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. Executive transitions may impact our ability to implement our business strategy and could have a material adverse effect on our business.

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, and the labor market in our industry is becoming increasingly competitive. 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 Decipher Prostate, Prosigna, Percepta, Envisia, Decipher Bladder and Immunoscore tests, 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. 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 U.S. 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. Finally, we rely, in part, on equity awards to compensate and incentivize our employees to drive our further growth. As the equity capital markets have been highly volatile in recent periods and the price of our common stock has declined, certain of our employees' equity awards have lost some or all of their value, which may limit their effectiveness as retention tools and, in the event we fail to retain such employees, may adversely affect our business, results of operations and financial condition.

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 began using the new CPT code 81546 to bill for our Afirma classifier, and code 81545 was retired. Effective October 1, 2020, we began using the CPT code 0204U to bill for Afirma Xpression Atlas, and CPT code 0208U to bill for Afirma MTC. We ceased billing 0208U on January 1, 2022 as the CPT code was deleted by the CPT editorial panel. Effective January 1, 2020, we began using CPT code 81542 to bill for Decipher Prostate Biopsy and Decipher Prostate RP tests. 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. Effective January 1, 2021, we began using the new CPT code 81554 to bill for our Envisia classifier. Effective October 1, 2020, we began using CPT code 0016M to bill for our Decipher Bladder test. Effective October 1, 2021, we began using the new CPT code 0261U to bill for the Immunoscore test.

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 total revenue. 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 total revenue 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 revenue 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 total 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 tests that requires us to devote considerable resources to research and development. We may face challenges obtaining sufficient numbers of samples to validate a genomic signature for a molecular diagnostic product. We must provide sufficient clinical validity and utility studies that meet individual payer evidence requirements to obtain reimbursement. Even after launching new products, we must complete additional studies that meet the clinical evidence required by individual payers 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 pandemic.

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, regulatory, and compliance 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 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.

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 to those standards in 2013 pursuant to the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, which strengthened and expanded HIPAA privacy and security compliance requirements, increased penalties for violators, extended enforcement authority to state attorneys general, and imposed new 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 covered recipients, including physicians, as defined by such law, teaching hospitals, and certain healthcare providers as well as ownership or investment interests that physicians or physicians' immediate family members hold with the reporting entity;
- 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 IVD MDs), 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 and 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.

Aspects of our international business expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our business strategy currently includes international presence and 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. In 2021, we acquired HalioDx, an immuno-oncology diagnostics company that is based in Marseille, France, and operates globally. 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, including payers mandating additional evidence requirements for reimbursement consideration;
- 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 (including as a direct or indirect result of the conflict in Ukraine); 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 operating results may be adversely affected by unfavorable economic and market conditions.

Our business or financial results may be adversely impacted by uncertain economic conditions, including: the impact of the COVID-19 pandemic, adverse changes in interest rates, foreign currency exchange rates, tax laws or tax rates; inflation; a recession; contraction in the availability of credit in the marketplace due to legislation or other economic conditions, which may potentially impair our ability to access the capital markets on terms acceptable to us or at all; and the effects of government initiatives to manage economic conditions. Many of the countries in which we operate, including the U.S. and those in Europe, have experienced and continue to experience uncertain economic conditions, including increased inflation rates, resulting from global as well as local factors. For example, in February 2022, Russia launched a significant military action against Ukraine, the short and long-term implications of which are difficult to predict at this time. The impact to Ukraine as well as actions taken by other countries, including new and stricter sanctions imposed by the U.S. and the European Union, and other countries and companies and organizations, could adversely affect the global economy and financial markets and thus could affect our business and results of operations, as well as the price of our common stock and our ability to raise additional capital when needed on acceptable terms.

Moreover, we cannot predict how future economic conditions will affect our customers, suppliers and distributors and any negative impact on our critical customers, suppliers or distributors may also have an adverse impact on our results of operations or financial condition. A severe or prolonged economic downturn, as result of a global pandemic such as the COVID-19 pandemic or otherwise, could result in a variety of risks to our business, including weakened demand for our products and services and our ability to raise additional capital when needed on favorable terms, if at all. A weak or declining economy could strain our collaborators, possibly resulting in supply disruption, or cause delays in their payments to us. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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.

Errors or defects in our products or services could harm our reputation, decrease market acceptance of our products or services or expose us to product liability claims, and we could face substantial liabilities that exceed our resources.

We are creating new tests, products and services, many of which are initially based on novel technologies. Our new tests and products may contain undetected errors or defects that are not identified until after they are first introduced to the market. As all of our tests, products and services progress, we or others may determine that we made unintended scientific or technological mistakes or omissions. Furthermore, the testing processes utilize a number of complex and sophisticated biochemical, informatics, optical and mechanical processes, many of which are highly sensitive to external factors and variation between testing runs. Refinements to our processes may initially result in unanticipated issues that reduce efficiency or increase variability. In particular, sequencing, which is a key component of these processes, could be inefficient with higher-than-expected variability. This could increase total sequencing costs and reduce the number of samples we can process in a given time period, which may negatively impact customer turnaround time. Additionally, our laboratory operations could result in any number of errors or defects. Our quality assurance system or product development processes may fail to prevent us from inadvertent problems with samples, sample quality, lab processes including sequencing, software, data upload or analysis, raw materials, reagent manufacturing, assay quality or design, or other components or processes. Moreover, our assays may have quality or design errors, and we may have inadequate procedures or instrumentation to process samples, assemble our proprietary primer mixes and commercial materials, upload and analyze data, or otherwise conduct our laboratory operations. Additionally, 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 Decipher Prostate, Prosigna, Percepta, Envisia, Decipher Bladder and Immunoscore tests, as well as tests we may develop or acquire in the future.

Any of the foregoing defects or errors could harm our reputation, decrease market acceptance of our products or services or expose us to product liability claims. A product liability or errors and omissions liability claim could further 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, decrease market acceptance of our products or cause us to recall or 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, including any developments or consequences of the conflict in Ukraine or related sanctions, 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. Our laboratory in Richmond, Virginia performs our Immunoscore test. 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 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. 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 our or our third-party service providers' data systems 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, other personally identifiable information, 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 protect sensitive information and prevent business interference, which could harm our ability to conduct business and/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 currently aware of any such attack or breach having occurred, if such event were to occur and cause interruptions in our operations, our networks would be compromised and the information we store on those networks could potentially 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, and penalties under federal, state, and international laws and regulations that protect the privacy and security of personal information, such as the HIPAA regulations and the EU General Data Protection Regulation, or GDPR. Unauthorized access, loss or dissemination of such data also could 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, and manage the administrative aspects of our business, any of which could adversely affect our business, including by materially damaging our reputation.

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 enforced in a manner that we have not anticipated in designing our practices and compliance policies. 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 under section 319 of the Public Health Service Act during the Public Health Emergency, or PHE, 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, 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 in 2018, 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 or similar laws on our business or operations, but they 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 imposed 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 to disclose to data subjects how their personal data is to be used, protected, and shared; 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. Continued compliance with these obligations could cause us to change our business practices, and we risk 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-protective transfer mechanism has been put in place. On July 16, 2020, the Court of Justice of the European Union, or CJEU, issued a decision undermining the validity of the data-protective transfer mechanisms previously relied on, creating widespread uncertainty about compliance with the GDPR rules on data transfers to non-“adequate” jurisdictions.

While the CJEU generally confirmed the validity of the European Commission-approved “Standard Contractual Clauses”, or SCCs, as a personal data-protective transfer mechanism, it made clear that reliance on the SCCs alone may not necessarily be sufficient in all circumstances. Use of the SCCs 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. In response to the CJEU decision, the European Commission has published revised SCCs; existing SCC arrangements must be migrated to the revised SCCs by December 27, 2022. We must implement the revised SCCs, in relation to relevant existing contracts and certain additional contracts and arrangements, by that date. In addition, the revised SCCs are not to be relied on for data transfers to non-EEA entities subject to the GDPR, and we are waiting for further guidance on valid mechanisms for data transfers from the EEA to such entities.

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 developments may lead to additional costs and increase our overall risk exposure.

In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil and criminal penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

The CCPA established individual privacy rights for California consumers and places increased privacy and data security obligations on entities handling personal information of consumers or households. The CCPA was amended several times after its enactment, most recently by the California Privacy Rights Act, or the CPRA, which, as of its effective date of January 1, 2023, gives California residents expanded privacy rights, including the right to opt out of certain personal information sharing, the use of "sensitive personal information," and the use of personal information for automated decision-making or targeted advertising. The CCPA and CPRA provide for civil penalties and a private right of action for data breaches that is expected to increase data breach litigation. The CCPA and CPRA may increase our compliance costs and potential liability. Following the lead of California, several other states, including Colorado, Utah, Virginia and Connecticut have each enacted laws similar to the CCPA/CPRA and other states are considering enacting privacy laws as well. The multiple layers of privacy law within the United States could increase our potential liability, increase our compliance costs, and adversely affect our business.

Other countries outside of the United States and Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency and restricting cross-border data transfer, which could increase the cost and complexity of delivering our services and operating our business. For example, Brazil recently enacted the General Data Protection Law (Lei Geral de Proteção de Dados Pessoais or LGPD) (Law No. 13,709/2018), and effective November 1, 2021 was China's Personal Information Protection Law (个人信息保护法, PIPL), both of which broadly regulate the processing of personal information and impose compliance obligations and penalties comparable to those of the GDPR.

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 SCCs cannot be used, and/or commence enforcement actions, 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, urological diagnostics, breast cancer diagnostics, lung 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, the patent laws of the United States allow for various post-grant opposition proceedings, and their outcome can be difficult to predict. 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, 2021, we had net operating loss, or NOL, carryforwards of approximately $437.1 million, $87.6 million and $133.1 million available to reduce future taxable income, if any, for federal, California and other state income tax purposes, respectively. The U.S. federal NOL carryforwards will begin to expire in 2026 while for state purposes, the NOL carryforwards begin to expire in 2022. In addition, as of December 31, 2021, we had foreign net operating loss carryforwards of approximately $74.7 million and $31.3 million available to reduce future taxable income, if any, for Canadian and French income tax purposes, respectively. The Canada net operating loss carryforwards will begin to expire in 2034, while for French purposes, the net operating losses will carryforward indefinitely. 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 consolidated 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 acquisitions of HalioDx and Decipher Biosciences each present 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 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 (including, for example, systems integration), 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 and requiring issuers to maintain accurate books and records or maintain appropriate accounting controls, fair competition regulations, the U.S. Office of Foreign Assets Control sanctions compliance program, 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, our ability to enter into governmental sale, supply, or service contracts, 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, such as the recent strengthening of the U.S. dollar relative to the Euro, may also affect the relative prices at which we are able to sell products in the same market. Our revenue 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 accounting and 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.

Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain investors, employees, regulators and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, matters. Some investors may use these non-financial performance factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our policies and actions relating to corporate responsibility are inadequate. We may face reputational damage in the event that we do not meet the ESG standards set by various constituencies.

Furthermore, if our competitors' corporate social responsibility performance is perceived to be better than ours, potential or current investors may elect to invest with our competitors instead. In addition, in the event that we communicate certain initiatives and goals regarding environmental, social and governance matters, we could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could be criticized for the scope of such initiatives or goals. If we fail to satisfy the expectations of investors, employees and other stakeholders or our initiatives are not executed as planned, our reputation and business, results of operations, and financial condition could be adversely affected.

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, including inflation and changes in interest rates, 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.

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. We may 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 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

ITEM 6. EXHIBITS

		Incorporated by Reference				
Exhibit Number	**Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**	**Filed Herewith**
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 3, 2022

VERACYTE, INC.

By:	/s/ Rebecca Chambers
	Rebecca Chambers *Chief Financial Officer*

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, 2022;

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 3, 2022

/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, 2022;

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 3, 2022

/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, 2022, 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 3, 2022

/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, 2022, 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 3, 2022

/s/ Rebecca Chambers

Rebecca Chambers
Chief Financial Officer
(Principal Financial Officer)