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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 March 31, 2024
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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	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 ☒

As of May 3, 2024, there were 76,448,070 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:

- the factors that may impact our financial results;
- 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;
- our expectations with respect to the impact of inflation, rising interest rates and foreign exchange fluctuations, as well as regional conflicts globally, energy and supply chain disruptions, and the resulting market volatility on our business;
- our beliefs with respect to the optimization of our processes for the analysis of ribonucleic acid, or RNA, samples;
- our beliefs with respect to importance of maintaining libraries of clinical evidence;
- our expectations regarding the Percepta Nasal Swab classifier for early lung cancer detection;
- our expectations regarding the addition of minimal residual detection capabilities to our diagnostic platform;
- our expectations regarding the timing and success of our transition to offering more of our tests as in vitro diagnostic tests on multiple platforms worldwide;
- our ability to continue to receive quality reagents and other raw materials from certain single source suppliers;
- our ability to successfully integrate C2i Genomics, Inc., or C2i, HalioDx and Decipher Biosciences into our business and our ability to deploy the nCounter Analysis System successfully and run our tests on this and other platforms worldwide;
- our expectations regarding our partnerships and agreements;
- our expectations regarding capital expenditures, our anticipated cash needs and our estimates regarding our capital requirements and profitability;
- our business strategy and our ability to execute on our strategy;
- our ability to obtain and maintain Medicare, other government payer, and other commercial third party payer reimbursement at acceptable levels and our expectations regarding the timing of reimbursement;
- our expectations with regard to the estimated number of patients eligible for our tests and the attributes and potential benefits of our tests and any future tests we may develop to patients, physicians, and payers;
- our expectations on our ability to drive demand for and reimbursement of our tests; our sales, marketing and distribution capabilities and strategy;
- our intellectual property position;
- the impact of government laws and regulations, policies, guidance agency interpretations and judicial decisions; and
- our beliefs in our competitive position.

We caution you that the foregoing list does not contain all of the forward-looking statements made in this report. 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)

	March 31, 2024	December 31, 2023 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 209,188	$ 216,454
Accounts receivable	46,665	40,378
Supplies and inventory	18,328	16,128
Prepaid expenses and other current assets	16,237	12,661
Total current assets	290,418	285,621
Property, plant and equipment, net	21,566	20,584
Right-of-use assets, operating leases	11,167	10,277
Intangible assets, net	116,348	88,593
Goodwill	753,853	702,984
Restricted cash	1,082	876
Other assets	5,639	5,971
Total assets	$ 1,200,073	$ 1,114,906
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 12,152	$ 12,943
Accrued liabilities	30,293	38,427
Current portion of deferred revenue	2,602	2,008
Current portion of acquisition-related contingent consideration	6,934	2,657
Current portion of operating lease liabilities	5,982	5,105
Current portion of other liabilities	89	101
Total current liabilities	58,052	61,241
Deferred tax liabilities	1,340	734
Acquisition-related contingent consideration, net of current portion	13,446	518
Operating lease liabilities, net of current portion	8,058	7,525
Other liabilities	528	786
Total liabilities	81,424	70,804
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 125,000,000 shares authorized, 76,425,272 and 73,264,738 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	76	73
Additional paid-in capital	1,617,465	1,536,168
Accumulated deficit	(469,985)	(468,121)
Accumulated other comprehensive loss	(28,907)	(24,018)
Total stockholders' equity	1,118,649	1,044,102
Total liabilities and stockholders' equity	$ 1,200,073	$ 1,114,906

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 March 31,	
	2024	**2023**
Revenue:		
Testing revenue	$ 90,303	$ 72,396
Product revenue	3,537	3,892
Biopharmaceutical and other revenue	3,004	6,134
Total revenue	96,844	82,422
Operating expenses:		
Cost of testing revenue	25,979	19,648
Cost of product revenue	2,644	2,162
Cost of biopharmaceutical and other revenue	2,838	4,419
Research and development	15,965	12,769
Selling and marketing	23,782	26,130
General and administrative	26,210	21,053
Impairment of long-lived assets	429	1,410
Intangible asset amortization	3,653	5,329
Total operating expenses	101,500	92,920
Loss from operations	(4,656)	(10,498)
Other income, net	2,748	2,407
Loss before income taxes	(1,908)	(8,091)
Income tax benefit	(44)	—
Net loss	$ (1,864)	$ (8,091)
Net loss per common share, basic and diluted	$ (0.02)	$ (0.11)
Shares used to compute net loss per common share, basic and diluted	74,759,789	72,175,457

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 March 31,	
	2024	**2023**
Net loss	$ (1,864)	$ (8,091)
Other comprehensive income (loss):		
Change in currency translation adjustments	(4,889)	4,480
Net comprehensive loss	$ (6,753)	$ (3,611)

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 December 31, 2023	73,265	$ 73	$ 1,536,168	$ (468,121)	$ (24,018)	$ 1,044,102
Issuance of common stock and options for acquisition	2,698	3	74,142	—	—	74,145
Issuance of common stock upon exercise of stock options and vesting of restricted stock units	382	—	1,271	—	—	1,271
Issuance of common stock under employee stock purchase plan (ESPP)	80	—	1,697	—	—	1,697
Tax portion of vested restricted stock units	—	—	(3,832)	—	—	(3,832)
Stock-based compensation expense (employee)	—	—	7,728	—	—	7,728
Stock-based compensation expense (ESPP)	—	—	291	—	—	291
Net loss	—	—	—	(1,864)	—	(1,864)
Other comprehensive income	—	—	—	—	(4,889)	(4,889)
Balance at March 31, 2024	76,425	$ 76	$ 1,617,465	$ (469,985)	$ (28,907)	$ 1,118,649

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	71,959	$ 72	$ 1,500,191	$ (393,717)	$ (31,346)	$ 1,075,200
Issuance of common stock upon exercise of stock options and vesting of restricted stock units	332	—	1,988	—	—	1,988
Issuance of common stock under ESPP	92	—	1,974	—	—	1,974
Tax portion of vested restricted stock units	—	—	(2,277)	—	—	(2,277)
Stock-based compensation expense (employee)	—	—	7,612	—	—	7,612
Stock-based compensation expense (ESPP)	—	—	373	—	—	373
Net loss	—	—	—	(8,091)	—	(8,091)
Other comprehensive loss	—	—	—	—	4,480	4,480
Balance at March 31, 2023	72,383	$ 72	$ 1,509,861	$ (401,808)	$ (26,866)	$ 1,081,259

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

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

	Three Months Ended March 31,	
	2024	**2023**
Operating activities		
Net loss	$ (1,864)	$ (8,091)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,590	6,670
Loss on disposal of property, plant and equipment	30	121
Stock-based compensation	8,019	7,985
Deferred income taxes	(120)	—
Noncash lease expense	1,139	903
Revaluation of acquisition-related contingent consideration	5	(485)
Effect of foreign currency on operations	637	(224)
Impairment loss	429	1,410
Changes in operating assets and liabilities:		
Accounts receivable	(6,459)	(1,302)
Supplies and inventory	(2,303)	1,055
Prepaid expenses and other current assets	(2,738)	(3,064)
Other assets	259	(491)
Operating lease liabilities	(1,053)	(950)
Accounts payable	(1,544)	2,012
Accrued liabilities and deferred revenue	(8,993)	(7,721)
Net cash used in operating activities	(8,966)	(2,172)
Investing activities		
Acquisition of C2i, net of cash acquired	5,012	—
Purchase of short-term investments	—	(19,700)
Proceeds from sale of short-term investments	—	39,773
Proceeds from maturity of short-term investments	—	5,000
Purchases of property, plant and equipment	(2,134)	(993)
Net cash provided by investing activities	2,878	24,080
Financing activities		
Payment of taxes on vested restricted stock units	(3,832)	(2,277)
Proceeds from the exercise of common stock options and employee stock purchases	2,968	3,962
Net cash (used in) provided by financing activities	(864)	1,685
Increase (decrease) in cash, cash equivalents and restricted cash	(6,952)	23,593
Effect of foreign currency on cash, cash equivalents and restricted cash	(108)	50
Net increase (decrease) in cash, cash equivalents and restricted cash	(7,060)	23,643
Cash, cash equivalents and restricted cash at beginning of period	217,330	154,996
Cash, cash equivalents and restricted cash at end of period	$ 210,270	$ 178,639
Supplementary cash flow information:		
Purchases of property, plant and equipment included in accounts payable and accrued liability	$ 1,754	$ 1,624

Cash, Cash Equivalents and Restricted Cash:

	March 31, 2024	**December 31, 2023**
Cash and cash equivalents	$ 209,188	$ 216,454
Restricted cash	1,082	876
Total cash, cash equivalents and restricted cash	$ 210,270	$ 217,330

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

VERACYTE, INC.
Notes to Financial Statements
(unaudited)

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

Veracyte, Inc., or Veracyte, or the Company, is a global diagnostics company that provides clinicians with tests to diagnose cancer. Veracyte's tests are used by clinicians for diagnostic, prognostic and treatment decisions.

Veracyte was incorporated in the state of Delaware on August 15, 2006, as Calderome, Inc. Calderome operated as an incubator until early 2008. On March 4, 2008, the Company changed its name to Veracyte, Inc. The Company's headquarters are in South San Francisco, California, and it also has operations in San Diego, California; Austin, Texas; and Marseille, France.

The Company currently offers tests in thyroid cancer (Afirma); prostate cancer (Decipher Prostate); breast cancer (Prosigna); and bladder cancer (Decipher Bladder). The Company's Percepta Nasal Swab test is being run in its Clinical Laboratory Improvement Amendments of 1988, or CLIA, certified lab in support of clinical studies and its test for lymphoma is in development as a companion diagnostic.

The Company serves global markets with two complementary models. In the United States, it offers laboratory developed tests, or LDTs, through its centralized, CLIA certified laboratories in South San Francisco and San Diego, California, supported by its cytopathology expertise in Austin, Texas. Additionally, primarily outside of the United States, the Company provides its Prosigna test to patients through distribution to laboratories and hospitals that can perform the tests locally as an IVD test that runs on the nCounter Analysis System.

In February 2024, the Company acquired C2i, a minimal residual disease, or MRD, detection company. Refer to Note 4 Business Combination for additional information.

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 March 31, 2024, the condensed consolidated statements of operations for the three months ended March 31, 2024 and 2023, the condensed consolidated statements of comprehensive loss for the three months ended March 31, 2024 and 2023, the condensed consolidated statements of stockholders' equity for the three months ended March 31, 2024 and 2023, and the condensed consolidated statements of cash flows for the three months ended March 31, 2024 and 2023 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, 2023 has been derived from audited financial statements. The results for the three months ended March 31, 2024 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, 2023.

Reclassifications

Certain prior period balances have been reclassified to conform to current period presentation of the Company's 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 three months ended March 31, 2023, the Company reclassified $1.4 million of impairment of long-term assets from the general and administrative caption in the condensed consolidated statements of operations to a separate caption within operating expenses.

VERACYTE, INC.
Notes to Financial Statements
(unaudited)

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, plant and equipment; the recoverability of long-lived assets; the incremental borrowing rates 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 majority of the Company's cash and cash equivalents are deposited with two major financial institutions in the United States. Deposits in these institutions 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 Analysis system and some of the related service kits, are obtained from single-source suppliers. If these single-source suppliers fail to satisfy the Company's requirements on a timely basis, or are unable to provide the Company with reagents that perform to specifications, 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 March 31, 2024, the Company has derived most of its revenue 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 March 31, 2024.

The Company's total 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 March 31,	
	2024	**2023**
Medicare	31 %	31 %
UnitedHealthcare	9 %	10 %
	40 %	41 %

The Company's significant third-party payers in excess of 10% of total accounts receivable and their related accounts receivable balance as a percentage of total accounts receivable were as follows:

	March 31, 2024	**December 31, 2023**
Medicare	20 %	20 %

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.

Restricted Cash

The Company had deposits of $1.1 million and $0.9 million included in long-term assets as of March 31, 2024 and December 31, 2023, respectively, restricted from withdrawal and held by banks in the form of collateral for irrevocable standby letters of credit held as security for the Company's leases.

Revenue Recognition

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 recognizes revenue from the sale of tests performed for customers, including patients and institutions, at the time test results are reported to physicians. Most tests requested by customers are sold without a written agreement; however, the Company determines that an implied contract exists with its customers for whom a physician will order the test. The Company identifies each sale of its test to a customer as a single performance obligation. A stated contract price does not exist and the transaction price for each implied contract with a customer represents variable consideration. The Company estimates the variable consideration under the portfolio approach and considers the historical reimbursement data from third-party commercial and governmental payers and patients, as well as known or anticipated reimbursement trends not reflected in the historical data. The Company monitors the estimated amount to be collected in the portfolio at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. Both the estimate and any subsequent revision contain uncertainty and require the use of significant judgment in the estimation of the variable consideration and application of the constraint for such variable consideration. The Company analyzes its actual cash collections over the expected reimbursement period and compares it with the estimated variable consideration for each payer group and any difference is recognized as an adjustment to estimated revenue after the expected reimbursement period, subject to assessment of the risk of future revenue reversal. For the three months ended March 31, 2024 and 2023, the Company recorded $3.0 million and $2.3 million as revenue, respectively, resulting from cash collections exceeding the estimated variable consideration related to tests reported in previous years, including revenue received from successful appeals of reimbursement denials, net of recoupments.

Product Revenue

The Company's products consist of the Prosigna breast cancer assay, the nCounter Analysis System, related diagnostic kits and services. 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 to license or provide access to its assets or services, including clinical and testing services, research and development, contract manufacturing and development, as well as other services, which are classified under biopharmaceutical and other revenue. Such arrangements may require the Company to deliver various rights, data, test results, manufactured diagnostic test kits, services and/or samples, including intellectual property rights/licenses and biopharmaceutical research and development 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 $4.0 million at March 31, 2024 and $6.0 million at December 31, 2023. There was $2.6 million and $2.0 million of deferred revenue related to these agreements at March 31, 2024 and December 31, 2023, respectively. Revenue included in biopharmaceutical and other revenue for the three months ended March 31, 2024 and 2023 was as follows (in thousands of dollars):

	Three Months Ended March 31,	
	2024	2023
Biopharmaceutical revenue	$ 953	$ 4,447
Contract manufacturing and testing	2,051	1,687
Total	$ 3,004	$ 6,134

Cost of Testing Revenue

The components of the Company's 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 the Company's 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 license or provide access to its assets or services, including clinical and testing services, research and development, contract manufacturing and development, as well as other services.

Pension Liability

The Company offers a defined benefit pension plan to certain non-U.S. employees of its Veracyte SAS subsidiary. As of March 31, 2024 and December 31, 2023, the total pension obligation was $0.5 million and $0.8 million, respectively, and is included in other liabilities on the condensed consolidated balance sheets.

Recent Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board issued ASU No. 2023-09, *Improvements to Income Tax Disclosures (Topic 740)*. This update requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as additional information on income taxes paid. This ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is also permitted for annual financial statements that have not yet been issued or made available for issuance. This ASU will result in the required additional disclosures being included in the Company's consolidated financial statements, once adopted.

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 March 31,	
	2024	**2023**
Shares of common stock subject to outstanding options	3,627,695	3,767,086
Employee stock purchase plan	29,334	33,998
Restricted stock units	2,936,332	2,349,151
Total common stock equivalents	6,593,361	6,150,235

3. Balance Sheet Components

Goodwill

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

	Amounts
Balance as of December 31, 2023	$ 702,984
Goodwill acquired - C2i	55,974
Effect of foreign currency translation on Goodwill acquired - HalioDx	(5,105)
Balance as of March 31, 2024	$ 753,853

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):

	March 31, 2024			December 31, 2023			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	$ (9,600)	$ 6,400	$ 16,000	$ (9,333)	$ 6,667	6
Prosigna product technology	4,120	(1,190)	2,930	4,120	(1,122)	2,998	11
Prosigna customer relationships	2,430	(2,106)	324	2,430	(1,985)	445	1
LymphMark product technology	990	(613)	377	990	(577)	413	3
Decipher product technology	90,000	(27,484)	62,516	90,000	(25,234)	64,766	7
Decipher trade names	4,000	(2,443)	1,557	4,000	(2,243)	1,757	2
HalioDx developed technology	1,404	(374)	1,030	1,435	(346)	1,089	7
HalioDx customer relationships	2,699	(1,436)	1,263	2,760	(1,331)	1,429	2
HalioDx customer backlog	4,166	(2,734)	1,432	4,258	(2,529)	1,729	1
C2i developed technology	25,300	(281)	25,019	—	—	—	15
Total finite-lived intangibles	151,109	(48,261)	102,848	125,993	(44,700)	81,293	8.7
In-process research and development	13,500	—	13,500	7,300	—	7,300	
Total intangible assets	$ 164,609	$ (48,261)	$ 116,348	$ 133,293	$ (44,700)	$ 88,593	

Acquisition-related intangibles are generally finite-lived and are carried at cost less accumulated amortization. Amortization of the finite-lived intangible assets is recognized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized.

Amortization expense of $3.7 million and $5.3 million was recognized for the three months ended March 31, 2024 and 2023, respectively.

The estimated future aggregate amortization expense as of March 31, 2024 is as follows (in thousands of dollars):

Year Ending December 31,	Amounts
2024 remainder of year	$ 11,332
2025	14,250
2026	12,773
2027	12,169
2028	12,169
Thereafter	40,155
Total	$ 102,848

Impairment of Long-Lived Assets

Impairment of long-lived assets for the three months ended March 31, 2024 and 2023 was $0.4 million and $1.4 million, respectively, of impairment of right-of-use and fixed assets in relation to exiting our Watertown and Richmond facilities.

Supplies and Inventory

As of March 31, 2024 and December 31, 2023, supplies and inventory consisted of $13.7 million and $12.2 million, respectively, of lab supplies and reagents consumed in the performance of testing services, and $4.6 million and $4.0 million, respectively, of inventory related to finished and semi-finished components used in the assembly of diagnostic kits related to product sales and raw materials consumed in the contract manufacturing process.

Accrued Liabilities

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

	March 31, 2024	December 31, 2023
Accrued compensation expenses	$ 16,948	$ 26,430
Accrued other	13,345	11,997
Total accrued liabilities	$ 30,293	$ 38,427

4. Business Combination

On February 5, 2024, or the Closing Date, the Company acquired 100% of the outstanding equity interests of C2i, or the C2i Acquisition. C2i was a privately-held company that developed a novel method for estimating tumor burden in cancer patients by analyzing a patient's cell free DNA sequence and offered post-surgery monitoring of cancer recurrence and progression by analyzing subtle changes in the pattern of the tumor's DNA. The consideration to acquire C2i was $100.2 million, comprised of $73.3 million in the form of approximately 2.7 million shares of the Company's common stock based on the Company's share price on the Closing Date, $0.8 million of pre-combination portion of replacement stock options issued to C2i's continuing employees, $17.2 million of contingent consideration that has been agreed to be paid on achievement of certain milestones and the remainder in cash. The Company incurred $4.9 million of transaction costs related to the of C2i Acquisition, which were recorded as general and administrative expense.

As part of the agreement, the Company deposited $8.0 million of the cash consideration into escrow for meeting any unresolved or unsatisfied claims for indemnifiable damages against C2i and any special tax claims. The balance after meeting these indemnification obligations will be paid directly to the securityholders of C2i. After deducting the expenses for indemnifiable damages and tax claims the escrow amount of $5.0 million will be released 18 months from the Closing Date and the balance of $3.0 million will be released 36 months after the Closing Date. As this payment is dependent on the resolution of claims that existed as of the Closing Date, the amount deposited into escrow is included in the purchase price.

VERACYTE, INC.
Notes to Financial Statements
(unaudited)

In addition, pursuant to the Agreement and Plan of Merger, dated as of January 5, 2024, by and among the Company, C2i, Canary Merger Sub I, Inc., a Delaware corporation and wholly owned subsidiary of the Company, Veracyte Diagnostics, LLC, a Delaware limited liability company and a wholly owned subsidiary of the Company, and Fortis Advisors LLC, as the securityholders' agent, or the Merger Agreement, the C2i noteholders are entitled to receive from the Company up to $25.0 million in contingent consideration that is dependent on the achievement of specified training requirements, licensing, regulatory and commercialization milestones and are payable in cash or shares of the Company's common stock, at the Company's election.

The Company included financial results of C2i in its consolidated financial statements from the acquisition date, which contributed zero and $4.2 million of revenue and operating loss, respectively, including $1.3 million of severance and retention charges and $0.7 million of impairment of right-of-use asset and intangible asset amortization during the three months ended March 31, 2024.

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the resulting amount of goodwill. The following table summarizes the preliminary fair values of assets acquired and liabilities assumed in the C2i Acquisition at the Closing Date (in thousands):

	Amount
Assets acquired:	
Cash and cash equivalents	$ 13,677
Prepaid expenses and other current assets	998
Property, plant and equipment, net	277
Right of use assets, operating leases	1,277
Intangible assets, net	31,500
Restricted cash	188
Total identifiable assets acquired	47,917
Accounts payable	(59)
Accrued Liabilities	(1,540)
Current portion of deferred revenue	(94)
Current portion of operating lease liabilities	(441)
Deferred tax liability	(726)
Operating lease liabilities, net of current portion	(836)
Net identifiable assets acquired	44,221
Goodwill	55,974
Total purchase price	$ 100,195

Based on the guidance provided in ASC 805 Business Combinations, the Company accounted for the C2i Acquisition as a business combination in which the Company determined that C2i was a business which combines inputs and processes to create outputs, and substantially all of the fair value of gross assets acquired was not concentrated in a single identifiable asset or group of similar identifiable assets.

The Company's purchase price allocation for the C2i Acquisition is preliminary and subject to revision as additional information about the fair value of the assets and liabilities becomes available. The fair values assigned to tangible and intangible assets acquired, and liabilities assumed, are based on management's estimates and assumptions and may be subject to change as additional information is received. Primary areas that are not yet finalized are related to certain income tax items, intangible assets and goodwill. Additional information that existed as of the closing date but not known at the time of this filing may become known to the Company during the remainder of the measurement period, a period not to exceed 12 months from the Closing Date.

The intangible assets acquired included IPR&D assets and developed technology. The preliminary fair value of the Company's intangible assets as of the acquisition date and the method used to value these assets as well as the estimated economic lives for amortizable intangible assets were as follows (in thousands, except useful life which is in years):

	Fair Value	Estimated Useful Life	Valuation Method
Intangible Assets Acquired:			
Developed Technology	$ 25,300	15	Relief from royalty method
IPR&D assets	6,200	Indefinite	Multi-period excess earnings method
Total intangible assets acquired	$ 31,500		

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

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. The C2i acquisition resulted in the recognition of $56.0 million of goodwill which the Company believes consists primarily of expanded market and product opportunities, including an MRD platform, which will enable new areas of genomic testing.

In connection with the C2i Acquisition, a net deferred tax liability was assumed with a fair value of $0.7 million which primarily relates to future intangible asset amortization which is not deductible for income tax purposes.

Pro forma financial information (unaudited)

The supplemental pro forma financial information has been prepared using the acquisition method of accounting and is based on the historical financial information of C2i. The supplemental pro forma financial information does not necessarily represent what the combined companies' revenue or results of operations would have been had the acquisitions been completed on January 1, 2023, nor is it intended to be a projection of future operating results of the combined company. It also does not reflect any operating efficiencies or potential cost savings that might be achieved from synergies of combining C2i and the Company.

The unaudited supplemental pro forma financial information has been calculated after adjusting the results of the combined company to reflect incremental amortization expense resulting from the fair value adjustments for acquired intangible assets. Further, adjustments related to transaction costs and stock- based compensation expense are also reflected in the pro forma financial information in the table below:

	For the three months ended March 31,	
	2024	2023
Total revenue	$ 96,844	$ 82,422
Net loss	$ (4,019)	$ (20,087)

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 $13.7 million and $1.4 million as of March 31, 2024 and December 31, 2023, respectively, and are Level I assets as described above. The deposits for the leases, included in restricted cash, were $1.1 million and $0.9 million as of March 31, 2024 and December 31, 2023, respectively, and are Level I assets as described above. There were no transfers between Levels 1, 2 or 3 for the three months ended March 31, 2024 and 2023.

As part of the Company's agreement to acquire the exclusive global diagnostic license to the nCounter Analysis System, the Company may pay up to an additional $10.0 million in cash, contingent upon first achievement or occurrence, by or on behalf of the Company, 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, with the corresponding changes included in general and administrative expense in the Company's condensed consolidated statements of operations. As of March 31, 2024 and December 31, 2023, this contingency was remeasured to $3.2 million and $3.2 million, respectively. For the three months ended March 31, 2024, no expense was recorded. For the three months ended March 31, 2023, reversals of expense $0.5 million was recorded. As of March 31, 2024, the achievement of one of the milestones is forecasted to occur within the next 12 months. As a result, $2.7 million of the contingent consideration is included in short term liabilities at March 31, 2024. In addition, the contingent consideration related to the C2i Acquisition as discussed in Note 4, is dependent on the achievement of certain milestones and is payable in cash or shares of the Company's common stock, at the Company's election, of up to $25 million and was valued at $17.2 million. The fair value of the contingent consideration related to the C2i Acquisition will be remeasured to fair value at each reporting date until the contingent consideration is settled, with the corresponding changes included in general and administrative expense. As of March 31, 2024, the achievement of one of the milestones is forecasted to occur within the next 12 months. As a result, $4.3 million of the contingent consideration is included in short term liabilities at March 31, 2024. The fair value of 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 March 31, 2024 and December 31, 2023, the Company calculated the estimated fair value of the milestones using the following significant unobservable inputs:

	Value or Range (Weighted-Average)	
Unobservable input	**March 31, 2024**	**December 31, 2023**
Discount rate	6.0%	6.8%
Probability of achievement	0% - 90% (64%)	10% - 80% (69%)

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; Richmond, Virginia; and Watertown, Massachusetts, and leases certain equipment under various non-cancelable lease agreements. The lease terms extend to January 2029 and contain extension of lease terms and expansion options. The leases have a weighted average remaining lease term of 2.9 years as of March 31, 2024. The Company had deposits of $1.1 million and $0.9 million included in long-term assets as of March 31, 2024 and December 31, 2023, respectively, restricted from withdrawal and held by banks in the form of collateral for irrevocable standby letters of credit held as security for the leases.

The Company determined its operating lease liabilities using payments through their current expiration dates and a weighted average discount rate of 8.0% 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.

Future minimum lease payments under non-cancelable operating leases as of March 31, 2024 are as follows (in thousands of dollars):

Year Ending December 31,		**Amounts**
Remainder of 2024	$	4,993
2025		6,520
2026		1,964
2027		781
2028		746
Thereafter		535
Total future minimum lease payments		15,539
Less: amount representing interest		1,499
Present value of future lease payments		14,040
Less: short-term lease liabilities		5,982
Long-term lease liabilities	$	8,058

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 March 31,			
	2024		**2023**	
Operating lease expense	$	1,543	$	1,123
Cash paid for amounts included in the measurement of lease liabilities	$	1,629	$	1,177

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 $0.1 million and $0.1 million, respectively, as of both March 31, 2024 and December 31, 2023, and are included in property, plant and equipment, net and other liabilities in the accompanying condensed consolidated balance sheets.

The Company’s wholly owned foreign subsidiary has entered into an arrangement under which it expects to sign a lease agreement for facilities which are being constructed in Marseille, France. The lease will commence upon completion of the construction of the office building 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 $1.3 million, which is subject to change based on final construction and excludes common area maintenance costs.

Contingencies

From time to time, the Company may be involved in legal proceedings arising in the ordinary course of business. The Company believes there is no litigation pending that could have, either individually or in the aggregate, a material impact on the Company's consolidated financial statements.

7. Stockholders' Equity

Common Stock

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

	March 31, 2024	December 31, 2023
Stock options and restricted stock units issued and outstanding	7,187,609	6,318,389
Stock options and restricted stock units available for grant under stock option plans	3,848,279	5,194,399
Common stock available for the Employee Stock Purchase Plan	1,109,722	1,189,513
Total	12,145,610	12,702,301

8. Components of Other Income

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

	Three Months Ended March 31,	
	2024	2023
French research tax credits	$ 570	$ 1,009
Interest income	2,695	1,189
Interest expense	—	(7)
Loss on currency revaluation	(560)	229
Other	43	(13)
	$ 2,748	$ 2,407

9. Income Taxes

The Company recorded income tax benefit of $44 thousand for the three months ended March 31, 2024 and no income tax benefit for the three months ended March 31, 2023.

The Inflation Reduction Act of 2022 was signed into law August 16, 2022, and includes significant legislation addressing taxes, inflation, climate change and renewable energy incentives, and healthcare. Key tax provisions include a 15% corporate minimum tax, clean energy incentives, and a 1% excise tax on stock buybacks. The provisions of such legislation have not had any impact on the effective tax rate of the Company and the Company will continue to evaluate the tax effects should any provisions become applicable to the Company.

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, Afirma, Percepta, Envisia, Prosigna, Lymphmark, Decipher, GRID, HalioDx, TMExplore, Brightplex, Immunosign, C2i Genomics, C2intelligence, C2inform and the Veracyte logo are registered or pending trademarks of Veracyte, Inc. and its subsidiaries in the United States and selected countries. nCounter is the registered trademark of NanoString Technologies, Inc., or NanoString, in the United States and selected countries and used by Veracyte under license. Immunoscore is the registered trademark of Institut National de la Santé et de la Recherche Médicale, or Inserm, in the United States and selected countries and used by Veracyte under license.

Overview

We are a global diagnostics company that empowers clinicians with the high-value insights they need to guide and assure patients at pivotal moments in the race to diagnose and treat cancer. Our high-performing tests enable clinicians to make more confident diagnostic, prognostic and treatment decisions, helping patients avoid unnecessary procedures and interventions, and accelerating time to appropriate treatment, thereby improving outcomes for patients all over the world.

We currently offer tests in thyroid cancer (Afirma); prostate cancer (Decipher Prostate); breast cancer (Prosigna); and bladder cancer (Decipher Bladder). Our Percepta Nasal Swab test is being run in our CLIA lab in support of clinical studies and our test for lymphoma is in development as a companion diagnostic.

We serve global markets with two complementary models. In the United States, we offer LDTs through our centralized CLIA certified laboratories in South San Francisco and San Diego, California, supported by our cytopathology expertise in Austin, Texas. Additionally, primarily outside of the United States, we provide tests to patients through distribution to laboratories and hospitals that can perform the tests locally. Today, this includes our Prosigna test, and in the future, we intend to offer the Decipher Prostate and Percepta Nasal Swab tests as IVD tests. We believe our broad menu of advanced diagnostic tests, combined with our ability to deliver them globally, differentiates us in the diagnostics industry.

In February 2024, we acquired C2i, a MRD detection company, which aims to expand our role across the patient cancer journey, moving from providing early decision support to following the patient through treatment, where we will be able to help monitor the success of a therapeutic or surgical intervention, and determine the best course of action for each patient.

Macroeconomic Factors

Recent interest rate increases and inflation in the United States and other markets globally, as well as turmoil in the global banking and finance system, have heightened the risk of an economic downturn or recession and volatility and have resulted in recent volatility in the capital or credit markets in the United States and globally. Moreover, the continued fluctuation of the U.S. dollar compared to other currencies, 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. In addition, regional conflicts like those between Russia and Ukraine have increased the risk of disruptions to energy supplies in Europe, which may impact our ability to manufacture tests or perform services from our facility in Marseille, France, and other conflicts may adversely impact our business and operating results. Finally, the ongoing conflict in the Middle East may disrupt our Israel business operations and employees that we acquired through the C2i Acquisition.

The extent of the macroeconomic factors on our future liquidity and operational performance will depend on certain developments, 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 purchased by our customers. Factors impacting the number of tests that we report as completed include, but are not limited to:

- 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 or our customers to perform our tests and report the results, including as a result of supply chain challenges (including quality of reagents);
- the seasonality inherent in our business, such as the impact of workdays 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 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. Revenue growth also depends on our ability to secure reimbursement from government payers at a reimbursement rate that is consistent with past reimbursement rates.

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 typically 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, related diagnostic kits, and services. 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 clinical and testing 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 and other companies. The underlying terms of these arrangements generally provide for consideration paid to us in the form of nonrefundable fees; payments on delivery of data, test results or manufactured products; costs of service plus margin; performance milestone payments; expense reimbursements and possibly royalty and/or other payments. Net sales of data or other services to our customers are recognized in accordance with ASC 606 and are classified under biopharmaceutical and other revenue. Payments received that are not related to sales or services to a customer 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 March 31, 2024, we 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 March 31,	
	2024	**2023**
Medicare	31 %	31 %
UnitedHealthcare	9 %	10 %
	40 %	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 sample collection kit costs, reagent 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 process enhancements such as automation, 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, components for the manufacturing of diagnostic kits, service 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, contract testing services, commercialization, and contract manufacturing and development. This expense is mainly composed of compensation, manufacturing and laboratory supplies, and pass-through costs.

Research and Development

Research and development expenses include expenses incurred to collect clinical samples and conduct clinical studies to develop and support our products and pipeline, as well as develop future technology. 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 2023 and in the three months ended March 31, 2024 in support of our early-stage products, including Percepta Nasal Swab, as well as the development of new IVD products and discovery. Going forward, we expect to incur significant expense as we invest in the continued development of our innovation engine, early-stage products including our MRD tests, required clinical studies and the development of current tests on multiple IVD platforms.

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 110 representatives is organized by business unit in the U.S., with separate teams calling on thyroid cancer, and urologic cancer 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 and sales teams 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, acquisition related costs and miscellaneous expenses, offset by allocation of facility and information technology expenses to other functions. We expect general and administrative expenses to continue to increase as we build our infrastructure to scale revenue growth, and to decline as a percentage of revenue 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 $14 million per year through 2025 and decrease thereafter.

Other Income (Loss), Net

Other income (loss), net consists primarily of interest income from our cash held in interest bearing accounts, realized and unrealized gains and losses on foreign currency transactions, and French research tax credits. 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 subsidiaries, Veracyte SAS and C2i Genomics, Ltd., are the Euro and the Israeli Shekel, respectively. 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 months ended March 31, 2024 and 2023 (in thousands of dollars, except percentages and test volume):

	Three Months Ended March 31,			
	2024	**2023**	**Change**	**%**
Revenue:				
Testing revenue	$ 90,303	$ 72,396	$ 17,907	25%
Product revenue	3,537	3,892	(355)	(9)%
Biopharmaceutical and other revenue	3,004	6,134	(3,130)	(51)%
Total revenue	96,844	82,422	14,422	17%
Operating expense:				
Cost of testing revenue	25,979	19,648	6,331	32%
Cost of product revenue	2,644	2,162	482	22%
Cost of biopharmaceutical and other revenue	2,838	4,419	(1,581)	(36)%
Research and development	15,965	12,769	3,196	25%
Selling and marketing	23,782	26,130	(2,348)	(9)%
General and administrative	26,210	21,053	5,157	24%
Impairment of long-lived assets	429	1,410	(981)	(70)%
Intangible asset amortization	3,653	5,329	(1,676)	(31)%
Total operating expenses	101,500	92,920	8,580	9%
Loss from operations	(4,656)	(10,498)	5,842	(56)%
Other income, net	2,748	2,407	341	14%
Loss before income taxes	(1,908)	(8,091)	6,183	(76)%
Income tax benefit	(44)	—	(44)	N/M
Net loss	$ (1,864)	$ (8,091)	$ 6,227	(77)%
Other Operating Data:				
Diagnostic tests reported	30,969	25,848	5,121	20%
Product tests sold	2,455	2,940	(485)	(16)%
Total test volume	33,424	28,788	4,636	16%
Depreciation and amortization expense	$ 5,590	$ 6,670	$ (1,080)	(16)%
Stock-based compensation expense	$ 8,019	$ 8,101	$ (82)	(1)%

Revenue

Revenue increased $14.4 million for the three months ended March 31, 2024 compared to the same period in 2023. This was primarily due to a $17.9 million increase in testing revenue, partially offset by a $3.1 million decrease in our Biopharmaceutical and other revenue. The 25% growth in testing revenue was primarily driven by a 20% volume increase and a

4% average selling price increase between our Afirma and Decipher products for the three months ended March 31, 2024. Our diagnostic test volumes include Afirma GSC tests, as well as Decipher Prostate and Bladder, Percepta GSC and Envisia tests that are commercially run at our CLIA labs.

Product revenue decreased $0.4 million for the three months ended March 31, 2024 compared to the same period in 2023, primarily driven by lower demand for product test kits primarily as a result of customer adoption reductions and delays.

Biopharmaceutical and other revenue decreased by $3.1 million for the three months ended March 31, 2024 driven primarily by the reduction of customer projects given overall spending constraints across the industry.

Cost of revenue

Comparison of the three months ended March 31, 2024 and 2023 is as follows (in thousands of dollars, except percentages):

	Three Months Ended March 31,			
	2024	**2023**	**Change**	**%**
Cost of testing revenue:				
Laboratory costs	$ 13,291	$ 10,362	$ 2,929	28 %
Sample collection costs	3,057	2,515	542	22 %
Compensation expense	5,215	4,247	968	23 %
License fees and royalties	20	22	(2)	(9)%
Depreciation and amortization	427	309	118	38 %
Other expenses	1,026	699	327	47 %
Allocations	2,943	1,494	1,449	97 %
Total	$ 25,979	$ 19,648	$ 6,331	32 %
Cost of product revenue:				
Product costs	$ 1,263	$ 1,634	$ (371)	(23)%
License fees and royalties	436	362	74	20 %
Depreciation and amortization	225	43	182	423 %
Other expenses	599	123	476	387 %
Allocations	121	—	121	N/M
Total	$ 2,644	$ 2,162	$ 482	22 %
Cost of biopharmaceutical and other revenue:				
Compensation expense	$ 1,462	$ 2,286	$ (824)	(36)%
License fees and royalties	149	21	128	610 %
Depreciation and amortization	78	113	(35)	(31)%
Other expenses	722	1,896	(1,174)	(62)%
Allocations	427	103	324	315 %
Total	$ 2,838	$ 4,419	$ (1,581)	(36)%

Cost of testing revenue increased $6.3 million, or 32%, for the three months ended March 31, 2024 compared to the same period in 2023. The increase in cost of testing revenue was due to increased volume in testing, higher staffing to support testing performance and the build out of infrastructure related to current and future growth expectations, primarily related to Afirma and Decipher Prostate tests.

Cost of product revenue is related to sales of Prosigna and nCounter Analysis Systems. Cost of product revenue increased $0.5 million, or 22%, for the three months ended March 31, 2024 compared to the same period in 2023, driven by increased overhead costs related to the build out of our Marseille, France facilities to support the manufacture of our IVD kits.

Cost of biopharmaceutical and other revenue includes labor costs, laboratory supplies and pass-through expenses incurred on these projects. Cost of biopharmaceutical and other revenue decreased by $1.6 million driven by reductions of variable expenses related to projects.

Research and development

Comparison of the three months ended March 31, 2024 and 2023 is as follows (in thousands of dollars, except percentages):

	Three Months Ended March 31,			
	2024	2023	Change	%
Research and development expense:				
Compensation expense	$ 9,085	$ 7,301	$ 1,784	24 %
Direct research and development expense	3,874	2,741	1,133	41 %
Depreciation and amortization	239	163	76	47 %
Other expenses	1,280	1,724	(444)	(26)%
Allocations	1,487	840	647	77 %
Total	$ 15,965	$ 12,769	$ 3,196	25 %

Research and development expense increased $3.2 million, or 25%, for the three months ended March 31, 2024 compared to the same period in 2023. The increase is primarily driven by direct research and development expense related to our on-going clinical studies including, but not limited to, furthering the support and clinical utility evidence of our Percepta Nasal Swab test and urology products. In addition to clinical studies, the increase is partially driven by development costs related to our IVD and MRD strategies, as well as projects to enhance laboratory efficiencies.

Selling and marketing

Comparison of the three months ended March 31, 2024 and 2023 is as follows (in thousands of dollars, except percentages):

	Three Months Ended March 31,			
	2024	2023	Change	%
Selling and marketing expense:				
Compensation expense	$ 17,622	$ 19,671	$ (2,049)	(10)%
Direct marketing expense	1,138	1,348	(210)	(16)%
Other expenses	3,414	3,577	(163)	(5)%
Allocations	1,608	1,534	74	5 %
Total	$ 23,782	$ 26,130	$ (2,348)	(9)%

Selling and marketing expense decreased $2.3 million, or 9%, for the three months ended March 31, 2024 compared to the same period in 2023. The decrease in compensation expense was primarily due to a reversal of the stock-based compensation related to employee exits and reduced variable compensation, partially offset by severance costs associated with the decision to reduce the sales support for our Envisia product. Direct marketing expense decreased primarily due to timing of trade show events, which was partially offset by an increase in allocated expenses to support the growth of the Afirma and Decipher test volume.

General and administrative

Comparison of the three months ended March 31, 2024 and 2023 is as follows (in thousands of dollars, except percentages):

	Three Months Ended March 31,			
	2024	2023	Change	%
General and administrative expense:				
Compensation expense	$ 17,759	$ 15,573	$ 2,186	14 %
Occupancy expenses	2,553	1,437	1,116	78 %
Depreciation and amortization	966	712	254	36 %
Other expenses	11,518	7,302	4,216	58 %
Allocations	(6,586)	(3,971)	(2,615)	66 %
Total	$ 26,210	$ 21,053	$ 5,157	24 %

General and administrative expense increased by $5.2 million for the three months ended March 31, 2024, compared to the same period in 2023. Compensation expense for the three months ended March 31, 2024 compared to the same period in 2023 increased primarily due to annual compensation increases and expenses related to the C2i Acquisition. Occupancy expenses increased primarily due to our expansion of our San Diego facilities footprint to support Decipher growth, and other expenses increased $4.2 million primarily related to expenses related to the C2i Acquisition. 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.

Impairment of long-lived assets

Impairment of long-lived assets during the three months ended March 31, 2024 and 2023 was $0.4 million and $1.4 million, respectively, of impairment of right-of-use and fixed assets in relation to exiting our Watertown and Richmond facilities.

Other income, net

Other income, net, increased $0.3 million for the three months ended March 31, 2024 compared to the same period in 2023, primarily due to an increase of $1.5 million from interest income partially offset by a decrease of $0.4 million related to the French research tax credit and a decrease of $0.8 million due to foreign currency revaluation.

Income tax benefit

We recorded income tax benefit of $44 thousand for the three months ended March 31, 2024 and no income tax benefit for the three months ended March 31, 2023.

Given our current earnings, we believe that, within the next two years, sufficient positive evidence may become available to allow us to reach a conclusion that a portion of the valuation allowance recorded against the deferred tax assets held may be reversed. A reversal would result in an income tax benefit for the quarterly and annual period in which we determine to release the valuation allowance. However, the exact timing and amount of a valuation allowance release are subject to change on the basis of the level of profitability that we actually achieve.

Liquidity and Capital Resources

From inception through March 31, 2024, 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 three months ended March 31, 2024, we had a net loss of $1.9 million, and we expect to incur additional losses for the remainder of 2024 and potentially in future years. As of March 31, 2024, we had an accumulated deficit of $470.0 million.

We believe our existing cash and cash equivalents of $209.2 million as of March 31, 2024, and cash flows generated by 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, potential milestones associated with the C2i Acquisition, 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 cash flows from our 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 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. Moreover, any instability in the global banking system may impact liquidity both in the short term and long term and may result in adverse impacts to our or our customers' business, including in our customers' ability to pay for our products.

Operating Leases

We lease office and laboratory facilities in South San Francisco and San Diego, California; Austin, Texas; Marseille, France; Richmond, Virginia; and Watertown, Massachusetts, and lease certain equipment under various non-cancelable lease agreements. The lease terms extend to January 2033 and contain extension of lease term and expansion options. As of March 31, 2024, the leases have a weighted average remaining lease term of 2.9 years and total future minimum lease payments of $15.5 million.

Veracyte SAS has signed a lease agreement for facilities which are under construction in Marseille, France. The lease will commence upon completion of the construction of the office building 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 $1.3 million, which is subject to change based on final construction.

Acquisition-Related Contingent Consideration

C2i Acquisition Contingent Consideration

Pursuant to the Merger Agreement, we may pay up to an additional $25.0 million in cash or shares of our common stock, at our election, contingent upon the achievement of certain milestones. As of March 31, 2024, the achievement of one of the milestones contained in the Merger Agreement is forecasted to occur within the next 12 months, requiring payments totaling $5.0 million.

nCounter Analysis System Acquisition Contingent Consideration

As part of our agreement to acquire the exclusive global diagnostic license to the nCounter Analysis System, we may pay up to an additional $10.0 million in cash, contingent upon first achievement or occurrence, by us or on our behalf, of the commercial launch of the first, second and third diagnostic tests for use on the nCounter multiplex analysis system. As of March 31, 2024, the achievement of one of the milestones is forecasted to occur within the next 12 months, requiring payments totaling $3.5 million.

Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2024 and 2023 (in thousands of dollars):

	Three Months Ended March 31,	
	2024	2023
Net cash used in operating activities	$ (8,966)	$ (2,172)
Net cash provided by investing activities	2,878	24,080
Net cash (used in) provided by financing activities	(864)	1,685

Cash Flows from Operating Activities

Cash used in operating activities for the three months ended March 31, 2024 was $9.0 million. Our net loss of $1.9 million includes non-cash charges of $8.0 million of stock-based compensation expense, $5.6 million of depreciation and amortization, of which $3.7 million was related to intangible asset amortization, and the remainder was due to a non-cash lease expense of $1.1 million. Cash used as a result of changes in operating assets and liabilities was $22.8 million, primarily composed of a decrease in accrued liabilities and deferred revenue of $9.0 million, an increase in accounts receivable of $6.5 million, an increase in prepaids and other current assets of $2.7 million, an increase in supplies and inventory of $2.3 million, a decrease in accounts payable of $1.5 million, and a decrease in operating lease liability of $1.1 million, partially offset by a decrease in other assets of $0.3 million.

Cash used in operating activities for the three months ended March 31, 2023 was $2.2 million. The net loss of $8.1 million includes non-cash charges of $8.0 million of stock-based compensation expense, $6.7 million of depreciation and amortization, of which $5.3 million was related to intangible asset amortization, $1.4 million of impairment of right-of-use and fixed assets and non-cash lease expense of $0.9 million. Cash used as a result of changes in operating assets and liabilities was $10.5 million, primarily comprising a decrease in accrued liabilities and deferred revenue of $7.7 million, an increase in prepaids and other current assets of $3.1 million, an increase in accounts payable of $2.0 million, an increase in accounts receivable of $1.3 million, a decrease in supplies and inventory of $1.1 million, a decrease in operating lease liability of $1.0 million and a $0.5 million impact from other working capital accounts.

Cash Flows from Investing Activities

Cash provided by investing activities for the three months ended March 31, 2024 was $2.9 million, consisting of $5.0 million net cash acquired from C2i excluding post-close transactions costs, partially offset by $2.1 million used in the purchase of property, plant and equipment.

Cash provided by investing activities, for the three months ended March 31, 2023, was $24.1 million, consisting of $44.8 million generated from the sale and maturity of short-term investments, partially offset by $19.7 million used in the purchase of short-term investments and $1.0 million used in the purchase of property, plant and equipment.

Cash Flows from Financing Activities

Cash used in financing activities for the three months ended March 31, 2024 was $0.9 million, consisting of $3.8 million in tax payments during the period related to the vesting of restricted stock units granted to employees, partially offset by $3.0 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.

Cash provided by financing activities for the three months ended March 31, 2023, was $1.7 million, consisting of $4.0 million in proceeds from the exercise of options to purchase our common stock and the purchase of stock under our ESPP, partially offset by $2.3 million in tax payments during the period related to the vesting of restricted stock units granted to employees.

Recent Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board issued ASU No. 2023-09, *Improvements to Income Tax Disclosures (Topic 740)*. The update requires disaggregated information about a reporting entity's effective tax rate

reconciliation as well as additional information on income taxes paid. This ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is also permitted for annual financial statements that have not yet been issued or made available for issuance. We expect this ASU will result in the required additional disclosures being included in our consolidated financial statements, once adopted.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of the condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the condensed consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed in our Annual Report on Form 10-K for the year ended December 31, 2023, or Annual Report, which was filed with the Securities and Exchange Commission, or the SEC, on February 29, 2024 are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates. There have been no material changes to our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in our Annual Report.

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 $209.2 million as of March 31, 2024 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 condensed consolidated financial statements.

Foreign Currency Risk

As of March 31, 2024 we held $3.2 million of bank deposits denominated in Euros. Such Euro denominated deposits carry a degree of risk from changes in currency exchange rates as the gains or losses from changes in exchange rates are included in our net loss and comprehensive loss. As of March 31, 2024 a hypothetical 10% appreciation or depreciation of the U.S. dollar relative to the Euro would not have had a material impact on our condensed consolidated financial statements.

Inflation Risk

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

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. On February 5, 2024, we closed the C2i Acquisition and we are in the process of incorporating C2i into our evaluation of internal control over financial reporting. Other than the C2i Acquisition 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 March 31, 2024, 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 or products, 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; if one or more significant payers stops providing reimbursement or decreases the amount of reimbursement for our tests our revenue could decline.
- If payers do not provide reimbursement, rescind or modify their reimbursement policies, delay payments for our tests, recoup past payments, or if we are unable to successfully negotiate additional reimbursement contracts, our commercial success could be compromised.
- We may experience limits on our revenue if physicians decide not to order our tests or if patients decide not to use our tests as a result of increased costs, fees or changing insurer policies.
- 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 and/or the amount of cash we generate, 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 depend, in part, on our ability to adapt and manufacture select tests to be performed on multiple IVD platforms.
- The revenue that we are expecting in our biopharma and other services business may not transpire**.**
- We rely on sole suppliers for some of the reagents, equipment, and other materials used to perform or develop our tests, as well as certain sole service providers, and we may not be able to find replacements or transition to alternative suppliers or service providers, which may materially impact our ability to generate revenue.
- 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 tests, services or products, 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.
- FDA or foreign authorities regulation of those of our tests that they do not currently regulate could result in Veracyte incurring 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 compete successfully, we may be unable to increase or sustain our revenue and/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 in order to collect cash and 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 timeframes we announce and expect, our business will suffer and our stock price may decline.
- We must successfully integrate acquired businesses to realize the financial goals that we currently anticipate.
- 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 macroeconomic 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 or successfully defend our intellectual property effectively, our business may be harmed.
- We may be involved in litigation related to intellectual property, which may be time-intensive and costly and may adversely affect our business, operating results or financial condition.

*Risks Related to Being a Public Compa*ny

- 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 three months ended March 31, 2024 and 2023, we had net losses of $2 million and $8 million, respectively. As of March 31, 2024, we had an accumulated deficit of $470 million. We expect to incur additional losses in the future as we continue to invest in our business, including increasing adoption of and reimbursement for our molecular diagnostic portfolio of tests, expanding our platform and operations internationally, attracting and retaining team members, developing and enhancing our platform, marketing and sales, and enhancing our infrastructure, and we may never achieve revenue sufficient to offset our expenses. Additionally, ongoing widespread inflationary pressures in the United States and across global economies have 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 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. 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 and Decipher Prostate 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 or products, or we are unable to launch or commercialize our new tests, our business may suffer.

Although a number of our tests, such as Prosigna and Decipher Bladder, have not contributed significant revenue to date, we expect them to grow and become an increasingly important component of our portfolio, as well as our results of operations. We plan to introduce new tests going forward as well, including in MRD as a result of the C2i Acquisition. 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 some of our tests to international markets; 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; 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 macroeconomic uncertainty. 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 9%, respectively, of our revenue for the three months ended March 31, 2024, compared with 31% and 10%, respectively, for the three months ended March 31, 2023. 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 MolDX program, administered by Palmetto GBA, under a Local Coverage Determination, or LCD. In August 2023, a new Proposed LCD was issued for "Molecular Testing for Risk Stratification of Thyroid Nodules" through the MolDX program. We believe that this Proposed LCD would, if finalized, cover the Afirma classifier. There is no guarantee that this Proposed LCD will be finalized, or that the coverage criteria for the Afirma classifier under this Proposed LCD, if finalized, would be as advantageous as under the current LCD. Modifications to the current Medicare coverage of the Afirma classifier could have an adverse effect on our business, financial condition and results of operations.

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. In December 2022, through the Consolidated Appropriations Act of 2023, Congress further delayed the next reporting period to 2024. In November 2023, through the Further Continuing Appropriations and Other Extensions Act of 2024, Congress further delayed the next reporting period to 2025. The applicability of the payment rates based on 2017 reporting thus now extend through December 31, 2025. 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 the Centers for Medicare & Medicaid Services, or CMS, priced

81546 at the same rate of $3,600 as 81545. Since the Afirma GSC CPT code 81546 was newly issued in 2021, the first PAMA data reporting period for 81546 under the current triennial data reporting process is expected to be January 2028 through March 2028, resulting in a new potential reimbursement rate effective January 1, 2029. There is no guarantee that the Afirma GSC Medicare rate will not be negatively impacted in future PAMA reporting cycles based on the reported weighted median of private commercial payers.

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. In August 2023, a new Proposed LCD was issued for "Gene Expression Profile Tests for Decision-Making in Castration Resistant and Metastatic Prostate Cancers" through the MolDX program. We believe that this Proposed LCD, if finalized, would broaden our Decipher Prostate coverage for Castration Resistant and Metastatic prostate cancer patients. There is no guarantee that this Proposed LCD will be finalized, or that the coverage criteria for the Decipher Prostate tests classifier under this Proposed LCD, if finalized, would be as advantageous as under the current LCD. Modifications to the current Medicare coverage of the Decipher Prostate tests could have an adverse effect on our business, financial condition and results of operations.

Our Decipher Prostate tests were assigned a new American Medical Association Current Procedural Terminology code, or CPT code, 81542, in 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, under which the individual MACs set the payment rate for the test 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. 81542 has been priced at $3,873 since January 1, 2021, based on CMS' revision of the median of payment rates set by the MACs through the gapfilling process. Since the CPT code was issued in 2020, we expect the next PAMA reporting period to take place between January 2028 and March 2028, resulting in a potential new reimbursement rate effective January 1, 2029. 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 Prosigna payment rate will not decrease during subsequent reporting cycles under PAMA.

An LCD was issued by Noridian Healthcare Solutions to provide 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 as defined under the ADLT regulations 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. Effective January 1, 2024, the Medicare payment rate for 81554 is $5,500. 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. Current ADLT PAMA regulations require us to report these private payer rates for Envisia, 81554, annually.

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 submit claims to Medicare for Decipher Bladder using CPT code 0016M. CMS assigned 0016M to the gapfilling process in 2021. Since January 1, 2022, the payment rate for 0016M has been $3,489.63, based on the median of payment rates set by the MACs through the gapfilling process. There is no assurance that the Medicare payment rate for Decipher Bladder will not decrease during a future reporting cycle under PAMA.

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, with or without notice, for technical or other reasons, 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, many private payers now require prior authorization for molecular diagnostic tests. Potential reductions in reimbursement rates or increases in the difficulty of achieving payment could have a negative effect on our revenue.

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

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

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

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

We are an out-of-network provider with some commercial payers in the United States 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, Envisia and Decipher Bladder, as well as 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 across our entire portfolio of tests. 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.

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 Genomic Classifier have led to the test's inclusion in leading clinical guidelines. For example, the Decipher test received a "Level 1B" evidence designation in the 2024 NCCN Guidelines(R), or NCCN Guidelines, for prostate cancer, distinguishing it as the only gene-expression test to do so.

Although Decipher Prostate Genomic Classifier has 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, are unable to cause our genomic tests to be included in other influential guidelines, or if our competitors are successful at achieving similar or more extensive guidelines for their tests, we may be at a disadvantage in gaining market acceptance and market share relative to our competitors.

Our Envisia test is included but not yet recommended in 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 Genomic Classifier, Envisia, and Decipher Bladder testing services are performed by our certified laboratories under the 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 as a result of increased costs, fees or changing insurer policies.

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. In addition, rising interest rates and ongoing inflation in the United States and globally may put further pressure on insurers and other providers to raise prices or reduce reimbursement, increasing the cost to the patient. 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.

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; or Austin, Texas 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, 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 or San Diego 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, it could result in a delay in processing

tests during that transition and increased costs. 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 the New York State Department of Health, and we may not be able to offer our new tests until such approvals are received. Furthermore, certain state agencies have been experiencing delays in their response time which may cause delay in our receipt of our corresponding approvals or renewals for our tests.

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 and/or the amount of cash we generate, 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 United States 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 analytical and clinical validation studies, as well as clinical utility studies;
- expend significant funds;
- expand and scale-up our laboratory processes;
- expand and train our sales force;
- gain acceptance from a large number of ordering clinicians;
- 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 analytical and clinical validation data to support the effectiveness of the test, or lack of clinical utility data to support the value 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;
- manufacturing constraints due to limited energy supply in Europe or other supply constraints; 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 laboratory operations as well as 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. If a clinical utility study fails to demonstrate the value of a particular test, we may choose not to commercialize, or we may not be able to obtain reimbursement for, the test.

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

As an element of our growth strategy, we have, from time to time, pursued 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 recently acquired C2i. 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. 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 depend, in part, on our ability to adapt and manufacture select tests to be performed on multiple IVD platforms.

Our strategy to expand into international markets depends on our ability to successfully adapt our menu of diagnostic tests on multiple in vitro diagnostic, or IVD, platforms, and secure necessary regulatory approvals. Currently, the Prosigna breast cancer assay is the only commercially-available test on the nCounter Analysis System platform. If we are not able to adapt our current or future tests to be performed on quantitative polymerase chain reaction, or qPCR, or next generation sequencing, or NGS, IVD platforms or if our tests fail to be competitive against competing products in international markets, 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 our tests in international markets. For commercialization of our tests on other IVD platforms, we will be dependent on third parties for the supply, support and clinical registration of their platforms.

The revenue that we are expecting in our biopharma and other services business may not transpire.

In 2023, we experienced significant declines in biopharma and other services revenue as a result of reductions in customer projects, extended sales cycles and overall spending constraints across the industry. Despite this, we continue to offer our biopharma services offerings to pharmaceutical partners with services such as clinical and testing services, research and development, contract manufacturing and development, as well as other services. The success of our biopharma services business depends in part on our ability to identify and successfully negotiate with appropriate pharma partners. We cannot guarantee that we will be successful in the identification of appropriate pharma partners or the successful and timely negotiation with such partners, or that existing partners will not terminate their agreements with us.

We rely on sole suppliers for some of the reagents, equipment and other materials used to perform our tests, as well as certain sole service providers, and we may not be able to find replacements or transition to alternative suppliers or service providers, which may materially impact our ability to generate revenue.

We rely on sole suppliers for critical supply of reagents, equipment and other materials and services that we use to perform our tests, to access the nCounter Analysis System for diagnostic use and for components related to the Prosigna test kits sold to customers, as well as service kits. 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 and their inability to provide us with reagents that perform to specifications, could negatively impact our ability to provide timely response and reports to our customers and, as a result, may materially impact our ability to generate revenue.

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.

We rely on NanoString for the supply of the nCounter Analysis System for diagnostic use, components and raw materials for the Prosigna Test Kits and, service of the nCounter Analysis System. We have largely completed the transition of the manufacturing of the test kits for the nCounter from NanoString to our facility in Marseille, France. In February 2024, NanoString filed for bankruptcy under Chapter 11 of the United States Bankruptcy Code in the U.S. Bankruptcy Court in Delaware, which may negatively affect NanoString's ability to satisfy its supply, service, and license obligations and potentially harm our business or ability to generate revenue.

We rely on sole service providers for certain services such as cytopathology professional diagnoses on thyroid fine needle aspiration. If any of these service providers were unable to provide the quality or quantity of services that we require, or if we were unable to agree on commercial terms and our relationships with such service providers were to terminate, our business could be harmed until we were able to secure the services of another provider.

While we have developed alternate sourcing strategies for many materials, vendors and service providers, 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 macroeconomic trends. Periodically we experience supply chain disruptions, although, to date, this has not resulted in delays in our ability to timely return test results. 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.

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 tests, services or products, our business could suffer.

As demand for our tests, services and products grow, we will need to continue to scale our capacity and processing technology, expand customer service, billing and systems processes, enhance our internal quality assurance program and expand our manufacturing capacity. We will also need additional certified laboratory scientists as well as other scientific and technical personnel to process higher volumes. We cannot assure that any increases in scale, related improvements, supply of reagents to perform testing, and quality assurance measures will be successfully implemented or that appropriate personnel will be available and able to be hired. 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 or fulfill our product, testing, or service commitments 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, became subject to a reduction of 2% due to the automatic expense reductions (sequester). 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 involved 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. Effective for dates of service on or after July 1, 2022, the cap at 80% of the Medicare rate has been replaced with a cap at 100% of the lowest maximum allowance established by the federal Medicare program for the same or similar services.

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 many 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 and "Criterion A" ADLTs 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. In December 2022, through the Consolidated Appropriations Act of 2023, Congress further delayed the next reporting period to 2024. In November 2023, through the Further Continuing Appropriations and Other Extensions Act of 2024, Congress further delayed the next reporting period to 2025. 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 Decipher Prostate Biopsy, Decipher Prostate RP or Decipher Bladder 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. Envisia's Medicare price on the CLFS is based on private payer rates collected and reported annually, which can lead to the Medicare price fluctuating on January 1st of each year. 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 took effect on 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 have implemented the No Surprises Act through rulemakings issued on July 1, 2021, September 30, 2021, and August 19, 2022. 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 molecular pathology 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 and Criterion A ADLTs 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, 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, 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.

FDA or foreign authorities regulation those of our tests that they do not currently regulate, could result in Veracyte incurring 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 concerning LDTs. While the FDA has historically maintained its authority to regulate LDTs, it has generally exercised 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. We believe that the Afirma, Decipher Prostate Biopsy, Decipher Prostate RP, Envisia, and Decipher Bladder classifiers, have been developed and are performed in a manner consistent with the FDA's enforcement discretion policy concerning LDTs.

On April 29, 2024, the FDA released final regulations under 21 CFR Part 809 under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to make explicit that IVD products are devices under the FD&C Act, removing much of the FDAs historical enforcement discretion for most LDTs. In conjunction with this final rule, the FDA proposed to phase out its general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs. This final rule also provides that FDA intends to exercise enforcement discretion and generally not enforce premarket review and quality system requirements (except for requirements under Part 820, subpart M (records)) for currently marketed IVDs offered as LDTs that were first marketed prior to April 29, 2024 and intends to exercise enforcement discretion and generally not enforce premarket review requirements for LDTs approved by the New York State Clinical Lab Evaluation Program (NYS CLEP). We believe that Afirma, Decipher Prostate Biopsy, Decipher Prostate RP, Envisia, and Decipher Bladder classifiers will enjoy the continued FDA enforcement discretion in their current forms. Additionally, pursuant to the final rule, the FDA will gradually end its general enforcement discretion approach in five stages over a four-year period for other LDTs not approved by NYS CLEP or not already on market. Each stage of the proposed phaseout period would subject LDTs to a set of regulatory requirements. For example, the first stage of the phaseout would require LDT developers to comply with medical device reporting requirements and correction and removal reporting requirements within one year after the FDA publishes the final rule. LDTs that are considered higher risk IVDs would be subject to premarket review requirements within three and a half years, and LDTs that are considered moderate or low risk IVDs would be subject to premarket submission requirements within four years after the FDA publishes the final rule. While the enforcement policy is phased out, the FDA could still decide to pursue enforcement action at any time against LDTs that it

deems to be violative of its regulations when appropriate. We cannot predict when, or if, the proposed rule will be finalized and, if it is, whether any substantial changes will be made to the rule.

While we enjoy continued FDA enforcement discretion under this final rule for our existing tests, if the FDA were to determine that Afirma, Decipher Prostate Biopsy, Decipher Prostate RP, Envisia and Decipher Bladder classifiers, or modifications thereof, are not within the scope of the FDA's enforcement discretion policy for LDTs for any reason, including based on these final rules or new rules, regulations, policies or guidance, or due to changes in statute, our existing tests may become subject to extensive FDA requirements, or our business may otherwise be adversely affected and lead to potential adverse effects on our business, prospects, results of operations and financial condition. Furthermore, under the terms of this FDA final rule as drafted, any future Veracyte tests developed and commercialized, not currently on market, are likely to be subject to extensive FDA requirements which may adversely impact our business, prospects, results of operations and financial conditions.

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. 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 or modifications we make to existing products could be delayed by the implementation of FDA or foreign regulations. The cost of complying with premarket review or certification requirements, including obtaining clinical data, could be significant. In addition, any future regulation by the FDA or foreign authorities could subject our business to further regulatory risks and costs. For example, 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 raised potential concerns where companies 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. 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 as RUO or IUO, the distribution, sale, or use of the product could violate the misbranding or adulteration provisions of 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 medical device, or 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 as 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 the 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.

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.

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. Alternatively, we may be able to obtain marketing authorization through a *De Novo* classification process rather than through a PMA for class I or class II devices if the 510(k) pathway is not available. If the FDA finalizes the proposed rule to regulate LDTs as medical devices as it is currently drafted, we will need to obtain the appropriate marketing clearance, approval, or authorization for each or our tests that are currently offered as LDTs in accordance with the timelines provided in the final rule.

In September 2013, Prosigna was granted FDA 510(k) clearance as a prognostic indicator for distant recurrence-free survival at ten years in post-menopausal women with Stage I/II lymph node-negative or Stage II lymph node-positive (1-3 positive nodes), hormone receptor-positive breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors after they have undergone surgery in conjunction with locoregional treatment and consistent with the standard of care.

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 medical device product for which we obtain marketing authorization, including any tests that are currently offered as LDTs, 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 medical devices, 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. If the FDA finalizes its proposed rule to regulate LDTs as medical devices as it is currently drafted, these regulatory requirements will become applicable to our tests that are currently offered as LDTs in stages, including any applicable premarket approval, clearance, or authorization requirements. 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, 510(k) clearance, or De Novo authorization from the FDA and are therefore supplementing our operational capabilities to manage the more complex processes needed to obtain and maintain marketing authorization. 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. Additionally, in Great Britain, all medical devices will require a UK Conformity Assessed, or UKCA, mark but CE marks (IVDD self-certified or IVDR issued by EU notified regulatory bodies, subject to validity of the certificate in the EU)

will remain valid until June 30, 2030. Manufacturers may choose to use the UKCA mark on a voluntary basis until June 30, 2030.

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. For IVD medical devices, the regime is expected to come into force in July 2030, 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, 2030, subject to validity on the certificate. For medical devices, including IVD MDs, placed on the market in Great Britain after this period, the UKCA marking will be mandatory and subject to positive review and issuance of a certificate by an accredited Authorized Body. In contrast, UKCA marking and certificates issued by UK notified regulatory bodies are not yet 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, or MRA, aligning IVD regulations between the European Union and Switzerland has officially expired following the In Vitro Diagnostic Medical Devices Regulation’s, or 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, or 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 or other IVD platforms 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. We cannot guarantee that the regulatory authorization or certification for Prosigna will be granted or, if granted, will not be revoked, which could adversely impact our business, financial condition, and operations.

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 are dependent on third party platform and technology providers to maintain their platforms and technology in accordance with the requirements of applicable regulatory bodies. We cannot assure investors that we will be successful in obtaining or maintaining regulatory clearances, certifications, approvals, or marketing authorizations of our existing or future tests or technology, including nCounter. If we do not obtain or maintain regulatory clearances, certifications, approvals, or marketing authorizations for existing or future diagnostic kit products or technology, 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 related to our IVD strategy 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, the 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 Prosigna for use on nCounter is our only product that will require recertification. 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, or a failure or delay in our ability to recertify Prosigna for use on nCounter 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 becomes applicable five years after publication on May 26, 2022 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, the FDA has recently finalized a 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 in the United States are limited to the indications for use 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 the 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 and/or achieve profitability.

We operate in a highly competitive market. For our Afirma genomic classifier we face competition from companies and academic institutions that use NGS technology or other methods to measure mutational markers such as BRAF and KRAS, along with numerous other mutations. These organizations include Interpace Diagnostics Group, Inc., CBLPath, Inc./University of Pittsburgh Medical Center and others who are developing new products or technologies that may compete with our tests. In the future, we may also face competition from companies developing new products or technologies.

Our Decipher Prostate test faces competition from Myriad Genetics and MDx Health, 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 in addition to new technologies such as artificial intelligence, or AI, and digital pathology. 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 Envisia classifiers will similarly come from traditional methods used by physicians to diagnose the related diseases. For the Percepta Nasal Swab 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, including into the MRD space, we may also face competition from companies informing treatment decisions such as Personalis, Natera, Guardant Health or Foundation Medicine, Inc. Competition could also emerge 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, Quest Diagnostics, and Sonic Healthcare USA, with strong infrastructure to support the commercialization of diagnostic services. We face potential competition from companies such as Thermo Fisher Scientific Inc., which has 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., and we also may face competition from competitors of our biopharma services such as Neogenomics, Adaptive Biotechnologies, Tempus and Akoya.

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, products and services, we will face many of these same competitive risks.

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 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 salespeople.

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, we may have difficulties recruiting and training additional sales personnel or retaining qualified salespeople, 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 person 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 in order to collect cash and 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, commercial 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 including cash collections. Furthermore, third-party payers may reduce or refuse to pay for our tests, with or without notice.

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;
- individual payers may argue technical contract noncompliance and withhold payment;
- 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 our tests, including 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 January 1, 2020, we began using CPT code 81542 to bill for Decipher Prostate Biopsy and Decipher Prostate RP tests. 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.

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 subsequent updates, 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 and products. If we fail to establish our molecular diagnostic tests and products in the marketplace, it could have a negative effect on our ability to sell subsequent molecular diagnostic tests and products, thereby hindering the desired expansion of our business. We have growing, however limited, historical experience forecasting the direct sales of our molecular diagnostics tests and 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 timeframes 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. We cannot be certain that we will meet our projected targets and if we do not meet these as publicly announced, the commercialization of our tests 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 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 our products. We must provide sufficient clinical and analytical validity, as well as clinical 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.

In order to develop and commercialize diagnostic tests to be run in our CLIA lab, 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 test and 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. If a clinical utility study fails to demonstrate the value of a particular test, we may not be able to obtain reimbursement for the test. 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, 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 (including physicians and labs), 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, and we cannot ensure that all our employees, agents, contractors, vendors, licensees, partners or collaborators will comply, or have

historically complied, with all applicable laws and regulations. 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.

We must successfully integrate acquired businesses to realize the financial goals that we currently anticipate.

Risks we face in connection with the integration of C2i and the ongoing integration of HalioDx and Decipher Biosciences include:

- 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 use of innovative technologies we acquire, including AI, presents risk and challenges, including flawed algorithms or insufficient or biased datasets, which could adversely impact the reliability of our data and subject us to delays and competitive harm, regulatory action, or legal liability, as well as brand or reputational harm;
- 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;
- Prior to the acquisitions, none of HalioDx, Decipher Biosciences, or C2i were 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. Over the course of 2021 and 2022, we integrated the operations of HalioDx and Decipher Biosciences into our internal control structure and implemented additional internal controls where needed and, beginning in 2024, we began to integrate similar internal control structures for C2i. As we continue to integrate and improve the operations of HalioDx, Decipher Biosciences, and C2i, we may need to implement additional controls. 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, Decipher Biosciences', and C2i's 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 successfully manufacture the test kits for the nCounter from our manufacturing facility in Marseille, France, for a variety of reasons, including that we may experience manufacturing irregularities or challenges in

connection with the manufacturing transition from NanoString to our Marseille, France facility, such as sole supplier challenges and rolling blackouts due to energy shortages in Europe;

- We may experience disagreements, challenges, strikes, and litigation associated with the French employee work council or French union;
- We may experience disruption in integrating key talent from the C2i Acquisition due to the ongoing conflict in the Middle East and the ability to travel in and out of the conflicted area; and
- We may have failed to identify or assess the magnitude of certain liabilities, shortcomings or other circumstances prior to acquiring our acquired businesses, which could result in unexpected litigation or regulatory exposure, unfavorable accounting or tax treatment, a diversion of management's attention and resources, and other adverse effects on our business, financial condition, and operating results.

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

Changes in the value of the relevant currencies may affect the cost of certain items required in our operations and contractual agreements. Changes in currency exchange rates may also affect the relative prices at which we are able to sell products in the same market. Our 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.

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. In 2024, we acquired C2i, an oncology diagnostics company based in Tel Aviv, Israel, with global operations. 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;
- difficulties in maintaining the manufacturing output we anticipate at the Marseille, France facility as a result of rolling blackouts due to energy shortages in Europe resulting from the Russian invasion of Ukraine, as well as general impacts of geopolitical conflicts;
- potential disruptions to the development and launch of additional products or services as a result of having technology and research and development operations in Israel, including disruptions related to maintaining key research and development employees in Israel and the potential impact of the conflict in the Middle East on Company personnel who are performing, or on reserve to perform, military services as a result of such conflict;
- failure by us to obtain regulatory approvals, authorizations, 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, political unrest and other regional conflicts, outbreak of disease, including pandemics, 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 macroeconomic and market conditions.

Our business or financial results may be adversely impacted by uncertain economic conditions, including: regional conflicts globally, turmoil in the global banking and finance system, adverse changes in interest rates, foreign currency exchange rates, tax laws or tax rates; inflation; a recession; the impact of disease outbreak; 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 United States and those in Europe, have experienced and continue to experience uncertain economic conditions, including increased inflation and interest rates, resulting from global as well as local factors. For example, the short and long-term implications of the military conflict between Russia and Ukraine are difficult to predict at this time, including as it relates to our site in Marseille, France. The impact to Ukraine as well as actions taken by other countries, including new and stricter sanctions imposed by the United States 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. Additionally, financial pressures may cause government or other third-party payers to more aggressively seek cost containment measures in healthcare and other settings. Furthermore, the C2i Acquisition included acquiring assets, including employees, based in Israel, and the impact of the military conflict in the Middle East is difficult to predict at this time. The conflict has the potential to disrupt operations and business continuity, including physical damage or impaired access to Company facilities, offices, or technology and disruptions in access to electricity, gasoline, or water, as well as potential impact on our key employees located in Israel, such as the mobilization of employees who are members of the Israeli military reserves to active duty, disrupted communication with employees and restrictions on movement in areas subject to armed conflict.

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, 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, Envisia, and Decipher Bladder 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 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.

Issues relating to the use of AI and machine learning in our offerings could adversely affect our business and operating results.

We continue to integrate AI and machine learning into certain of our product offerings. Issues relating to the use of new and evolving technologies such as AI and machine learning may cause us to experience brand or reputational harm, competitive harm, legal liability, and new or enhanced governmental or regulatory scrutiny, and we may incur additional costs to resolve such issues. As with many innovations, AI presents risks and challenges that could undermine or slow its adoption, and therefore harm our business. For example, perceived or actual technical, legal, compliance, privacy, security, ethical or other issues relating to the use of AI may cause public confidence in AI to be undermined, which could slow our customers' adoption of our products and services that use AI. In addition, litigation or government regulation related to the use of AI may also adversely impact our and others' abilities to develop and offer products that use AI, as well as increase the cost and complexity

of doing so. Developing, testing and deploying AI components in our product offerings may also increase the cost profile of our product offerings due to the nature of the computing costs involved in such AI systems, which could impact our product margin and adversely affect our business and operating results. Further, market demand and acceptance of AI technologies are uncertain, and we may be unsuccessful in our product development efforts.

Our business and the operations of our laboratories are subject to the risk of disruptions caused by pandemics, political events, war, terrorism, earthquakes, fire, power outages, severe weather, floods, and other catastrophic events.

War, terrorism, geopolitical uncertainties, including any developments or consequences of regional conflicts globally 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 and emergence of variants had a negative effect on consumer confidence and spending, and other impacts, which adversely affected our business.

In addition, we perform all of the Afirma 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 manufacturing facility in Marseille, France, produces many of our Prosigna tests, as well as products for our IVD manufacturing services, and is subject to the risk of power outages resulting from constrained European energy supply.

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, organically or inorganically.

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 companies have been highly volatile, 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 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.

In 2023, the global banking system experienced turmoil. Our ongoing cash management strategy is to maintain diversity in our deposit accounts across financial institutions, but deposits in these institutions may exceed the amount of insurance provided on such deposits and there can be no assurance that this strategy will be successful. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, then our ability to access our cash and cash equivalents and short-term investments may be threatened,

which could have a material adverse effect on our business and financial condition. Moreover, events such as the closure of large financial institutions, in addition to other global macroeconomic conditions, may cause further turbulence and uncertainty in the capital markets.

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 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 an 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 January 11, 2023. The Biden Administration lifted the PHE declaration on May 11, 2023. 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, most significantly in the form of amendments and expansions pursuant to the California Privacy Rights Act adopted by ballot measure in November 2020, 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.

Further, on July 26, 2023, the SEC adopted new cybersecurity disclosure rules for public companies that require disclosure regarding cybersecurity risk management (including the board of director's role in overseeing cybersecurity risks, management's role and expertise in assessing and managing cybersecurity risks and processes for assessing, identifying and managing cybersecurity risks) in annual reports on Form 10-K. These new cybersecurity disclosure rules also require the disclosure of material cybersecurity incidents through a Current Report on Form 8-K, within four business days of determining an incident is material. Our failure to comply with these requirements, and disclosures of any cybersecurity incidents pursuant to these requirements, could adversely impact our business, operating results and financial condition.

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 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 which, at that time, included the United States. The EU Commission announced July 2023 that it had adopted a new adequacy decision with respect to the United States under a new regulatory structure known as the EU-US Data Privacy Framework. Although the EU-US Data Privacy Framework potentially provides additional regulatory certainty regarding data transfers from the EU to the US, it is widely expected that the new data transfer framework may be challenged before the CJEU, and in addition, the EU-US Data Privacy Framework is not automatically available to all companies but requires a company to meet certain jurisdictional and procedural requirements in order to get the benefit of utilizing such framework as a data-protective transfer mechanism.

Additionally, 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 were required to be migrated to the revised SCCs by December 27, 2022. We were required to 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 processing the information of EU data subjects 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 are 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 Oregon, Texas, Florida, Montana and Washington each have laws that will come into effect in 2024 that include obligations on privacy, data protection and use of personal data. 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 international data transfer restrictions and laws requiring local data residency and restricting international data transfer, which could increase the cost and complexity of delivering our services and operating our business. For example, Brazil's General Data Protection Law (as amended by Law No. 13,853/2019) contains restrictions on international transfer and heightened requirements on data concerning health, genetic and biometric data. China's Personal Information Protection Law (effective November 2021), together with the Cyberspace Administration of China's Measures on Security Assessment on Cross-border Data Transfer, broadly regulate the processing and international transfer of personal information and impose compliance obligations and penalties comparable to those of the GDPR.

Furthermore, the C2i Acquisition included acquiring personal data that may originate from, be processed in, or be transferred to and from, Israel, the EU and other jurisdictions. Our ability to process, use and transfer such personal data may be subject to Israel's privacy and data protection laws including but not limited to Basic Law: Human Dignity and Liberty, 5752 -1992; the Protection of Privacy Law, 5741-1981 and the regulations promulgated thereunder, or the PPL, and the guidelines of the Israel Privacy Authority. Personal data acquired through the C2i Acquisition may be subject to third-party contractual restrictions, as well as privacy and data protection laws in additional jurisdictions. The additional layers of privacy laws in Israel, additional jurisdictions, and contractual requirements increases the complexity of our global data privacy and data protection compliance obligations and risks. This could increase our potential liability, compliance costs, and may adversely affect our business operations.

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 or successfully defend our intellectual property effectively, our business may 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.

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 may 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 attempts 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 may be 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 may make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions may 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 may result in significant cost and distraction.

Monitoring unauthorized disclosure may be difficult, and we may 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 may be expensive and time-consuming, and the outcome may 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 may 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 may result in substantial costs and be a distraction to management.

Further, competitors may 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 may be adversely affected, as may 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 may be time-intensive and costly and may adversely affect our business, operating results or financial condition.

There is a substantial amount of intellectual property litigation involving liquid biopsy technologies, including assays for detection or quantification of MRD in patients who have had cancer. 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 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 are aware of third-party patents and patent applications with claims related to our products, and there may be other relevant third-party patents or patent applications of which we are not aware. We cannot assure that our products do not, or will not, infringe third-party issued patents.

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 may 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 may 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 may be burdensome and expensive, even if we were to prevail. Any litigation that may be necessary in the future may result in substantial costs and diversion of resources and may 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 may 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 may block our ability to develop, commercialize and sell products, and may 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 may incur substantial costs related to royalty payments for licenses obtained from third parties, which may negatively affect our financial results. In addition, we may 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 may prevent us from commercializing products, and the prohibition of sale of any of our products may 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 may be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there may 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 may 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 may 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 may incur significant costs and expenses that may 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, 2023, we had net operating loss, or NOL, carryforwards of approximately $320.7 million, $77.4 million and $113.6 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 2035 while for state purposes, the NOL carryforwards begin to expire in 2024. In addition, as of December 31, 2023, we had foreign net operating loss carryforwards of approximately $71.0 million and $53.1 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.

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.

Changes to Internal Revenue Code Section 174 under the 2017 Tax Cuts and Jobs Act went into effect in 2022. The revised code no longer permits a deduction for research and development expenditures in the tax year that such costs are incurred. Instead, such costs must be capitalized and amortized over five or 15 years for U.S. and foreign costs, respectively. The new rules will change the utilization of our NOLs and it is uncertain whether the new rules will be repealed or modified in the future.

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. Given our current earnings, we believe that, within the next two years, sufficient positive evidence may become available to allow us to reach a conclusion that a portion of the valuation allowance recorded against the deferred tax assets held may be reversed. A reversal would result in an income tax benefit for the quarterly and annual period in which we determine to release the valuation allowance. The impact of releasing some or all of such valuation allowance in a future period could be material in the period in which such release occurs. However, the exact timing and amount of a valuation allowance release are subject to change on the basis of the level of profitability that we actually achieve.

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 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, plant 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 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, because C2i was a private company and was not subject to audits of internal controls, the C2i Acquisition requires or will require us to incorporate additional controls to the businesses acquired in the C2i Acquisition, 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. In addition, corporate responsibility criteria with respect to ESG could change, which could result in greater expectations of us and cause us to undertake more costly initiatives to satisfy such new criteria. For example, in 2023, California passed three separate climate bills governing disclosure of climate house gas emissions data, climate-related financial risks, and details around emissions-related claims and carbon offsets. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate and we may be subject to fines from regulatory authorities and may harm our reputation. We may face reputational damage in the event that we do not meet the ESG standards set by various constituencies. In addition, the SEC recently adopted a rule that requires climate disclosures in periodic and other filings with the SEC covering fiscal years beginning in 2025, which rule has been stayed pending the completion of a judicial review. To comply with this SEC rule, if such rule goes into effect in its current form, we will be required to establish additional internal controls, engage additional consultants and incur additional costs related to evaluating, managing and reporting on our environmental impact and climate-related risks and opportunities. If we fail to implement sufficient oversight or accurately capture and disclose on environmental matters, our reputation, business, operating results and financial condition may be materially adversely affected.

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 ongoing global macroeconomic impacts of rising interest rates or inflationary pressures;
- 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;
- instability in the global banking system;
- 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, with each class serving staggered three-year terms. However, beginning with our annual meeting of stockholders to be held in 2024, our board of directors will be declassified over a three-year period, with each class, beginning with the directors standing for election at the annual meeting of stockholders to be held in 2024, subject to an election for a term of one year expiring at the next succeeding annual meeting of stockholders;
- provide that our directors serving in a class of directors for a term expiring at the third annual meeting of stockholders following the election of such class 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

(C) Insider Trading Arrangements

During the three months ended March 31, 2024, the following Section 16 officers and directors adopted, modified or terminated "Rule 10b5-1 trading arrangements" (as defined in Item 408 of Regulation S-K of the Exchange Act).

- Muna Bhanji, director, adopted a new trading plan on February 27, 2024 (with the first trade under the new plan scheduled for approximately May 10, 2024). The trading plan will be effective until February 28, 2025 to sell an aggregate of 5,409 shares of our common stock.
- Evan Jones, director, adopted a new trading plan on February 28, 2024 (with the first trade under the new plan scheduled for June 10, 2024). The trading plan will be effective until December 31, 2025 to sell an aggregate of 24,731 shares of our common stock.
- jVen Capital LLC (Evan Jones, director, is the managing member of jVen Capital LLC) adopted a new trading plan on February 28, 2024 (with the first trade under the new plan scheduled for June 10, 2024). The trading plan will be effective until December 31, 2025 to sell an aggregate of 35,173 shares of our common stock.
- John Leite, Chief Commercial Officer, CLIA, adopted a new trading plan on March 1, 2024 (with the first trade under the new plan scheduled for June 4, 2024). The trading plan will be effective until February 27, 2025 to sell an aggregate of (i) 5,252 shares of our common stock, plus (ii) 100% of the net shares resulting from the vesting of 5,183 additional common stock during the plan period (net shares are net of tax withholding).
- Karin Eastham, director, adopted a new trading plan on March 8, 2024 (with the first trade under the new plan scheduled for June 7, 2024). The trading plan will be effective until March 7, 2025 to sell an aggregate of 13,870 shares of our common stock.
- Jens Holstein, director, adopted a new trading plan on March 11, 2024 (with the first trade under the new plan scheduled for June 10, 2024). The trading plan will be effective until December 31, 2024 to sell an aggregate of 10,000 shares of our common stock.

Each Rule 10b5-1 Plan included a representation from the director and/or officer to the broker administering the Rule 10b5-1 Plan that they were not in possession of any material nonpublic information regarding the Company or the securities subject to the respective Rule 10b5-1 Plan. A similar representation was made to the Company in connection with the adoption of each Rule 10b5-1 Plan under the Company's Insider Trading Policy. Those representations were made as of the date of adoption of each respective Rule 10b5-1 Plan and speak only as of such date. In making those representations, there is no assurance with respect to any material nonpublic information of which the director/officer was unaware, or with respect to any material nonpublic information acquired by the director/officer or the Company after the date of the representation.

ITEM 6. EXHIBITS

Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
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: May 8, 2024

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 March 31, 2024;

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: May 8, 2024

/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 March 31, 2024;

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: May 8, 2024

/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 March 31, 2024, 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: May 8, 2024

/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 March 31, 2024, 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: May 8, 2024

/s/ Rebecca Chambers

Rebecca Chambers
Chief Financial Officer
(Principal Financial Officer)