PROSPECTUS SUPPLEMENT NO. 1 (to Prospectus dated May 11, 2022)



Sema4 Holdings Corp. 160,864,198 Shares of Common Stock

This prospectus supplement supplements the prospectus dated May 11, 2022 (the "Prospectus"), which forms a part of our registration statement on Form S-1 (No. 333-264626). This prospectus supplement is being filed to update and supplement the information in the Prospectus with the information contained in our quarterly report on Form 10-Q, filed with the Securities and Exchange Commission (the "SEC") on May 12, 2022. Accordingly, we have attached the quarterly report on Form 10-Q to this prospectus supplement.

The Prospectus and this prospectus supplement relate to the offer and sale from time to time by the selling stockholders named in this prospectus (the "Selling Stockholders") of up to 160,864,198 shares of our Class A common stock, par value \$0.0001 per share ("Class A common stock"), consisting of (i) up to 80,000,000 shares of our Class A common stock (the "Stock Consideration Shares") issued to OPKO Health, Inc. ("OPKO") as a portion of the consideration for the Acquisition (as defined below), (ii) up to 30,864,198 shares of our Class A common stock (the "Milestone Shares") that may be issuable to OPKO in connection with the achievement of certain revenue-based milestones for each of the fiscal years ending December 31, 2022 and December 31, 2023 and (iii) up to 50,000,000 shares of our Class A common stock (the "PIPE Shares") issued in a private placement pursuant to subscription agreements each entered into on January 14, 2022 (the "PIPE Investment").

On April 29, 2022, we consummated the transactions contemplated by that certain Agreement and Plan of Merger, dated as of January 14, 2022 (as amended, the "Merger Agreement"), by and among us and our wholly-owned subsidiaries, Orion Merger Sub I, Inc. ("Merger Sub I") and Orion Merger Sub II, LLC ("Merger Sub II" and, together with Merger Sub I, "Merger Subs"), and GeneDx, Inc., a New Jersey corporation and wholly-owned subsidiary of OPKO ("GeneDx"), GeneDx Holding 2, Inc., which held 100% of GeneDx at the Effective Time (as defined below) ("Holdco2"), and OPKO. Pursuant to the terms of the Merger Agreement, we acquired GeneDx through the merger of Merger Sub I with and into Holdco2 (the "First Merger"), with Holdco2 as the surviving corporation in the First Merger. Immediately after the consummation of the First Merger, as part of the same overall transaction, Holdco2, as the surviving company. After giving effect to the Mergers and the other transactions contemplated by the Merger Agreement, GeneDx was converted into a Delaware limited liability company and became our wholly-owned indirect subsidiary. At the closing of the Acquisition, we paid OPKO \$150 million of Cash Consideration (as defined herein) and issued to OPKO the Stock Consideration Shares. Concurrently with the closing, we also consummated the PIPE Investment, issuing the PIPE Shares for aggregate gross proceeds of \$200 million. We have filed the registration statement to which this prospectus relates to satisfy certain registration rights obligations we have to the Selling Stockholders in respect of the Stock Consideration Shares, the Milestone Shares and the PIPE Shares.

Our common stock and public warrants are listed on the Nasdaq Global Select Market (the "Nasdaq") under the symbol "SMFR" and "SMFRW", respectively. On May 11, 2022, the last reported sales price of our common stock was \$1.56 per share and the last reported sales price of our public warrants was \$0.28 per warrant.

This prospectus supplement updates and supplements the information in the Prospectus and is not complete without, and may not be delivered or utilized except in combination with, the Prospectus, including any amendments or supplements thereto. This prospectus supplement should be read in conjunction with the Prospectus and if there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on the information in this prospectus supplement.

We are an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended, and, as such, have elected to comply with certain reduced disclosure and regulatory requirements.

Investing in our securities involves risks. See the section entitled "Risk Factors" beginning on page 8 of the Prospectus to read about factors you should consider before buying our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is May 12, 2022

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, 2022

OR

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

For the transition period from ______ to _____

Commission file number 001-39482



Sema4 Holdings Corp.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

333 Ludlow Street, North Tower, 8th Floor Stamford, Connecticut

(Address of Principal Executive Offices)

85-1966622 (I.R.S. Employer Identification No.)

06902 (Zip Code)

(800) 298-6470

Registrant's telephone number, including area code

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, par value \$0.0001 per share	SMFR	The Nasdaq Global Select Market
Warrants to purchase one share of Class A common stock, each at an exercise price of \$11.50 per share	SMFRW	The Nasdaq Global Select Market

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

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

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. (Check one):

Large accelerated filer	0	Accelerated filer	0
Non-accelerated filer	х	Smaller reporting company	х
		Emerging growth company	х

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. **o**

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

The registrant had outstanding 377,249,186 shares of Class A common stock as of April 29, 2022.

Table of Contents

		Page
Explanatory	<u>/ Note</u>	4
Cautionary	Note Regarding Forward Looking Statements	5
Part I. Fina	ncial Information	
<u>Item 1.</u>	Unaudited Condensed Consolidated Financial Statements	6
	Condensed Consolidated Balance Sheets	6
	Condensed Consolidated Statements of Operations and Comprehensive Loss	7
	Condensed Consolidated Statement of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)	8
	Condensed Consolidated Statements of Cash Flows	9
	Notes to Unaudited Condensed Consolidated Financial Statements	10
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	31
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	43
<u>Item 4.</u>	Controls and Procedures	44
Part II. Oth	er Information	
<u>Item 1.</u>	Legal Proceedings	46
Item 1A.	Risk Factors	46
<u>Item 2.</u>	Unregistered Sales of Equity Securities and Use of Proceeds	92
Item 3.	Defaults Upon Senior Securities	92
<u>Item 4.</u>	Mine Safety Disclosures	92
Item 5.	Other Information	92
<u>Item 6.</u>	Exhibits	92
Signatures		95

Signatures

EXPLANATORY NOTE

Unless otherwise stated in this report or the context otherwise requires, references to the "Company," "Sema4" and "we," "us" and "our" refer to (i) Mount Sinai Genomics, Inc. d/b/a as Sema4, or Legacy Sema4, prior to the consummation of our business combination with CM Life Sciences, Inc., or CMLS, on July 22, 2021 and (ii) Sema4 Holdings Corp. and its consolidated subsidiaries following the consummation of our business combination.

In addition, on April 29, 2022, we consummated the transactions contemplated by that certain Agreement and Plan of Merger, dated as of January 14, 2022 (as amended, the "Merger Agreement"), by and among us and our wholly-owned subsidiaries, Orion Merger Sub I, Inc. ("Merger Sub I") and Orion Merger Sub II, LLC ("Merger Sub II" and, together with Merger Sub I, "Merger Subs"), and GeneDx, Inc. ("GeneDx"), a New Jersey corporation and whollyowned subsidiary of OPKO Health, Inc. ("OPKO"), GeneDx Holding 2, Inc., which held 100% of GeneDx ("Holdco2"), and OPKO, which provided for, among other things, the acquisition of GeneDx from OPKO. Pursuant to the terms of the Merger Agreement, we acquired GeneDx through the merger of Merger Sub I with and into Holdco2 (the "First Merger"), with Holdco2 as the surviving corporation in the First Merger. Immediately after the consummation of the First Merger, as part of the same overall transaction, Holdco2, as the surviving corporation in the First Merger, merged with and into Merger Sub II (the "Second Merger" and, together with the First Merger, the "Mergers"), with Merger Sub II as the surviving company. After giving effect to the Mergers and the other transactions contemplated by the Merger Agreement, GeneDx was converted into a Delaware limited liability company and became our wholly-owned indirect subsidiary. At the closing of the Acquisition (as defined below), we paid OPKO gross cash consideration of \$150 million and issued to OPKO 80 million shares of our Class A common stock. We refer to these transactions herein as the "Acquisition." In addition, up to \$150 million is payable following the closing of the Acquisition, if certain revenue-based milestones are achieved for each of the fiscal years ending December 31, 2022 and December 31, 2023. Concurrently with the closing of the Acquisition, we also issued and sold in private placement 50,000,000 shares of our Class A common stock to certain institutional investors for aggregate gross proceeds of \$200 million (the "Acquisition PIPE Investment"). Unless stated otherwise in this report, all forward-looking information contained in this report does not take into account or give any effect to the impact of the Acquisition or the Acquisition PIPE Investment.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report, as well as other factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about:

- our estimates of the sufficiency of our existing capital resources combined with future anticipated cash flows to finance our operating requirements
- our expected losses;
- our expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- unforeseen circumstances or other disruptions to normal business operations, including supply chain interruptions and manufacturing constraints, arising from or related to the ongoing COVID-19 pandemic;
- our ability to realize the benefits expected from the Acquisition;
- our expectations for generating revenue or becoming profitable on a sustained basis;
- our expectations or ability to enter into service, collaboration and other partnership agreements;
- our expectations or ability to build our own commercial infrastructure to scale market and sell our products;
- actions or authorizations by the U.S. Food and Drug Administration, or the FDA, or other regulatory authorities;
- risks related to governmental regulation and other legal obligations, including privacy, data protection, information security, consumer protection, and anti-corruption and anti-bribery;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to compete against existing and emerging technologies;
- our stock price and its volatility;
- our ability to attract and retain key personnel;
- third-party payor reimbursement and coverage decisions;
- our reliance on third-party laboratories and service providers for our test volume in connection with our diagnostic solutions and data programs;
- our expectations for future capital requirements; and
- our ability to successfully implement our business strategy.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date that this report is signed. Except as required by law, we assume no responsibility for updating any forward-looking statements.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Sema4 Holdings Corp. **Condensed Consolidated Balance Sheets** (in thousands, except share amounts)

Part I - Financial Information

Item 1. Unaudited Condensed Consolidated Financial Statements

	March 31, 2022 (unaudited)		December 31, 2021	
Assets				
Current assets:				
Cash and cash equivalents	\$	315,002	\$	400,569
Accounts receivable, net		37,642		26,509
Due from related parties		125		54
Inventory, net		36,318		33,456
Prepaid expenses		17,241		19,154
Other current assets		4,096		3,802
Total current assets	\$	410,424	\$	483,544
Operating lease right-of-use assets		38,417		—
Property and equipment, net		60,976		62,719
Restricted cash		900		900
Other assets		6,953		6,930
Total assets	\$	517,670	\$	554,093
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable and accrued expenses	\$	68,880	\$	64,801
Due to related parties		3,237		2,623
Contract liabilities		66		473
Short-term lease liabilities		5,072		_
Other current liabilities		23,384		33,387
Total current liabilities	\$	100,639	\$	101,284
Long-term debt, net of current portion		11,000		11,000
Long-term lease liabilities		57,478		_
Other liabilities		500		21,907
Warrant liability		15,177		21,555
Earn-out contingent liability		3,432		10,244
Total liabilities	\$	188,226	\$	165,990
Commitments and contingencies (Note 10)				
Stockholders' equity:				
Preferred Stock, \$0.0001 par value: 1,000,000 and 0 shares authorized at March 31, 2022 and December 31, 2021, respectively; 0 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively		_		_
Class A common stock, \$0.0001 par value, 380,000,000 shares authorized, 245,154,475 shares issued and outstanding at March 31, 2022 and \$0.0001 par value: 380,000,000 shares authorized, 242,647,604 shares issued and outstanding at December 31, 2021		24		24
Additional paid-in capital		981,757\$		963,520
Accumulated deficit		(652,337)		(575,441)
Total stockholders' equity		329,444		388,103
Total liabilities and stockholders' equity	\$	517,670	\$	554.093
Total naomitos and stockholidels equity	*	217,070	Ψ	221,095

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

Sema4 Holdings Corp. Condensed Consolidated Statements of Operations and Comprehensive Loss (in thousands, except share and per share amounts) (unaudited)

	Three months	March 31,	
	 2022		2021 (1)
Revenue:			
Diagnostic test revenue (including related party revenue of \$170 and \$33 for the three months ended March 31, 2022 and 2021, respectively)	\$ 52,495	\$	62,760
Other revenue (including related party revenue of \$74 and \$27 for the three months ended March 31, 2022 and 2021, respectively)	1,446		1,441
Total revenue	53,941		64,201
Cost of services (including related party expenses of \$1,056 and \$278 for the three months ended March 31, 2022 and 2021, respectively)	48,316		68,524
Gross profit (loss)	5,625		(4,323)
Research and development	21,315		53,133
Selling and marketing	29,547		35,366
General and administrative	42,784		102,038
Related party expenses	1,284		1,797
Loss from operations	 (89,305)		(196,657)
Other income (expense), net:			
Change in fair market value of warrant and earn-out contingent liabilities	13,190		—
Interest income	27		21
Interest expense	(808)		(723)
Other income	 		5,584
Total other income (expense), net	12,409		4,882
Loss before income taxes	\$ (76,896)	\$	(191,775)
Income tax provision			
Net loss and comprehensive loss	\$ (76,896)	\$	(191,775)
Weighted average shares outstanding of Class A common stock	244,368,743		549,778
Basic and diluted net loss per share, Class A common stock	\$ (0.31)	\$	(348.82)

(1) As previously disclosed in Note 2, "Summary of Significant Accounting Policies" to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021, certain adjustments were made to reclassify certain expenses between cost of services and operating expenses. The adjustments are reflected as disclosed.

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

Sema4 Holdings Corp. Condensed Consolidated Statement of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) (in thousands, except share amounts) (unaudited)

	Three months ended March 31, 2022										
	Preferred	l Stock	Class A Cor	nmor	1 Stock						Total
	Shares	Par value	Shares		Par value	Ad	Additional paid- in capital		- Accumulated deficit		tockholders' equity
Balances at December 31, 2021			242,647,604	\$	24	\$	963,520	\$	(575,441)	\$	388,103
Net loss			—						(76,896)		(76,896)
Stock option exercises		—	2,108,502		—		678				678
Stock based compensation expense			_		_		17,559		_		17,559
Vested restricted stock units converted to common stock	_		398,369								
Balances at March 31, 2022	_	<u>\$</u> —	245,154,475	\$	24	\$	981,757	\$	(652,337)	\$	329,444

Three months ended March 31, 2021 (1)

	Redeemable Preferre		Class A Con	nmon Stock	Class B Cor	nmon Stock	Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	Shares	Par value	Shares	Par value	capital	deficit (1)	(deficit)
Balances at December 31, 2020	171,535,213	\$ 334,439	124	\$	130,557	\$ —	\$	\$ (330,051)	\$ (330,051)
Net loss		_		—	_			(191,775)	(191,775)
Common stock class B issued pursuant to stock options	_		_	_	618,204	_	_		_
Balances at March 31, 2021	171,535,213	\$ 334,439	124	\$ —	748,761	s —	\$	(521,826)	(521,826)

(1) As previously disclosed in Note 2, "Summary of Significant Accounting Policies" to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021, certain adjustments were made which impacted previously reported net loss for the first quarter of 2021 and the adjusted net loss is reflected as disclosed.

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

Sema4 Holdings Corp. Condensed Consolidated Statements of Cash Flows (in thousands) (unaudited)

		Three months ended March 31,		
		2022	2021 (1)	
Operating activities				
Net loss	\$	(76,896) \$	(191,775)	
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization expense		5,803	4,902	
Stock-based compensation expense		17,559	164,962	
Change in fair value of warrant and earn-out contingent liabilities		(13,190)	—	
Provision for excess and obsolete inventory		43	1,821	
Non-cash lease expense		167	191	
Amortization of deferred debt issuance costs		128		
Change in operating assets and liabilities:				
Accounts receivable		(11,132)	(1,296)	
Inventory		(2,904)	(9,828)	
Prepaid expenses and other current assets		1,596	(6,327)	
Due to/from related parties		543	(688)	
Other assets		(151)	_	
Accounts payable and accrued expenses		3,932	3,951	
Contract liabilities		(408)	1,027	
Other current liabilities		(6,584)	(9,148)	
Net cash used in operating activities		(81,494)	(42,208)	
Investing activities				
Purchases of property and equipment		(1,378)	(2,075)	
Development of internal-use software assets		(2,535)	(2,919)	
Net cash used in investing activities		(3,913)	(4,994)	
Financing activities				
Payment of deferred transaction costs		—	(1,254)	
Finance lease principal payments		(862)	(1,052)	
Long-term debt principal payments			(394)	
Exercise of stock options		702	422	
Net cash used in financing activities		(160)	(2,278)	
		<u>```</u>		
Net decrease in cash, cash equivalents and restricted cash		(85,567)	(49,480)	
Cash, cash equivalents and restricted cash, at beginning of period		401,469	118,960	
Cash, cash equivalents and restricted cash, at end of period	\$	315,902 \$	69,480	
Cash, cash equivalents and restricted cash, at end of period	<u>Ψ</u>		07,100	
Supplemental disclosures of cash flow information				
Cash paid for interest	\$	607 \$	723	
Cash paid for taxes	\$	168 \$		
Purchases of property and equipment in accounts payable and accrued expenses	\$	1,325 \$	1,164	
Software development costs in accounts payable and accrued expenses				
Unpaid deferred transaction costs included in accounts payable and accrued expenses	\$ \$	717 \$ 227 \$	1,570	
onpaid deterted transaction costs included in accounts payable and accrued expenses	\$	221 \$	4,228	

(1) As previously disclosed in Note 2, "Summary of Significant Accounting Policies" to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021, certain adjustments were made to certain current asset and liability accounts previously reported in the condensed balance sheets as of March 31, 2021. The adjustments are reflected accordingly as disclosed.

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

Notes to Unaudited Condensed Consolidated Financial Statements

1. Organization and Description of Business

Sema4 Holdings Corp. ("Sema4 Holdings") through its subsidiary Sema4 OpCo, Inc.,, formerly Mount Sinai Genomics Inc., a Delaware corporation ("Legacy Sema4"), as discussed further below, provides genomics-related diagnostic and information services and pursues genomics medical research. Legacy Sema4 utilizes an integrated portfolio of laboratory processes, software tools and informatics capabilities to process DNA-containing samples, analyze information about patient-specific genetic variation and generate test reports for clinicians and their patients. Legacy Sema4 provides a variety of genetic diagnostic tests and information with a focus on reproductive health, including pediatric, oncology and other conditions. Legacy Sema4 primarily serves healthcare professionals who work with their patients and bills third-party payors across the United States, with a substantial portion of its diagnostic testing volume occurring in New York, California, Florida, Connecticut and New Jersey.

On July 22, 2021 (the "Closing Date"), CM Life Sciences, Inc. ("CMLS") completed the acquisition of Legacy Sema4, pursuant to that certain Agreement and Plan of Merger (as amended, the "Prior Merger Agreement"), dated February 9, 2021. On the Closing Date, S-IV Sub, Inc. ("Prior Merger Sub") merged with and into the Legacy Sema4, with Legacy Sema4 surviving the merger as a wholly-owned subsidiary of CMLS (the "Prior Merger" and, together with the other transactions contemplated by the Prior Merger Agreement, the "Business Combination"). In connection with the consummation of the Business Combination, CMLS changed its name to "Sema4 Holdings Corp." and Legacy Sema4 changed its name to "Sema4 OpCo, Inc." All equity securities of Legacy Sema4 were converted into the right to receive the applicable portion of the merger consideration.

The Prior Merger was accounted for as a reverse recapitalization with Legacy Sema4 as the accounting acquirer and CMLS as the acquired company for accounting purposes. The shares and net loss per common share, prior to the Prior Merger, have been retroactively restated as shares reflecting the exchange ratio established in the Prior Merger (1 share of Legacy Sema4 Class A common stock for 123.8339 shares of Sema4 Holdings Class A common stock (the "Class A common stock")) (the "Conversion Ratio").

Prior to the Prior Merger, shares of CMLS Class A common stock, CMLS's public warrants, and CMLS's public units were traded on the Nasdaq Capital Market under the ticker symbols "CMLF", "CMFLW", and "CMLFU" respectively. On July 23, 2021, shares of Sema4 Holdings Class A common stock and Sema4 Holdings' public warrants began trading on the Nasdaq Global Select Market (the "Nasdaq") under the ticker symbols "SMFR" and "SMFRW," respectively. See Note 3, "Business Combination," for additional details.

Unless otherwise stated herein or unless the context otherwise requires, references in these notes to the "Company," or "Sema4" refer to (i) Legacy Sema4 prior to the consummation of the Business Combination; and (ii) Sema4 Holdings and its subsidiaries following the consummation of the Business Combination.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and pursuant to the accounting disclosure rules and regulations of the Securities and Exchange Commission (the "SEC") regarding interim financial reporting. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. As such, the accompanying unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements and notes thereto as of and for the years ended December 31, 2021, 2020 and 2019 included in the Company's Annual Report on Form 10-K for the year ended December 21, 2021 filed on March 14, 2022 (the "Annual Report").

The accompanying unaudited condensed consolidated financial statements reflect all normal recurring adjustments that are necessary to state fairly the results for the interim periods presented. Interim results are not necessarily indicative of the results of operations or cash flows for a full year or any subsequent interim period.

The Company's historical financial information includes costs of certain services historically provided by Icahn School of Medicine at Mount Sinai ("ISMMS") pursuant to the Transition Services Agreement ("TSA") and service agreements.



Notes to Unaudited Condensed Consolidated Financial Statements

As discussed in the Company's Annual Report, the Company identified the misclassification of certain expenses and out of period adjustments generally related to the recognition of cost of services. The impact of these adjustments were disclosed in the Company's Annual Report and are reflected in the condensed consolidated statements of operations and comprehensive loss, condensed consolidated statement of redeemable convertible preferred stock and stockholders' equity (deficit) and condensed consolidated statements of cash flows for the period ended March 31, 2021.

Although the Company has incurred recurring losses in each year since inception, the Company expects its cash and cash equivalents will be sufficient to fund operations for at least the next twelve months from the date of filing of this Form 10-Q.

Segment Information

The Company operates and manages its business as one reportable operating segment based on how the Chief Executive Officer, who is the Company's chief operating decision maker ("CODM"), assesses performance and allocates resources across the business.

Use of Estimates

The preparation of unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and the related disclosures at the date of the unaudited condensed consolidated financial statements as well as the reported amounts of revenues and expenses during the periods presented. The Company bases these estimates on current facts, historical and anticipated results, trends and various other assumptions that it believes are reasonable in the circumstances, including assumptions as to future events. These estimates include, but are not limited to, the transaction price for certain contracts with customers, the capitalization of software costs and the valuation of stock-based awards, inventory, earn-out contingent liability and earn-out Restricted Stock Units ("RSUs"). Actual results could differ materially from those estimates, judgments and assumptions.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable.

The Company's cash and cash equivalents are deposited with high-quality financial institutions. The Company has balances in financial institutions that exceed federal depository insurance limits. Management believes these financial institutions are financially sound and, accordingly, that minimal credit risk exists. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company assesses both the self-pay patient and, if applicable, the third-party payor that reimburses the Company on the patient's behalf when evaluating the concentration of credit risk. Significant customers and payors are those that represent more than 10% of the Company's total revenues for the period or accounts receivable balance at each respective balance sheet date. The significant concentrations of accounts receivable as of March 31, 2022 and December 31, 2021 were primarily from large managed care insurance companies and a reference laboratory. There was no individual patient that accounted for 10% or more of the Company's revenue or accounts receivable for any of the periods presented. The Company does not require collateral as a means to mitigate customer credit risk.

For each significant payor, revenue as a percentage of total revenues and accounts receivable as a percentage of total accounts receivable are as follows:

Notes to Unaudited Condensed Consolidated Financial Statements

	Rev	Revenue		Receivable
	Three months of	Three months ended March 31,		As of December 31,
	2022	2021	2022	2021
Payor A	24%	14%	26%	15%
Payor B	*	*	19%	15%
Payor C	*	12%	*	*
Payor D	10%	12%	11%	*
*less than 10%				

The Company is subject to a concentration of risk from a limited number of suppliers for certain reagents and laboratory supplies. One supplier accounted for approximately 13% and 11% for the three months ended March 31, 2022 and 2021, respectively. This risk is managed by maintaining a target quantity of surplus stock.

Impact of COVID-19

Beginning in April 2020, the Company's diagnostic test volumes decreased significantly as compared to the prior year as a result of the initial outbreak of the COVID-19 pandemic and the related limitations and priorities across the healthcare system. In response, beginning in May 2020, the Company entered into several service agreements with state governments and healthcare institutions to provide testing for the presence of COVID-19 variants. While test volumes have since improved, the Company continues to experience changes in the mix of tests due to the impact of the COVID-19 pandemic. COVID-19 could continue to have a material impact on the Company's results of operations, cash flows and financial condition for the foreseeable future.

In March 2020, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was signed into law which was a stimulus bill that, among other things, provided assistance to qualifying businesses and individuals and included funding for the healthcare system. During 2020, as part of the stimulus provided by the CARES Act, the Company received \$5.4 million, comprised of \$2.6 million received under the Provider Relief Fund ("PRF") distribution and \$2.8 million received under the Employee Retention Credit ("ERC") distribution which was recorded in other current liabilities and reflected in this balance as of March 31, 2022 and December 31, 2021.

During the three months ended March 31, 2021, the Company received an additional \$5.6 million under the PRF distribution, which was recognized in other income in the condensed consolidated statements of operations and comprehensive loss.

Additionally, under the CARES Act, the Company deferred payment of U.S. social security taxes in 2020. As a result, \$3.8 million of employer payroll tax payments were initially deferred as of December 31, 2020 with \$1.9 million paid in December 2021 and the remaining \$1.9 million payment will be made in December 2022. As of March 31, 2022, the remaining payable is recorded in other current liabilities.

Following the Company's announcement that it would discontinue COVID-19 testing services by March 31, 2022, the Company no longer provides COVID-19 testing services. During the three months ended March 31, 2022, the Company wrote off an accounts receivable balance of \$0.5 million related to COVID-19 testing services.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist of amounts invested in money market funds. Carrying values of cash equivalents approximate fair value due to the short-term nature of these instruments.

Notes to Unaudited Condensed Consolidated Financial Statements

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported on the condensed consolidated balance sheets that sum to the total of the same amounts shown on the condensed consolidated statements of cash flows (in thousands):

	Μ	As of [arch 31, 2022	As of December 31, 2021		
Cash and cash equivalents	\$	315,002	\$	400,569	
Restricted cash		900		900	
Total	\$	315,902	\$	401,469	

Restricted cash as of March 31, 2022 consists of money market deposit accounts that secure an irrevocable standby letter of credit that serves as collateral for security deposit operating leases (see Note 9, "Leases").

Warrant Liability

As of the consummation of the Prior Merger in July 2021, there were 21,995,000 warrants to purchase shares of Class A common stock outstanding, including 14,758,333 public warrants and 7,236,667 private placement warrants. As of December 31, 2021, there were 21,994,972 warrants to purchase shares of Class A common stock outstanding, including 14,758,305 public warrants and 7,236,667 private placement warrants outstanding. Each warrant expires five years after the Business Combination or earlier upon redemption or liquidation, and entitles the holder to purchase one share of Class A common stock at an exercise price of \$11.50 per share, subject to adjustment, at any time commencing on September 4, 2021.

The Company may redeem the outstanding public warrants if the price per share of the Class A common stock equals or exceeds \$18.00 as described below:

- in whole and not in part;
- at a price of \$0.01 per public warrant;
- upon not less than 30 days' prior written notice of redemption to each warrant holder; and
- if, and only if, the closing price of the Class A common stock equals or exceeds \$18.00 per share (as adjusted) for any 20 trading days within a 30trading day period ending three trading days before sending the notice of redemption to warrant holders.

The Company may redeem the outstanding public warrants if the price per share of the common stock equals or exceeds \$10.00 as described below:

- in whole and not in part;
- at \$0.10 per warrant upon a minimum of 30 days' prior written notice of redemption provided that holders will be able to exercise their warrants on a
 cashless basis prior to redemption and receive that number of shares based on the redemption date and the fair market value of the common stock;
- if, and only if, the closing price of the Class A common stock equals or exceeds \$10.00 per share (as adjusted) for any 20 trading days within the 30trading day period ending three trading days before the Company sends the notice of redemption to the warrant holders; and
- if the closing price of the common stock for any 20 trading days within a 30-trading day period ending three trading days before the Company sends notice of redemption to the warrant holders is less than \$18.00 per share (as adjusted), the private placement warrants must also be concurrently called for redemption on the same terms as the outstanding public warrants, as described above.

The private placement warrants were issued to CMLS Holdings, LLC, Mr. Munib Islam, Dr. Emily Leproust and Mr. Nat Turner, and are identical to the public warrants underlying the units sold in the initial public offering, except that (1) the private placement warrants and the common stock issuable upon the exercise of the private placement warrants would

Notes to Unaudited Condensed Consolidated Financial Statements

not be transferable, assignable or salable until 30 days after the completion of a Business Combination, subject to certain limited exceptions, (2) the private placement warrants are exercisable on a cashless basis, (3) the private placement warrants are non-redeemable (except as described above, upon a redemption of warrants when the price per share of Class A common stock equals or exceeds \$10.00) so long as they are held by the initial purchasers or their permitted transferees, and (4) the holders of the private placement warrants are held by someone other than the initial purchasers or their permitted transferees, the private placement warrants are held by someone other than the initial purchasers or their permitted transferees, the private placement warrants will be redeemable by the Company and exercisable by such holders on the same basis as the public warrants.

The Company accounts for warrants as liability-classified instruments based on an assessment of the warrant terms and applicable authoritative guidance in accordance with ASC 480-Distinguishing Liabilities from Equity ("ASC 480") and ASC 815-Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether the warrants meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815. This assessment is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

Earn-out contingent liability

In connection with the Prior Merger, all Legacy Sema4 stockholders and option holders at that time became entitled to a pro rata share of 19,021,576 earn-out shares and earn-out RSUs. Based on an assessment of the earn-out shares for the Legacy Sema4 stockholders, the Company considered ASC 480 and ASC 815 and accounted for the earn-out shares as a liability. The Company subsequently measures the fair value of the liability at each reporting period and reports the changes in fair value recorded as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss.

The Company determined the fair value of the earn-out shares issued to the Legacy Sema4 stockholders as of March 31, 2022 was \$3.4 million.

As for the earn-out RSUs for the Legacy Sema4 option holders, a total of 2.7 million RSUs were granted on December 9, 2021. The vesting of such arrangement is conditioned on the satisfaction of both a service requirement and on the satisfaction of a market-based requirement. The market-based requirement would be achieved if the Company's stock price is greater than or equal to \$13 (Triggering Event I), \$15 (Triggering Event II) and \$18 (Triggering Event III) during the applicable performance period, based on the volume-weighted average price for a period of at least 20 days out of 30 consecutive trading days. Therefore, the Company accounts for this arrangement in accordance with ASC 718- Compensation — Stock Compensation ("ASC 718") and stock-based compensation expense is recognized over the longer of the expected achievement period for the market-based requirement and the service requirement. The Company recorded \$0.5 million of stock-based compensation expense in relation to the earn-out RSUs for the quarter ended March 31, 2022. In the event that any earn-out RSUs that are forfeited as a result of a failure to achieve the service requirement, the underlying shares will be reallocated on an annual basis to the Legacy Sema4 stockholders and to the Legacy Sema4 option holders who remain employed as of the date of such reallocation. The Company accounts for the re-allocations to Legacy Sema4 option holders as new grants.

The estimated fair value of the earn-out is determined using a Monte Carlo valuation analysis.

Capitalized Internal-Use Software Costs

The Company capitalizes certain costs incurred related to the development of its software applications for internal use during the application development state. If a project constitutes an enhancement to existing software, the Company assesses whether the enhancement creates additional functionality to the software, thus qualifying the work incurred for capitalization. Costs incurred prior to meeting these criteria together with costs incurred for training and maintenance are expensed as incurred. Once the project is available for general release, capitalization ceases and the Company estimates the useful life of the asset and begins amortization.

Restructuring Costs

During the three months ended March 31, 2022, the Company's Compensation Committee of the Board of Directors approved by written consent dated February 17, 2022 a restructuring plan which was executed by management and

Notes to Unaudited Condensed Consolidated Financial Statements

\$2.7 million of restructuring charges were incurred and recorded in connection therewith. These costs include severance packages offered to the employees impacted by the plan and third party consulting costs. Additionally, as discussed in the "Note 14—Subsequent Events", the Board of Directors approved additional headcount reductions in an effort to streamline operations and the Company expects to recognize expenses of \$5.4 million during the second quarter of 2022.

Emerging Growth Company

The Company is an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. As such, the Company is eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including reduced reporting and extended transition periods to comply with new or revised accounting standards for public business entities. The Company has elected to avail itself of this exemption and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recently Adopted Accounting Pronouncements in the First Quarter of 2022

In February 2016, the FASB issued ASU 2016-02, Leases ("Topic 842"), which requires lessees to recognize right-of-use assets and lease liabilities for most leases on their balance sheets. Expense recognition for lessees under ASC 842 is similar to current lease accounting. ASC 842 requires enhanced disclosures to help the financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. The Company adopted ASC 842 as of January 1, 2022, utilizing the modified retrospective adoption approach. In transition to the ASC 842, the Company elected to use the package of practical expedients permitted under the transition guidance that allowed us to not reassess: (i) whether any expired or existing contracts are or contain leases, (ii) the lease classification for any expired or existing leases, or (iii) initial direct costs for any existing leases. Additionally, the Company did not elect the hindsight practical expedient which would have permitted the use of hindsight in determining the lease term and assessing impairment. The Company elected to combine lease and non-lease components that are fixed and also elected not to recognize right-of-use assets and lease liabilities for leases with terms of 12 months or less ("short-term leases"). The adoption of the ASC 842 as of January 1, 2022, resulted in the recognition of operating lease right-of-use assets and operating lease liabilities of \$39.2 million and \$42.2 million, respectively. The adoption did not have material impact on finance leases. The adoption did not have material impact on the condensed consolidated statements of operations and comprehensive loss. Refer to "*Note 9 Leases*" for a discussion of the Company's lease accounting following the adoption of ASC 842.

In November 2021, the FASB issued ASU 2021-10, Government Assistance (Topic 832), Disclosures by Business Entities About Government Assistance, which requires entities to provide disclosures on material government assistance transactions for annual reporting periods. The disclosures include information around the nature of the assistance, the related accounting policies used to account for government assistance, the effect of government assistance on the entity's financial statements, and any significant terms and conditions of the agreements, including commitments and contingencies. The Company adopted ASU 2021-10 effective January 1, 2022. The Company did not receive any such grants during the three months ended March 31, 2022.

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). The new credit losses standard changes the impairment model for most financial assets and certain other instruments. For trade and other receivables, contract assets recognized as a result of applying ASC 606, loans and certain other instruments, entities will be required to use a new forward looking "expected loss" model that generally will result in earlier recognition of credit losses than under today's incurred loss model. As an emerging growth company, ASU 2016-13 is effective for annual periods beginning after December 15, 2022, with early adoption permitted. Application of the amendments is through a cumulative-effect adjustment to the opening retained earnings as of the beginning of the first reporting period in which the guidance is effective. The Company is currently evaluating the impact of the new guidance on its consolidated financial statements and related disclosures.

Notes to Unaudited Condensed Consolidated Financial Statements

3. Business Combination

As discussed in Note 1, on July 22, 2021, the Company consummated the Business Combination and received net cash proceeds of \$510.0 million.

Pursuant to the Business Combination, the following occurred:

- Holders of 10,188 shares of CMLS's Class A common stock sold in its initial public offering (the "public shares") exercised their right to have such shares redeemed for a full pro rata portion of the trust account holding the proceeds from CMLS's initial public offering (the "IPO"), which was approximately \$10.00 per share, or \$101,880 in aggregate.
- Each share of CMLS's Class B common stock was automatically converted into common stock of the Company.
- Each share of the Legacy Sema4 Class B common stock was converted into 1/100th of a share of Legacy Sema4 Class A common stock and each share of Legacy Sema4 common stock and preferred stock was canceled and received a portion of the merger consideration, resulting in certain Legacy Sema4 stockholders receiving \$230,665,220 of cash and the Legacy Sema4 stockholders receiving an aggregate of 178,336,298 shares of common stock of the Company.
- Pursuant to subscription agreements entered into on February 9, 2021, certain investors agreed to subscribe for an aggregate of 35,000,000 newlyissued shares of common stock at a purchase price of \$10.00 per share for an aggregate purchase price of \$350,000,000 (the "PIPE Investment"). Concurrently with the closing of the Business Combination, the Company consummated the PIPE Investment.
- After giving effect to the Prior Merger, the redemption of public shares and the conversion of the CMLS Class B common stock as described above, and the consummation of the PIPE Investment, there were 240,190,402 shares of the Company's common stock issued and outstanding.

In 2021, the Company recorded \$51.8 million of transaction costs which consisted of direct, incremental legal, professional, accounting, and other thirdparty fees that were directly related to the execution of the Prior Merger in additional paid-in capital. Upon consummation of the Prior Merger, \$9.0 million of the transaction costs relates to costs incurred by Legacy Sema4 and reclassed to offset against equity from prepaid expense and other current assets.

4. Revenue Recognition

Diagnostic Revenue

The Company's diagnostic test revenue contracts typically consist of a single performance obligation to deliver diagnostic testing services to the ordering facility or patient and therefore allocation of the contract transaction price is generally not applicable. Revenue from diagnostic testing services is recorded at the estimated transaction price, subject to the constraint for variable consideration, upon transfer of control of the service. Control over diagnostic testing services is generally transferred at a point in time when the customer obtains control of the promised service which is upon delivery of the test.

Other Revenue

The Company enters into both short-term and long-term project-based collaboration and service agreements with third parties, whereby the Company provides diagnostic testing, research and related data aggregation reporting services. The consideration to which the Company is entitled pursuant to its collaboration and service agreements includes non-refundable upfront payments, fixed and variable payments based upon the achievement of certain milestones during the contract term. Non-refundable upfront payments are generally received in advance of performing the services and, therefore, are recorded as a contract liability upon receipt. Fixed and variable milestone payments are included in the transaction price only when it is probable that doing so will not result in a significant reversal of cumulative revenue recognized when the uncertainty associated with the milestone is subsequently resolved. Revenue for such collaboration and service agreements is recognized over time using an input measure based on costs incurred to satisfy the performance obligation.

Notes to Unaudited Condensed Consolidated Financial Statements

Disaggregated revenue

The following table summarizes the Company's disaggregated revenue by payor category (in thousands):

	Three n	Three months ended March 31,			
	2022	2021			
Diagnostic test revenue					
Patients with third-party insurance	\$ 47	,462 \$ 46,197			
Institutional customers	2	,031 15,664			
Self-pay patients]	,002 899			
Total diagnostic test revenue	52	,495 62,760			
Other revenue	1	,446 1,441			
Total	\$ 53	,941 \$ 64,201			

Reassessment of variable consideration

Subsequent changes to the estimate of the transaction price, determined on a portfolio basis when applicable, are generally recorded as adjustments to revenue in the period of the change. The Company updates estimated variable consideration quarterly.

For the three months ended March 31, 2022, the quarterly change in estimate resulted in a net \$3.6 million increase to revenue for tests in which the performance obligation of delivering the test results was met in prior periods. The change in estimate is a result of changes in the estimated transaction price due to contractual adjustments, obtaining updated information from payors and patients that was unknown at the time the performance obligation was met and settlements with third party payors. The quarterly change in estimate did not result in material adjustments to the Company's previously reported revenue or accounts receivable amounts.

Remaining performance obligations

For certain long-term collaboration service agreements with original expected durations of more than one year, the Company's obligations pursuant to such agreement represents partially unsatisfied performance obligations as of March 31, 2022. The revenues under the agreements are estimated to be approximately \$10.3 million. The Company expects to recognize the majority of this revenue over the next 3 years.

Contract assets and liabilities

Contract assets consist of the Company's right to consideration that is conditional upon its future performance. Contract assets arise in collaboration and service agreements for which revenue is recognized over time but the Company's right to bill the customer is contingent upon the achievement of contractually-defined milestones.

Contract liabilities consist of customer payments in excess of revenues recognized. For collaboration and service agreements, the Company assesses the performance obligations and recognizes contract liabilities as current or non-current based upon forecasted performance.

Notes to Unaudited Condensed Consolidated Financial Statements

A reconciliation of the beginning and ending balances of contract assets and contract liabilities is shown in the table below (in thousands):

	Contract Assets	Contract Liabilities
December 31, 2021	\$ 3,296	\$ 3,769
Contract asset additions	453	—
Customer prepayments	—	350
Revenue recognized	—	(304)
March 31, 2022	\$ 3,749	\$ 3,815

The Company presents contract assets and contract liabilities with respect to customer contracts on a net basis on its condensed consolidated balance sheets. As of March 31, 2022 and December 31, 2021, \$0.1 million and \$0.5 million is recorded as current contract liabilities, respectively.

Revenues recognized for the three months ended March 31, 2022 and March 31, 2021 that were included in the contract liability balance at the beginning of each period were \$0.5 million and \$0.5 million, respectively.

Costs to fulfill contracts

Costs associated with fulfilling the Company's performance obligations pursuant to its collaboration service agreements include costs for services that are subcontracted to ISMMS. Amounts prepaid are expensed in line with the pattern of revenue recognition. Prepayment of amounts prior to the costs being incurred are recognized on the condensed consolidated balance sheets as current or non-current based upon forecasted performance.

As of March 31, 2022 and December 31, 2021, the Company had outstanding deferred costs to fulfill contracts of \$1.5 million and \$1.8 million, respectively. As of March 31, 2022 and December 31, 2021, all outstanding deferred costs were recorded as other current assets.

Amortization of deferred costs was \$0.3 million and \$0.3 million for the three months ended March 31, 2022 and 2021, respectively. The amortization of these costs is recorded in the cost of services on the condensed consolidated statements of operations and comprehensive loss.

5. Fair Value Measurements

Financial assets and liabilities are recorded at fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines the fair value of its financial instruments based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. The following hierarchy lists three levels of fair value based on the extent to which inputs used in measuring fair value are observable in the market:

Level 1: Observable inputs such as quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities.

Level 2: Observable inputs such as quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active or model-derived valuations whose significant inputs are observable.

Level 3: Unobservable inputs that are significant to the measurement of fair value but are supported by little to no market data.

The Company's financial assets and liabilities consist of cash and cash equivalents, restricted cash, accounts receivable, accounts payable, accrued liabilities, finance leases, warrant liability, earn-out contingent liability and long-



Notes to Unaudited Condensed Consolidated Financial Statements

term debt. The Company's cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to the relatively short-term nature of these accounts.

The Company's finance leases are classified within Level 1 of the fair value hierarchy because such finance lease agreements bear interest at rates for instruments with similar characteristics; accordingly, the carrying value of these liabilities approximate their fair values.

The Company's loan from the Connecticut Department of Economic and Community Development is classified within Level 2 of the fair value hierarchy. As of March 31, 2022, the long-term debt was recorded at its carrying value of \$11.0 million in the condensed consolidated balance sheet. The fair value was \$9.5 million, which is estimated based on discounted cash flows using the yields of similar debt instruments of other companies with similar credit profiles.

The following tables set forth the fair value of financial instruments that were measured at fair value on a recurring basis (in thousands):

	As of March 31, 2022						
	 Total		Level 1		Level 2		Level 3
Financial Assets:							
Money market funds	\$ 62,282	\$	62,282	\$	—	\$	
Total financial assets	\$ 62,282	\$	62,282	\$	—	\$	
	 			-			
Financial Liabilities:							
Public warrant liability	\$ 10,183	\$	10,183	\$	_	\$	
Private warrant liability	4,993		_		4,993		
Earn-out contingent liability	3,432		—		—		3,432
Total financial liabilities	\$ 18,608	\$	10,183	\$	4,993	\$	3,432

	As of December 31, 2021						
	 Total		Level 1		Level 2		Level 3
Financial Assets:							
Money market funds	\$ 385,370	\$	385,370	\$	_	\$	_
Total financial assets	\$ 385,370	\$	385,370	\$		\$	
Financial Liabilities:							
Public warrant liability	\$ 14,463	\$	14,463	\$	_	\$	_
Private warrant liability	7,092		_		7,092		_
Earn-out contingent liability	10,244		_		_		10,244
Total financial liabilities	\$ 31,799	\$	14.463	\$	7.092	\$	10.244

Of the \$315.0 million cash and cash equivalents presented on the condensed consolidated balance sheets as of March 31, 2022, \$62.3 million was in money market funds and was classified within Level 1 of the fair value hierarchy as the fair value was based on quoted prices in active markets.

The Company's outstanding warrants include publicly-traded warrants (the "Public Warrants") which were originally issued in the IPO and warrants sold in a private placement to CMLS Holdings LLC (the "Private Warrants"). The Company evaluated its warrants under ASC 815-40, Derivatives and Hedging— Contracts in Entity's Own Equity, and concluded that they do not meet the criteria to be classified in stockholders' equity. Since the Public Warrants and Private Warrants meet the definition of a derivative under ASC 815, the Company recorded these warrants as non-current liabilities on the balance sheet at fair value upon the closing of the Business Combination, with subsequent changes in their respective fair values recognized in other income (expense), net on the condensed consolidated statements of operations and comprehensive loss at each reporting date. As of March 31, 2022, the Public Warrants are classified within Level 1 of the fair value hierarchy as they are traded in active markets. The Private Warrants are classified within Level 2 of the fair

Notes to Unaudited Condensed Consolidated Financial Statements

value hierarchy as management determined the fair value of each Private Warrant is the same as that of a Public Warrant because the terms are substantially the same.

The contingent obligation to issue earn-out shares for Legacy Sema4 stockholders was accounted for as a liability and required remeasurement at each reporting date. The estimated fair value of the total earn-out shares as of March 31, 2022 is determined based on a Monte Carlo simulation valuation model. The fair value of the earn-out contingent liability is sensitive to expected volatility estimated based on selected guideline public companies' stock prices, the Company's implied volatility and Company's common stock price which is sensitive to changes in the forecasts of earnings and/or the relevant operating metrics. The key assumptions utilized in determining the valuation as of March 31, 2022 and December 31, 2021 were as follows:

	March 31, 2022	December 31, 2021
Stock price	\$3.07	\$4.46
Expected volatility	72.5%	62.5%
Expected term (in years)	1.3	1.6
Risk-free interest rate	1.83%	0.58%

The earn-out contingent liability is categorized as Level 3 of the fair value hierarchy as the Company utilizes unobservable inputs in estimating volatility rate. The fair value determined and recorded as of December 31, 2021 was \$10.2 million and during the three months ended March 31, 2022 a gain of \$6.8 million was recorded in the change in fair market value of warrant and earn-out contingent liability in the condensed consolidated statements of operations and comprehensive loss based on re-measurement performed as of the period end date.

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented.

6. Property and Equipment

Property and equipment, net consisted of the following (in thousands):

	As of March 31, 2022		As of December 31, 2021
Laboratory equipment	\$ 27,83	3 \$	28,552
Equipment under finance leases	21,384	1	21,384
Leasehold improvements	21,91	5	21,905
Capitalized software	27,79	7	25,693
Building under finance lease	6,270	5	6,276
Construction in-progress	2,709)	940
Computer equipment	7,530	5	6,634
Furniture, fixtures and other equipment	3,230)	3,241
Total property and equipment	118,68	5	114,625
Less: accumulated depreciation and amortization	(57,709))	(51,906)
Property and equipment, net	\$ 60,970	5 \$	62,719

For the three months ended March 31, 2022 and 2021, depreciation and amortization expense was \$5.8 million and \$4.9 million. This included software amortization expense of \$1.6 million and \$1.2 million for the three months ended

Notes to Unaudited Condensed Consolidated Financial Statements

March 31, 2022 and 2021. Depreciation and amortization expense is included within the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three mon	hs ended March 31,
	2022	2021
Cost of services	\$ 2,8	6 \$ 3,058
Research and development	1,84	1,251
Selling and marketing		1 —
General and administrative	1,1	37 593
Total depreciation and amortization expenses	\$ 5,8	3 \$ 4,902

7. Related Party Transactions

For three months ended March 31, 2022 and 2021, the Company incurred certain related party costs. There were no expenses recognized under the TSA for the three months ended March 31, 2022 and \$1.4 million for the three months ended March 31, 2021 which is presented within related party expenses in the condensed consolidated statements of operations and comprehensive loss. The Company had no TSA payables due to ISMMS as of March 31, 2022 and December 31, 2021.

Expenses recognized pursuant to other service arrangements with ISMMS, including certain sub-lease arrangements the Company has through ISMMS, totaled \$1.9 million and \$0.7 million for the three months ended March 31, 2022 and 2021, respectively. These amounts include certain lease expenses the Company incurs and pay to ISMMS for certain sub-lease arrangements. They are included in either cost of services or related party expenses on the condensed consolidated statements of operations and comprehensive loss depending on the particular activity to which the costs relate. Payables due to ISMMS for the other service arrangements were \$2.5 million \$2.6 million as of March 31, 2022 and December 31, 2021, respectively. These amounts include unpaid lease payments the Company accrued for the payments to be made to ISMMS and are included within due to related parties on the Company's condensed consolidated balance sheets.

Additionally, since the closing of the Prior Merger in July 2021 the Company has purchased \$0.7 million of diagnostic testing kits and materials of which \$0.4 million was recorded in cost of services for the three months ended March 31, 2022 from an affiliate of a member of the Board of Directors who has served in the role since July 2021. The prices paid represent market rates. Payables due were \$0.7 million and \$0.1 million as of March 31, 2022 and December 31, 2021, respectively.

Total related party costs are included within cost of services and related party expenses in the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

		Three months e	ended Ma	arch 31,
	—	2022		2021
Cost of services	\$	1,056	\$	278
Related party expenses		1,284		1,797
Total related party costs	\$	2,340	\$	2,075

8. Long-Term Debt

Loan and Security Agreement (the "SVB Agreement")

On November 15, 2021, the Company and Sema4 OpCo, Inc. (together, the "Borrower") entered into a Loan and Security Agreement (the "SVB Agreement") with Silicon Valley Bank ("SVB"). The SVB Agreement provides for a revolving credit facility (the "Revolver") up to an aggregate principal amount of \$125.0 million, including a sublimit of \$20.0 million for Letters of Credit (as such terms are defined in the SVB Agreement). The outstanding principal amount of any Advance (as such term is defined in the SVB Agreement) will bear interest at a floating rate per annum equal to the greater of (1) 4.00% and (2) the Prime Rate plus the Prime Rate Margin. The Revolver will mature on November 15, 2024. In connection with entering into the SVB agreement, the Company paid \$0.5 million in debt issuance costs during 2021.

Notes to Unaudited Condensed Consolidated Financial Statements

The Company will pay an additional \$0.5 million in fees to SVB at each anniversary of the SVB Agreement date for a total of \$1.0 million and these fees are recorded in other current liabilities and other liabilities in the condensed consolidated balance sheets as of March 31, 2022. These costs are capitalized and amortized on a straight-line basis over the contractual term. Any unused fees charged on the Revolver is expensed as incurred.

The obligations under the SVB Agreement are secured by a first priority perfected security interest in substantially all of the Borrower's assets except for (i) Governmental Collection Accounts (as defined in the SVB Agreement), (ii) more than 65% of the presently existing and thereafter arising issued and outstanding shares of capital stock owned by Borrowers in a Foreign Subsidiary (as such term is defined in the SVB Agreement) and (iii) intellectual property pursuant to the terms of the SVB Agreement.

The SVB Agreement contains affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, and dividends and other distributions.

The SVB Agreement requires the Borrower to comply with certain financial covenants if Liquidity (as such term is defined in the SVB Agreement) falls below \$135.0 million. These financial covenants include (i) a minimum Adjusted Quick Ratio (as such term is defined in the SVB Agreement) and (ii) the achievement of certain minimum revenue targets. On a monthly basis, the Borrowers would be required to maintain a minimum Adjusted Quick Ratio of greater than or equal to 1.25 to 1.0. The Borrower must also maintain certain trailing six-month minimum revenue targets through maturity if outstanding borrowings under the Revolver exceed \$50.0 million.

The SVB Agreement also includes customary events of default, including failure to pay principal, interest or certain other amounts when due, material inaccuracy of representations and warranties, violation of covenants, certain bankruptcy and insolvency events, certain undischarged judgments, material invalidity of guarantees or grant of security interest, material adverse change, and involuntary delisting from the Nasdaq Stock Market, in certain cases subject to certain thresholds and grace periods. If one or more events of default occurs and continues beyond any applicable cure period, SVB may, without notice or demand to the Borrower, terminate its commitment to make further loans and declare all of the obligations of the Borrowers under the SVB Agreement to be immediately due and payable. The Company was in compliance with all covenants as of March 31, 2022.

No amounts have been drawn under the SVB Agreement as of March 31, 2022.

2016 Funding Commitment

In June 2017, ISMMS assigned a loan funding commitment from the Connecticut Department of Economic and Community Development ("DECD") to the Company (as amended, the "DECD Loan Agreement"). The DECD Loan Agreement, provides for a total loan commitment of \$15.5 million at a fixed annual interest rate of 2.0% for a term of 10 years. The Company is required to make interest-only payments through July 2023 and principal and interest payments commencing in August 2023. The final payment of principal and interest is due in July 2028. However, under the terms of the DECD Loan Agreement, the DECD may grant partial principal loan forgiveness of up to \$12.3 million in the aggregate. Such forgiveness is contingent upon the Company achieving job creation and retention milestones and \$7.3 million has been forgiven as of March 31, 2022. This commitment is collateralized by providing a security interest in certain machinery and equipment the Company acquired from ISMMS, as defined in a separate security agreement.

The outstanding loan balance from the DECD Loan Agreement was \$11.0 million as of March 31, 2022 and December 31, 2021.

Notes to Unaudited Condensed Consolidated Financial Statements

Maturities of Long-Term Debt

As of March 31, 2022, long-term debt matures as follows (in thousands):

2022 (remainder of year)	\$	
2023	Ψ	875
2024		2,131
2025		2,174
2026		2,218
Thereafter		3,602
Total maturities of long-term debt		11,000
Less: current portion of long-term debt		—
Total long-term debt, net of current maturities	\$	11,000

2020 Master Loan Agreement

In August 2020, the Company entered into a loan and security agreement with a bank (the "Master Loan Agreement"), in which the Company received a loan of \$6.3 million and deposited the proceeds into a deposit account held by the bank. The Company was required to make sixty consecutive monthly payments of principal and interest at a fixed monthly amount of \$0.1 million beginning in November 2020. Interest payments were fixed at an annual interest rate of 4.75%.

In July 2021, the Company terminated the Master Loan Agreement by paying off the full amount, including \$5.4 million principal and interest and \$0.1 million in early payment penalties assessed pursuant to the terms of the agreement.

2020 Master Lease Agreement

In December 2020, the Company entered into a lease agreement with a lender whereby the Company agreed to sell certain equipment and immediately lease back the equipment, resulting in proceeds of \$3.6 million. Per the terms of the agreement, a financial institution issued an irrevocable standby letter of credit to the lender for \$3.6 million. The Company was required to make sixty consecutive monthly payments of principal and interest at a fixed monthly amount of \$0.1 million beginning in February 2021. Interest payments were fixed at an annual interest rate of 3.54%.

The Company was required to maintain an aggregate amount on deposit equal to at least 105% of the value of any outstanding letters of credit issued by the financial institution on the Company's behalf. The letter of credit was required to be in place until all obligations had been paid in full. Further, the Company was required to furnish annual audited financial statements and other financial information to the lender on a regular basis.

In July 2021, the Company terminated the Master Lease Agreement by paying off the full amount, including \$3.3 million principal and interest and early payment penalties of \$0.2 million assessed pursuant to the terms of the agreement.

9. Leases

Lease Accounting

The Company enters into contracts in the normal course of business and assesses whether any such contracts contain a lease. The Company determines if an arrangement is a lease at inception if it conveys the right to control the identified asset for a period of time in exchange for consideration. The Company classifies leases as operating or financing in nature. All lease liabilities are measured at the present value of the associated payments, discounted using the Company's incremental borrowing rate determined based on the rate of interest that the Company would pay to borrow on a

Notes to Unaudited Condensed Consolidated Financial Statements

collateralized basis an amount equal to the lease payments for similar term and in a similar economic environment on a collateralized basis, unless there is a rate implicit in the lease that is readily determinable.

Operating Leases

The Company's operating lease arrangements are principally for office space and laboratory facilities. The Company's headquarter lease was initially entered into via sub-lease agreements with ISMMS and a third party and they will expire in 2034. The agreements include escalating rent and rent-free period provisions. Pursuant to the terms of the lease agreement, the Company was required to have issued an irrevocable standby letter of credit to the lessor for \$0.9 million, which was included in restricted cash on the condensed consolidated balance sheets as of March 31, 2022 and consolidated balance sheets as of December 31, 2021.

In April 2019, the Company entered into a sublease agreement to rent a building to be used for office and laboratory facility (the "Stamford Lease") for a base term of 325 months, expiring in October 2046. The Company has the option to renew the lease at the end of the initial base term for either one period of 10 years, or two periods of 5 years. There is also an early termination option in which the Company may cancel the lease after the 196th month with cancellation fees. At inception of the Stamford Lease, the value of the land was determined to be more than 25% of the total value and therefore the building is accounted for as a finance lease and the land as an operating lease.

In January 2020, the Company entered into a lease agreement which expanded the Company's existing laboratory facility in Branford, Connecticut. The lease commenced in February 2020 with a 10 year term. The lease includes escalating rent fees over the lease term.

Finance Leases

The Company enters into various finance lease agreements to obtain laboratory equipment that contain bargain purchase commitments at the end of the lease term. The leases are secured by the underlying equipment. As discussed above, the Company also leases a building used for office and laboratory space in which the building is accounted for as a finance lease and the land is as an operating lease. The interest rate used for the Stamford Lease is 13.1%, which is used to measure the operating and finance lease liability.

The tables below present financial information associated with the Company's leases. This information is only presented as of, and for the three months ended, March 31, 2022 because, the Company adopted the ASC 842 using a transition method that does not require application to periods prior to adoption (in thousands).

	Classification		urch 31, 2022
Assets			
Operating lease assets	Operating lease right-of-use assets	\$	38,41
Finance lease assets	Property and Equipment, net		13,19
Total lease assets		\$	51,60
Liabilities			
Current			
Operating	Due to related parties	\$	50
	Short-term lease liabilities		1,89
Finance	Due to related parties		3(
	Short-term lease liabilities		3,18
Non-current			
Operating	Long-term lease liabilities		39,64
Finance	Long-term lease liabilities		17,82
Total lease liabilities		\$	63,42

Notes to Unaudited Condensed Consolidated Financial Statements

Lease cost	Three months	ended March 31, 2
Operating lease cost		
Operating lease cost	\$	1,38
Short-term lease cost		16
Variable lease cost		12
Total operating lease cost	\$	1,67
Finance lease cost		
Depreciation and amortization of leased assets	\$	9
Interest on lease liabilities		5:
Total finance lease cost	\$	1,40
Total lease cost	\$	3,14

Future minimum lease payments under non-cancellable leases as of March 31, 2022 are as follows:

Maturity of lease liabilities	Operatin	g leases	Finance lease	5	Total
2022 (remainder of the year)	\$	3,862	\$	3,808	\$ 7,6
2023		4,338		3,584	7,92
2024		4,440		2,763	7,20
2025		4,835		2,451	7,28
2026		4,949		2,003	6,9:
Thereafter		51,920		49,884	101,80
Total	\$	74,344	\$	64,493	\$ 138,83
Less: imputed interest	\$	(32,237)	\$	(43,180)	\$ (75,41
Present value of lease liabilities	\$	42,107	\$	21,313	\$ 63,42

Other information related to leases as of and the three months ended March 31, 2022 are as follows:

	March 31, 2022
<u>Weighted-average remaining lease term (years)</u>	
Operating leases	13.5
Finance leases	17.8
Weighted-average discount rate	
Operating leases	6.8%
Finance leases	10.5%
Cash paid for amounts included in the measurement of lease liabilities	
Operating cash flows from operating leases	\$1,236
Operating cash flows from finance leases	\$552
Financing cash flows from finance lease	\$862



Notes to Unaudited Condensed Consolidated Financial Statements

10. Commitments and Contingencies

Purchase Obligations

In the normal course of business, the Company enters into various purchase commitments primarily related to material and service agreements, laboratory supplies and software. At March 31, 2022, the Company's total future payments under noncancelable unconditional purchase commitments having a remaining term of over one year were \$19.4 million.

Contingencies

The Company is a party to various actions and claims arising in the normal course of business. The Company does not believe that the outcome of these matters will have a material effect on the Company's condensed consolidated financial position, results of operations or cash flows. However, no assurance can be given that the final outcome of such proceedings will not materially impact the Company's condensed consolidated financial condition or results of operations.

The Company was not a party to any material legal proceedings as of March 31, 2022, nor is it a party to any material legal proceedings as of the date of issuance of these unaudited condensed consolidated financial statements.

11. Stock-Based Compensation

Stock Incentive Plans

The Company's 2017 Equity Incentive Plan (the "2017 Plan"), as amended in February 2018, allowed the grant of options, restricted stock awards, stock appreciation rights and restricted stock units. No options granted under the 2017 Plan are exercisable after 10 years from the date of grant, and option awards generally vest over a four-year period.

The 2017 Plan was terminated in connection with the adoption of the Company's 2021 Equity Incentive Plan (the "2021 Plan"). Any awards granted under the 2017 Plan that remained outstanding as of the Closing Date and were converted into awards with respect to the Company's Class A common stock in connection with the consummation of the Business Combination continue to be subject to the terms of the 2017 Plan and applicable award agreements, except for a modification of the repurchase provision, which is discussed further below.

On July 22, 2021, in connection with the Business Combination, the 2021 Plan became effective and 32,734,983 authorized shares of Class A common stock were reserved for issuance thereunder. This Plan will be administered by the Compensation Committee of the Company's Board of Directors, including determination of the vesting, exercisability and payment of the awards to be granted under this Plan. No awards granted under the 2021 Plan are exercisable after 10 years from the date of grant, and the awards granted under the 2021 Plan generally vest over a four-year period on a graded vesting basis.

Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan (the "2021 ESPP") became effective in connection with the Business Combination. The 2021 ESPP authorizes the issuance of shares of Class A common stock pursuant to purchase rights granted to employees. On each January 1 of each of 2022 through 2031, the aggregate number of shares of Class A common stock reserved for issuance under the 2021 Plan may be increased automatically by the number of shares equal to one percent (1%) of the total number of shares of all classes of common stock issued and outstanding immediately preceding December 31. The Company did not make any grants of purchase rights under the 2021 ESPP during the quarter ended March 31, 2022. A total of 7,229,799 shares of Class A common stock have been reserved for future issuance under the 2021 ESPP.

Stock Option Activity

Under the 2017 Plan, the Company had a call option to repurchase awards for cash from the plan participants upon termination of the participant's employment or consulting agreement (the "2017 Plan Call Option"). The options granted under the 2017 plan were accounted for as liability awards due to the 2017 Plan Call Option. The Company had a history of repurchase practice and the intention to repurchase the vested options. Therefore, the fair value of the liability awards was remeasured at each reporting period until the stockholder bears the risks and rewards of equity ownership for a reasonable period of time, which the Company concludes is at least six months.

Notes to Unaudited Condensed Consolidated Financial Statements

Upon consummation of the Business Combination, the Company's Board of Directors waived the Company's right under the 2017 Plan Call Option to repurchase awards for cash from the plan participants upon termination of the participant's employment or consulting agreement. As such, the Company modified the liability awards to equity awards and reclassified the modification date fair value of the awards to stockholders' equity in the condensed consolidated financial statements as of July 22, 2021.

All stock options granted under the 2021 Plan are accounted for as equity awards.

The following summarizes the stock option activity, which reflects the conversion of the options granted under the 2017 Plan into awards with respect to the Company Class A common stock in connection with the consummation of the Business Combination (in thousands, except share and per share amounts):

	Stock Options Outstanding		ghted Average xercise Price
Balance at December 31, 2021	30,905,543	\$	1.24
Options granted	851,884	\$	3.37
Options exercised	(2,108,502))\$	0.32
Options forfeited or canceled	(759,629)) \$	2.98
Balance at March 31, 2022	28,889,296	\$	1.33
Options exercisable at March 31, 2022	21,620,867	\$	0.54

As of March 31, 2022, unrecognized stock-based compensation cost related to the unvested portion of the Company's stock options was \$22.1 million, which is expected to be recognized on a graded-vesting basis over a weighted-average period of 1.5 years.

The fair value of the stock option awards for the period ended March 31, 2022, and March 31, 2021 were estimated using the Black-Scholes option pricing model with the following assumptions:

	Three Months ended March 31,		
	2022	2021	
Expected volatility	65.20% - 67.60%	68.50%- 75.60%	
Expected term (in years)	5.48-6.06	0.50-1.75	
Risk-free interest rate	1.65%-1.70%	0.05%- 0.16%	
Dividend yield			
Fair value of Class A common stock	\$3.29-\$3.45	\$4.57- \$12.51	

The Company estimated a volatility factor for the Company's options based on analysis of historical share prices of a peer group of public companies. The Company did not rely on the volatility of the Company's Class A common stock because its limited trading history. The Company estimated the expected term of options granted using the "simplified method," which is the mid-point between the vesting date and the ending date of the contractual term. The Company did not rely on the historical holding periods of the Company's options due to the limited availability of exercise data. The Company used a risk-free interest rate based on the U.S. Treasury yield curve in effect for bonds with maturities consistent with the expected term of the option.

Restricted Stock Units (RSUs)

The Company issued time-based RSUs to employees under the 2021 Plan. The RSUs automatically convert to shares of Class A common stock on a onefor-one basis as the awards vest. The Company measures the value of RSUs at fair value based on the closing price of the underlying Class A common stock on the grant date. The RSUs granted generally vest over a four year vesting period from the grant date, however, the Company also granted certain RSUs during the three

Notes to Unaudited Condensed Consolidated Financial Statements

months ended December 31, 2021, which were vesting beginning 12 months from the grant date and vesting immediately on the grant date. The following table summarizes the activity related to the Company's time-based RSUs:

	Restricted Stock Units Outstanding	Weighted Average Grant Date Fair Value Per Unit
Balance at December 31, 2021	12,589,558	\$7.64
Restricted Stock Units granted	762,190	\$3.48
Restricted Stock Units vested	(398,369)	\$7.63
Restricted Stock Units forfeited	(830,620)	\$7.62
Balance at March 31, 2022	12,122,759	\$7.38

As of March 31, 2022, unrecognized stock-based compensation cost related to the unvested portion of the Company's RSUs was \$60.2 million, which is expected to be recognized on a graded-vesting basis over a weighted-average period of 1.6 years.

Earn-out RSUs

The grant date fair value determined for Triggering Event I, II and III was \$1.82, \$1.39 and \$0.94 per unit, respectively. Any re-allocated RSUs due to the Sema4 Legacy option holders' forfeiture activities during the three months ended March 31, 2022 were accounted for as new grants and the fair value determined for Triggering Event I, II and III was \$0.29, \$0.21 and \$0.12 per unit, respectively. Based on the grant date fair value, the Company expects to record total expense related to the earn-out RSU awards of \$2.7 million without considering the impact of the Sema4 Legacy option holders' forfeiture activities. The Company expects to recognize the stock-compensation cost over the longer of the derived service period or service period.

Stock Appreciation Rights (SAR) Activity

The Company historically granted SAR to one employee and one consultant with exercise condition of a liquidation event. As a result of the Business Combination, settlement of the outstanding vested SARs in exchange for a cash payment and to cancel the outstanding unvested SARs was agreed upon and an expense of \$3.8 million related to the vested SAR was recognized by the Company. There were no outstanding SARs as of March 31, 2022.

During the three months ended March 31, 2022, the Company recorded a reversal of stock-based compensation of \$5.2 million due to forfeiture activities upon employee terminations. Stock-based compensation expense for all awards granted and outstanding is included within the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three m	Three months ended March 31,		
	2022		2021	
Cost of services	\$ 1	381 \$	18,475	
Research and development	4	341	38,187	
Selling and marketing	2	825	18,688	
General and administrative	9	012	89,612	
Total stock-based compensation expense	\$ 17	559 \$	164,962	

12. Income Taxes

Income taxes for the three months ended March 31, 2022 are recorded at the Company's estimated annual effective income tax rate, subject to adjustments for discrete events, should they occur. The Company's estimated annual effective tax rate was 0.0% for the three months ended March 31, 2022. The primary reconciling item between the federal statutory

Notes to Unaudited Condensed Consolidated Financial Statements

rate of 21.0% for these periods and the Company's overall effective tax rate of 0.0% was related to the effects of the valuation allowance recorded against the full amount of its net deferred tax assets.

A valuation allowance is required when it is more likely than not that some portion or all of the Company's deferred tax assets will not be realized. The realization of deferred tax assets depends on the generation of sufficient future taxable income during the period in which the Company's related temporary differences become deductible. The Company has recorded a full valuation allowance against its net deferred tax assets as of March 31, 2022 since management believes that based on the earnings history of the Company, it is more likely than not that the benefits of these assets will not be realized.

13. Net Loss per Share

Basic and diluted loss per share attributable to common stockholders was calculated as follows (amounts in thousands, except for share and per share amounts):

	Three months ended March 31,	
	 2022	2021
Numerator:		
Net loss attributable to common stockholders	\$ (76,896) \$	(191,775)
Denominator:		
Denominator for basic and diluted earnings per share-weighted-average common shares	244,368,743	549,778
Basic and diluted loss per share	\$ (0.31) \$	(348.82)

As a result of the Prior Merger, the Company has retroactively adjusted the weighted-average number of shares of common stock outstanding prior to the Prior Merger by multiplying them by the conversion ratio of 123.8339 used to determine the number of shares of common stock into which they converted. The common stock issued as a result of the redeemable convertible preferred stock conversion upon closing of the Prior Merger was included in the basic and diluted earnings/(loss) per share calculation on a prospective basis.

Prior to the consummation of the Prior Merger, the Company applied the two-class method to calculate its basic and diluted net loss per share of common stock, as there were outstanding Class B common stock and redeemable convertible preferred stock that were participating securities. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. As the securities were all converted into Sema4 Holdings Class A common stock upon consummation of the Prior Merger, all outstanding Legacy Sema4 Class B common stock has been retroactively converted to the Sema4 Holdings Class A common stock.

The following tables summarize the outstanding shares of potentially dilutive securities that were excluded from the computation of diluted net loss per share attributable to common stockholders for the period presented because including them would have been anti-dilutive:

	Three months ended March 31,	
	2022	2021
Outstanding options and RSUs to purchase Class A common stock	41,012,055	29,608,717
Outstanding warrants	21,994,972	_
Outstanding earn-out shares	16,611,117	
Outstanding earn-out RSUs	2,410,459	_
Redeemable convertible preferred stock (on an if-converted basis)		171,535,214
Total	82,028,603	201,143,931

Notes to Unaudited Condensed Consolidated Financial Statements

14. Subsequent Events

GeneDx Acquisition

On April 29, 2022, the Company completed the acquisition (the "Acquisition") of GeneDx LLC ("GeneDx"), from OPKO Health Inc. ("OPKO"). Sema4 acquired GeneDx for an upfront payment of \$150 million in cash, subject to adjustment, plus 80 million shares of Sema4's Class A common stock, with up to an additional \$150 million payable if certain revenue-based milestones are achieved over the next two years (which will be payable in cash or shares of Sema4's Class A common stock at Sema4's discretion). Based on the closing stock price of Sema4's Class A common stock as of April 29, 2022, the trading day on the closing of the transaction, the total upfront consideration represents approximately \$322 million, subject to adjustment, and the total aggregate consideration including potential milestones is approximately \$472 million. The transaction was announced on January 18, 2022 and the issuance of the shares of Sema4's Class A common stock in connection with the acquisition, among other proposals, received approval from Sema4 stockholders on April 27, 2022.

Subscription Agreements and Acquisition PIPE Investment (Private Placement)

In connection with the Acquisition of GeneDx, the Company also closed a private placement financing (the "Acquisition PIPE Investment") in which it issued 50 million shares of Sema4's Class A common stock at a price of \$4.00 per share with a syndicate of institutional investors, receiving gross proceeds of \$200 million.

Restructuring

On May 2, 2022, the Company's Compensation Committee of the Board of Directors approved by written consent for the Company to implement an employee restructuring plan, which is intended to reduce costs and optimize its organizational and operational efficiency. The Company's management executed the plan and expects to recognize expenses of \$5.4 million during the second quarter of 2022. The costs primarily consist of the cost of benefits provided pursuant to the severance programs for the employees impacted by the plan and third party consulting costs expected to be incurred.

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 together with our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report and our audited financial statements for the year ended December 31, 2021 and the related notes in our Annual Report on Form 10-K for the year ended December 31, 2021. This discussion contains forward-looking statements and involves numerous risks and uncertainties. Actual results may differ materially from the results described in or implied by the forward-looking statements. You should carefully read the section entitled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from these forward-looking statements.

Overview

We are a patient-centered, health intelligence company with a mission to use artificial intelligence, or AI, and machine learning to enable personalized medicine for all. By leveraging leading data scientists and technology, our platform powers remarkable and unique insights that transform the practice of medicine including how disease is diagnosed, treated, and prevented.

On June 1, 2017, we signed a contribution and funding agreement and other agreements with Icahn School of Medicine at Mount Sinai, or ISMMS, whereby ISMMS contributed certain assets and liabilities related to our operations, provided certain services to us, and also committed to funding us up to ### in future capital contributions in exchange for equity in Legacy Sema4, of which ### was drawn as of December 31, 2019. Following the transaction, we commenced operations as a commercial entity that could effectively engage diverse patient populations and health care institutions at scale.

We have since established and deployed our comprehensive and integrated genomic and clinical data platform and established a mature diagnostic testing business. We now maintain a database that includes more than 12 million de-identified individual clinical records, many with genomic profiles. We also manage a data asset over 49 petabytes in size, that has been expanding at more than 1 petabyte per month with an accelerating growth rate.

Currently, we derive the majority of our revenue from our diagnostic test solutions. Our diagnostic business generates revenue and engages with healthcare professionals working with patients primarily through our Women's Health and Oncology solutions.

Our Women's Health solutions sequence and analyze an industry-leading number of genes and use interpretive information tools to translate raw sequencing and clinical data efficiently and accurately into digestible clinical reports that guide decision-making by patients and physicians. Our Oncology diagnostic solutions feature both somatic tumor profiling and hereditary cancer screenings, along with a foundational whole exome and whole transcriptome sequencing approach. Our Sema4 Signal Hereditary Cancer solution determines if a patient carries an inherited genetic change that increases the risk of cancer or informs on cancer treatment. We believe our Signal Whole Exome and Transcriptome solution is one of the most comprehensive molecular profiling solutions from a commercial entity to receive New York State approval. Beginning in May of 2020 through March 31, 2022, we also provided diagnostic testing services to identify the presence of COVID-19.

We have also expanded beyond diagnostic testing to enter into service agreements with third parties to provide diagnostic testing, research, and related data aggregation reporting services. We have established and continue to seek strategic relationships with pharmaceutical and biotech, or Biopharma, companies to enable innovation across the entire drug lifecycle, from next-generation drug discovery and development, to post-market efficacy surveillance, to informing on bioavailability, toxicity, tolerability, and other features critical to drug development.

Factors Affecting Our Performance

We believe several important factors have impacted, and will continue to impact, our performance and results of operations. While each of these areas presents significant opportunities for us, they also pose significant risks and challenges that we must address. See the section titled "*Item 1A. Risk Factors*" for more information.

Number of resulted tests

A test is resulted once the appropriate workflow is completed and details are provided to the ordered patients or healthcare professional for reviews, which corresponds to the timing of our revenue recognition. We believe the number of



resulted tests in any period is important and useful to our investors because it directly correlates with long-term patient relationships and the size of our genomic database.

Success obtaining and maintaining reimbursement

Our ability to increase the number of billable tests and our revenue therefrom will depend on our success in achieving reimbursement for our tests from third-party payors. Reimbursement by a payor may depend on several factors, including a payor's determination that a test is appropriate, medically necessary, cost-effective, and has received prior authorization. Since each payor makes its own decision as to whether to establish a policy or enter into a contract to provide coverage for our tests, as well as the amount it will reimburse us for a test, seeking these approvals is a time-consuming and costly process.

In cases where we or our partners have established reimbursement rates with third-party payors, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements often vary from payor to payor and are reassessed by third-party payors regularly. As a result, in the past we have needed additional time and resources to comply with the requirements.

We expect to continue to focus our resources on increasing the adoption of, and expanding coverage and reimbursement for, our current and any future tests we may develop or acquire. If we fail to expand and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue and our future business prospects may be adversely affected.

Ability to lower the costs associated with performing our tests

Reducing the costs associated with performing our diagnostic tests is both our focus and a strategic objective. We source, and will continue to source, components of our diagnostic testing workflows from third parties. We also rely upon third-party service providers for data storage and workflow management.

Increasing adoption of our services by existing and new customers

Our performance depends on our ability to retain and broaden the adoption of our services with existing customers as well as our ability to attract new customers. Our success in retaining and gaining new customers is dependent on the market's confidence in our services and the willingness of customers to continue to seek more comprehensive and integrated genomic and clinical data insights.

Investment in platform innovation to support commercial growth

We are seeking to leverage and deploy our Centrellis and Traversa platforms to develop a pipeline of future disease-specific research and diagnostic and therapeutic products and services. We have limited experience in the development or commercialization of clinical or research products in connection with our database and our Centrellis platform.

We operate in a rapidly evolving and highly competitive industry. Our business faces changing technologies, shifting provider and patient needs, and frequent introductions of rival products and services. To compete successfully, we must accurately anticipate technology developments and deliver innovative, relevant, and useful products, services, and technologies on time. As our business evolves, the competitive pressure to innovate will encompass a wider range of products and services. We must continue to invest significant resources in research and development, including investments through acquisitions and partnerships. These investments are critical to the enhancement of our current diagnostics and health information and data science technologies from which existing and new service offerings are derived.

We expect to incur significant expenses to advance these development efforts, but they may not be successful. New potential services may fail at any stage of development and, if we determine that any of our current or future services are unlikely to succeed, we may abandon them without any return on our investment. If we are unsuccessful in developing additional services, our growth potential may be impaired.

Key Performance Indicators

We use the following key financial and operating metrics to evaluate our business and operations, measure our performance, identify trends affecting our business, project our future performance, and make strategic decisions. These key financial and operating metrics should be read in conjunction with the following discussion of our results of operations

and financial condition together with our condensed consolidated financial statements and the related notes and other financial information included elsewhere in this report.

The principal focus of our commercial operations is to offer our diagnostic tests through both our direct sales force and laboratory distribution partners. Test volume correlates with genomic database size and long-term patient relationships. Thus, test volumes drive database diversity and enable potential identification of variants of unknown significance and population-specific insights. The number of tests resulted is a key indicator that we use to assess the operational efficiency of our business. Once the appropriate workflow is completed, the test is resulted and details are provided to ordered patients or healthcare professionals for reviews.

During the three months ended March 31, 2022, we resulted 151,264 tests in our laboratories, 66,339 tests of which were for COVID-19, compared to the three months ended March 31, 2021, in which we resulted 237,729 tests in our laboratories, 170,784 of which were for COVID-19. This 27% increase in resulted volumes, excluding COVID-19 tests volumes, largely resulted from an increase in our oncology testing.

COVID-19 Impact

COVID-19 has had, and continues to have, an extensive impact on the global health and economic environments since the initial outbreak in March 2020.

While test volumes have since improved, we continue to experience changes in the mix of tests due to the impact of COVID-19. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations, and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat it and the economic impact on local, regional, national and international markets and supply chains. Therefore, COVID-19 could continue to have a material impact on our results of operations, cash flows, and financial condition for the foreseeable future.

In March 2020, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), was signed into law which was a stimulus bill that, among other things, provided assistance to qualifying businesses and individuals and included funding for the healthcare system. We received \$5.4 million in 2020 as part of the stimulus, comprised of \$2.6 million received under the Provider Relief Fund (the "PRF"), and \$2.8 million received under the Employee Retention Credit (the "ERC"). In 2021, we received an additional \$5.6 million under the PRF.

Funds provided under the PRF to healthcare providers are not loans and will not be required to be repaid; however, as a condition to receiving these payments, providers must agree to certain terms and conditions and submit sufficient documentation demonstrating that the funds are being used for healthcare-related expenses or lost revenue attributable to the COVID-19 pandemic. We have concluded it is probable that all terms and conditions associated with the funds received under the PRF distribution have been met. As a result, we recorded the funds received under the PRF in other income in the statements of operations and comprehensive loss during the periods in which we received the funds.

Funds provided under the ERC are refundable tax credits for 50% of qualified wages paid to employees during the pandemic. A company is eligible for the ERC if it has not received a Paycheck Protection Program loan under the CARES Act and (1) its operations have been fully or partially suspended because of COVID-19 or (2) its gross receipts in a calendar quarter in 2020 declined by more than 50% from the same period in 2019. At the time of applying for the ERC, we concluded that it was reasonably possible the eligibility requirements would be met; however, due to a change in circumstances, we are re-evaluating our position. As such, we deferred the recognition of the funds received under the ERC and recorded the proceeds in other liabilities on the condensed consolidated balance sheets.

At this time, we are not certain of the availability, extent or impact of any future relief provided under the CARES Act or other stimulus initiatives.

Recent Developments

In January 2022, we and our wholly-owned subsidiaries, Orion Merger Sub I, Inc., or Merger Sub I, and Orion Merger Sub II, LLC, or Merger Sub II, entered into an Agreement and Plan of Merger and Reorganization (which we refer to, as amended, as the "Merger Agreement"), with GeneDx, Inc., a New Jersey corporation, or GeneDx, and a wholly-owned subsidiary of OPKO Health, Inc., or OPKO, GeneDx Holding 2, Inc., or Holdco, and OPKO to acquire 100% of GeneDx (which we refer to as the "Acquisition"). Subject to the terms and conditions of the Merger Agreement, we agreed to pay consideration to OPKO for the Acquisition of (i) \$150 million in cash at the closing of the Acquisition, subject to certain

adjustments as provided in the Merger Agreement, (ii) 80 million shares of our Class A common stock to be issued at the closing of the Acquisition and (iii) up to \$150 million payable following the closing of the Acquisition, if certain revenue-based milestones are achieved for each of the fiscal years ending December 31, 2022 and December 31, 2023. These milestone payments, if and to the extent earned under the terms of the Merger Agreement, will be satisfied through the payment and/or issuance of a combination of cash and shares of our Class A common stock (valued at \$4.86 per share), with such mix to be determined in our sole discretion.

The Acquisition closed on April 29, 2022. We expect to leverage the combined health information database of Sema4 and GeneDx to partner with additional health systems and biopharma companies to transform patient care and therapeutic development and enable precision medicine for all.

Concurrently with the execution of the Merger Agreement, we entered into subscription agreements with certain institutional investors, pursuant to, and on the terms and subject to the conditions of which, these investors collectively subscribed for 50 million shares of our Class A common stock for an aggregate purchase price equal to \$200 million (which we refer to as the "Acquisition PIPE Investment"). The Acquisition PIPE Investment was consummated substantially concurrently with the closing of the Acquisition.

Components of Results of Operations

Revenue

We derive the majority of our revenue from diagnostic testing services, which primarily relate to Women's Health, Oncology and COVID-19. We also recognize revenue from collaboration service agreements with Biopharma companies and other third parties pursuant to which we provide diagnostic testing and related data aggregation reporting services. As discussed above, we discontinued COVID-19 testing services as of March 31, 2022 and no longer provide such testing services.

We recognize revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration which we expect to be entitled to in exchange for those goods or services.

Diagnostic Test Revenue

We primarily generate revenue from performing diagnostic testing services for three groups of customers: healthcare professionals working with patients with third-party insurance coverage or without third-party insurance coverage or those who elect to self-pay; and institutional clients, such as hospitals, clinics, state governments and reference laboratories. Customers are billed upon delivery of test results. The amount of revenue recognized for diagnostic testing services depends on a number of factors, such as contracted rates with our customers and third-party insurance providers, insurance reimbursement policies, payor mix, historical collection experience, price concessions and other business and economic conditions and trends. To date, the majority of our diagnostic test revenue has been earned from orders received for patients with third-party insurance coverage.

Our ability to increase our diagnostic test revenue will depend on our ability to increase our market penetration, obtain contracted reimbursement coverage from third-party payers, enter into contracts with institutions, and increase our reimbursement rate for tests performed.

Other Revenue

We generate revenue from providing diagnostic testing and related data aggregation reporting services under both short-term and long-term project-based collaboration and service agreements with third parties. The terms of these contracts generally include non-refundable upfront payments, which we record as contract liabilities, and variable payments based upon the achievement of certain milestones during the contract term.

With respect to existing collaboration and service agreements, our revenue may fluctuate period to period due to the pattern in which we may deliver our services, our ability to achieve milestones, the timing of costs incurred, changes in estimates of total anticipated costs that we expect to incur during the contract period, and other events that may not be within our control. Our ability to increase our revenue will depend on our ability to enter into contracts with third-party partners.

Cost of Services

The cost of services reflect the aggregate costs incurred in performing services. These costs include expenses for reagents and laboratory supplies, personnel-related expenses (comprising salaries and benefits) and stock-based

compensation for employees directly involved in revenue generating activities, shipping and handling fees, costs of third-party reference lab testing and phlebotomy services and allocated genetic counseling, facility and IT costs associated with delivery services. Allocated costs include depreciation of laboratory equipment, facility occupancy, and information technology costs. The cost of services are recorded as the services are performed.

We expect the cost of services to generally increase in line with the anticipated growth in diagnostic testing volume and services we provide under our collaboration service agreements. However, we expect the cost per test to decrease over the long term due to the efficiencies we may gain from improved utilization of our laboratory capacity, automation, and other value engineering initiatives. These expected reductions may be offset by new tests which often have a higher cost per test during the introductory phases before we can gain efficiencies. The cost per test may fluctuate from period.

Research and Development Expenses

Research and development expenses represent costs incurred to develop our technology and future test offerings. These costs are principally associated with our efforts to develop the software we use to analyze data and process customer orders. These costs primarily consist of personnel-related expenses (comprising salaries and benefits), stock-based compensation for employees performing research and development, innovation and product development activities, costs of reagents and laboratory supplies, costs of consultants and third-party services, equipment and related depreciation expenses, non-capitalizable software development costs, research funding to our research partners as part of research and development agreements and allocated facility and information technology costs associated with genomics medical research. Research and development costs are generally expensed as incurred and certain non-refundable advanced payments provided to our research partners are expensed as the related activities are performed.

We generally expect our research and development expenses to continue to increase as we innovate and expand the application of our platforms. However, we expect research and development expenses to decrease as a percentage of revenue in the long term, although the percentage may fluctuate from period to period due to the timing and extent of our development and commercialization efforts and fluctuations in our compensation-related charges.

Selling and Marketing Expenses

Selling and marketing expenses primarily consist of personnel-related expenses (comprising salaries, and benefits) and stock-based compensation for employees performing commercial sales, account management, marketing, and allocation of genetic counseling services related to medical education. Selling and marketing costs are expensed as incurred.

We generally expect our selling and marketing expenses will continue to increase in absolute dollars as we expand our commercial sales and marketing and counseling teams and increase marketing activities. However, we expect selling and marketing expenses to decrease as a percentage of revenue in the long term, subject to fluctuations from period to period due to the timing and magnitude of these expenses.

General and Administrative Expenses

General and administrative expenses primarily consist of personnel-related expenses (comprising salaries and benefits) and stock-based compensation for employees in executive leadership, legal, finance and accounting, human resources, information technology, strategy and other administrative functions. In addition, these expenses include office occupancy and information technology costs. General and administrative costs are expensed as incurred.

We generally expect our general and administrative expenses to continue to increase in absolute dollars as we increase headcount and incur costs associated with operating as a public company, including expenses related to legal, accounting, and regulatory matters; maintaining compliance with requirements of Nasdaq and of the SEC; director and officer insurance premiums and investor relations. We expect these expenses to decrease as a percentage of revenue in the long term as revenue increases, although the percentage may fluctuate from period to period due to fluctuations in our compensation-related charges.

Related Party Expenses

Related party expenses consist of amounts due to ISMMS for expenses under our Transition Services Agreement, or TSA, with ISMMS which expired at the end of the first quarter of 2021, and other service agreements. Additional information can be found in the audited financial statements in Note 7, *"Related Party Transactions"* included within our Annual Report on Form 10-K for the year ended December 31, 2021, and our unaudited condensed consolidated financial statements in Note 7, *"Related Party Transactions"* included within this Quarterly Report.

We generally expect related party expenses to decrease as we establish our own internal and external resources to fulfill the administrative and other services we have historically procured from ISMMS.

Interest Income

Interest income consists of interest earned on money market funds.

Interest Expense

Interest expense consists of interest costs related to our finance leases and our long-term debt arrangements, including unused line fee and the amortization of deferred transaction costs related to the loan and security agreement entered into with Silicon Valley Bank to provide a \$125 million revolving credit facility described elsewhere in this report. No amounts have been drawn under the revolving credit facility as of March 31, 2022.

Other Income

Other income consists of funding received under the CARES Act. We recognized \$5.6 million of additional funding received under the CARES Act during the first quarter of 2021 and the amount is included in other income for the three months ended March 31, 2021.

Comparison of the three months ended March 31, 2022 and 2021

The following table sets forth our results of operations for the periods presented (in thousands):

	 Three months ended March 31,		
	 2022		2021 (1)
	(in tho	usands)	
Revenue			
Diagnostic test revenue	\$ 52,495	\$	62,760
Other revenue	1,446		1,441
Total revenue	53,941		64,201
Cost of services	 48,316		68,524
Gross profit (loss)	 5,625		(4,323)
Research and development	21,315		53,133
Selling and marketing	29,547		35,366
General and administrative	42,784		102,038
Related party expenses	 1,284		1,797
Loss from operations	(89,305)		(196,657)
Other income (expense), net:			
Change in fair market value of warrant and earn-out contingent liabilities	13,190		_
Interest income	27		21
Interest expense	(808)		(723)
Other income	—		5,584
Total other income (expense), net	12,409		4,882
Loss before income taxes	(76,896)		(191,775)
Income tax provision	_		
Net loss and comprehensive loss	\$ (76,896)	\$	(191,775)

(1) As previously disclosed in Note 2, "Summary of Significant Accounting Policies" to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021, certain adjustments were made to reclassify certain expenses between cost of services and operating expenses. The adjustments are reflected as disclosed.

Revenue

					Chang	ge
	Three months ended March 31,			2021 to 2022		2022
	 2022		2021		\$	%
	 (dollars in thousands)					
Diagnostic test revenue	\$ 52,495	\$	62,760	\$	(10,265)	(16)%
Other revenue	1,446		1,441		5	<u> %</u>
Total revenue	\$ 53,941	\$	64,201	\$	(10,260)	(16)%

Total revenue decreased by \$10.3 million, or 16%, to \$53.9 million for the three months ended March 31, 2022, from \$64.2 million for the three months ended March 31, 2021.

Diagnostic test revenue decreased by \$10.3 million, or 16%, to \$52.5 million for the three months ended March 31, 2022, from \$62.8 million for the three months ended March 31, 2021. The decrease was primarily attributable to a decrease in COVID-19 test volumes of 61%. Lower demand and the absence of new contracts during the three months ended March 31, 2022, a result of the decision to discontinue COVID-19 testing services at the end of the first quarter of 2022, were the key contributors for the decline in COVID-19 revenue. This was partially offset by oncology testing volumes, which increased by 159%. Women's health testing volume, including carrier screening and NIPT testing, increased by 23%, which was partially offset by a lower average selling price.

Other revenue increased by a nominal amount for the three months ended March 31, 2022, from the three months ended March 31, 2021.

Cost of Services

				Chan	ge	
	Three months ended March 31,2021 to 2		Three months ended March 31,		21 to 2022	
		2022	2021	\$	%	
			(dollars in	housands)		
Cost of services	\$	48,316 \$	68,524	\$ (20,208)	(29)%	

Cost of services decreased by \$20.2 million, or 29%, to \$48.3 million for the three months ended March 31, 2022, from \$68.5 million for the three months ended March 31, 2021. The decrease was primarily driven by the following components: a \$17.1 million decrease in stock-based compensation expense due to the higher expense recorded in the first quarter of 2021 as a result of the increased fair value of the awards and related expenses recorded in the first quarter of 2021 under liability accounting; a \$1.8 million decrease in the inventory obsolescence write-off as a result of discontinuing COVID-19 testing; and a \$1.3 million decrease in overall personnel-related expenses driven by reallocation of certain costs between departments during the fourth quarter of 2021 as a result of a change in estimate.

Research and Development

			Change	e
	Three months ended March 31,		2021 to 20	022
	 2022	2021	\$	%
		(dollars in t	housands)	
Research and development	\$ 21,315 \$	53,133	\$ (31,818)	(60)%

Research and development expense decreased by \$31.8 million, or 60%, to \$21.3 million for the three months ended March 31, 2022, from \$53.1 million for the three months ended March 31, 2021. The decrease was primarily attributable to a \$33.8 million decrease in stock-based compensation expense due to the higher expense recorded in the first quarter of 2021 as a result of the increased fair value of the awards and related expenses recorded in the first quarter of 2021 under liability accounting and a decrease in cost incurred for reagents and laboratory supplies and laboratory software of \$1.6 million for research and development activities. These decreases were offset by a \$2.6 million increase in other personnel-related expenses driven by headcount and a \$0.6 million increase in depreciation expense.

Selling and Marketing

			Chang	ge
	Three months ended March 31,		2021 to 2	022
	 2022	2021	\$	%
		(dollars in t	housands)	
Selling and marketing	\$ 29,547 \$	35,366	\$ (5,819)	(16)%

Selling and marketing expense decreased by \$5.8 million, or 16%, to \$29.5 million for the three months ended March 31, 2022, from \$35.4 million for the three months ended March 31, 2021. The decrease was primarily attributable to a \$15.8 million decrease in stock-based compensation expense due to the higher expense recorded in the first quarter of 2021 as a result of the increased fair value of the awards and related expenses recorded in the first quarter of 2021 under liability accounting. This decrease was partially offset by a \$5.9 million increase in other personnel-related expenses driven by an increase in headcount, a \$1.3 million increase in consulting service expenses to support revenue cycle transformation initiatives and a \$1.2 million increase in travel and business expenses due to the lifting of COVID-19 travel restrictions. Additionally, there was an increase of \$0.6 million in other lab services for genetic counseling related to medical education, and an increase of \$0.5 million in information technology-related expenses.

General and Administrative

				Change	e	
	Three months ended March 31,			2021 to 20	022	
	2022	2021		\$	%	
		(dollars	in thousand	ds)		
General and administrative	\$ 42,784 \$	102,038	\$	(59,254)	(58))%

General and administrative expense decreased by \$59.2 million, or 58%, to \$42.8 million for the three months ended March 31, 2022, from \$102.0 million for the three months ended March 31, 2021. The decrease was primarily attributable to a \$80.6 million decrease in stock-based compensation expense due to the higher expense recorded in the first quarter of 2021 as a result of the increased fair value of the awards and related expenses recorded in the first quarter of 2021 as a result of the increase in expenses of \$6.5 million for professional services incurred in connection with the Acquisition that are not capitalized, an increase in personnel-related costs of \$10.0 million driven by an increase in headcount, a \$2.4 million increase in information technology related expenses due to increased cloud storage requirements, a \$1.7 million increase in insurance expenses driven by the commencement of director's insurance policy, and a \$0.5 million increase due to reallocation of certain costs between departments during the fourth quarter of 2021 as a result of a change in estimate.

Related Party Expenses

			Change	•
	Three months ended March 31,		2021 to 20	22
	 2022	2021	\$	%
		(dollars in thou	sands)	
Related party expenses	\$ 1,284 \$	1,797 \$	(513)	(29)%

Related party expenses decreased by \$0.5 million, or 29%, to \$1.3 million for the three months ended March 31, 2022, from \$1.8 million for the three months ended March 31, 2021. The decrease was primarily attributable to the discontinued fees related to information technology support pursuant to the TSA with ISMMS as a result of the termination of the agreement after the first quarter of 2021 and a decrease in rent and facility expenses driven by a reduction of office and lab space leased from ISMMS pursuant to the TSA.

Interest Income

				Change	e
	Tł	hree months ended Mar	ch 31,	2021 to 20	022
	2	022	2021	\$	%
			(dollars in thousan	ds)	
Interest income	\$	27 \$	21 \$	6	29 %

Interest income increased by a nominal amount for the three months ended March 31, 2022 from the three months ended March 31, 2021.

Interest Expense

			Change	
	Three months ended March 31,		2021 to 202	22
	 2022	2021	\$	%
		(dollars in thous	sands)	
Interest expense	\$ (808) \$	(723) \$	(85)	12 %

Interest expense increased by \$0.1 million, or 12%, to \$0.8 million for the three months ended March 31, 2022, from \$0.7 million for the three months ended March 31, 2021. The increase was driven by the unused line fee and amortization of deferred transaction costs related to the loan and security agreement entered into with Silicon Valley Bank at the end of 2021.

Other Income

			Cha	nge
	Three months ended March 31,		2021 te	o 2022
	 2022	2021	\$	%
		(dollars in th	ousands)	
Other income	\$ — \$	5,584 \$	(5,584)	(100)%

Other income decreased by \$5.6 million, to zero for the three months ended March 31, 2022, from \$5.6 million for the three months ended March 31, 2021. This was attributable to the \$5.6 million in funding that was received and recognized as other income under the CARES Act in the first quarter of 2021.

Reconciliation of Non-GAAP Financial Measures

In addition to our results determined in accordance with GAAP, we believe the following non-GAAP measures are useful in evaluating our operating performance. We use the following non-GAAP financial information to evaluate our ongoing operations and for internal planning and forecasting purposes. We believe that non-GAAP financial information, when taken collectively, may be helpful to investors because it provides consistency and comparability with past financial performance. However, non-GAAP financial information presented for supplemental informational purposes only and should not be considered in isolation or as a substitute for financial information presented in accordance with GAAP. In addition, other companies, including companies in our industry, may calculate similarly-titled non-GAAP measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our non-GAAP financial measures as tools for comparison. A reconciliation is provided below for each non-GAAP financial measure to the most directly comparable financial measure stated in accordance with GAAP. Investors are encouraged to review the related GAAP financial measures and the reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measures, and not to rely on any single financial measure to evaluate our business.

Non-GAAP financial measures have limitations as analytical tools and you should not consider them in isolation, or as substitutes for analysis of our results as reported under GAAP. We may in the future incur expenses similar to the adjustments in the presentation of Non-GAAP financial measures. Other limitations include that Non-GAAP financial measures do not reflect:

• all expenditures or future requirements for capital expenditures or contractual commitments;

- changes in our working capital needs;
- provision for income taxes, which may be a necessary element of our costs and ability to operate;
- the costs of replacing the assets being depreciated, which will often have to be replaced in the future;
- · the non-cash component of employee compensation expense; and
- the impact of earnings or charges resulting from matters we consider not to be reflective, on a recurring basis, of our ongoing operations.

Adjusted Gross Profit and Adjusted Gross Margin

Adjusted Gross Profit is a non-GAAP financial measure that we define as revenue less cost of services, excluding stock-based compensation expense and restructuring costs. We define Adjusted Gross Margin as our Adjusted Gross Profit divided by our revenue. We believe these non-GAAP financial measures are useful in evaluating our operating performance compared to that of other companies in our industry, as these metrics generally eliminate the effects of certain items that may vary from company to company for reasons unrelated to overall operating performance.

The following is a reconciliation of revenue to our Adjusted Gross Profit and Adjusted Gross Margin for the three months ended March 31, 2022 and 2021:

	Three months e	nded March 31,
	2022	2021
	(in tho	usands)
venue	\$53,941	\$64,201
ost of services	48,316	68,524
ross Profit (Loss)	5,625	(4,323)
ross Margin	10%	(7)%
dd:		
tock-based compensation expense	1,381	18,475
estructuring costs ⁽¹⁾	106	
djusted Gross Profit	\$7,112	\$14,152
djusted Gross Margin	13%	22%

(1) Represents costs incurred for restructuring activities, which include severance packages offered to impacted employees and third party consulting costs incurred in the first quarter of 2022.

Adjusted EBITDA

Adjusted EBITDA is a non-GAAP financial measure that we define as net loss adjusted for interest expense, net, depreciation and amortization, stockbased compensation expenses, transaction and acquisition costs, restructuring costs, change in fair market value of warrant and earn-out contingent liabilities and other income. We believe Adjusted EBITDA is useful in evaluating our operating performance compared to that of other companies in our industry, as this metric generally eliminates the effects of certain factors that may vary from company to company for reasons unrelated to overall operating performance.

The following is a reconciliation of our net loss to Adjusted EBITDA for the three months ended March 31, 2022 and 2021:

	Three months ended March 31,		
	 2022	2021	
	(in thou	isands)	
Net loss	\$ (76,896)	\$ (191,775)	
Interest expense, net ⁽¹⁾	781	702	
Depreciation and amortization	5,803	4,902	
Stock-based compensation expense	17,559	164,962	
Transaction and acquisition costs ⁽²⁾	4,337	1,954	
Restructuring costs ⁽³⁾	2,729	_	
Change in fair market value of warrant and earn-out contingent liabilities (4)	(13,190)	_	
Other income ⁽⁵⁾	_	(5,584)	
Adjusted EBITDA	\$ (58,877)	\$ (24,839)	

(1) Represents the total of interest expense related to our finance leases and interest-bearing loans and interest income on money market funds. This also includes the unused line fee and amortization of deferred transaction costs related to the loan and security agreement entered into with Silicon Valley Bank.

(2) Represents professional service costs incurred in connection with pursuing the business combination transaction that did not meet the requirement for capitalization in 2021. For the first quarter of 2022, this represents professional service costs incurred in connection with the Acquisition transaction, which include due diligence and legal costs.

Represents costs incurred for restructuring activities, which include severance packages offered to impacted employees and third party consulting costs incurred in the first quarter of 2022.
 Represents the change in fair market value of the liabilities associated with our public warrants and private placement warrants and the earn-out shares issuable under the terms of the merger

agreement related to our business combination with CMLS.

(5) For the three months ended March 31, 2021, primarily consists of funding received under the CARES Act Provider Relief Fund.

Liquidity and Capital Resources

On July 22, 2021, we completed the business combination with CMLS, consummated the related private placement financing, and received net cash proceeds of \$510 million. Management determined that the cash proceeds received from the business combination provides us with sufficient liquidity to meet our obligations for at least twelve months from the date of this Quarterly Report.

On November 15, 2021, we entered into a loan and security agreement, or the SVB Agreement, with Silicon Valley Bank, or SVB, whereby SVB agreed to provide a \$125 million revolving credit facility with a maturity date of November 15, 2024. No amounts were drawn as of December 31, 2021. Advances under the SVB Agreement will bear interest at a floating rate per annum equal to the greater of (1) 4.00% and (2) the prime rate plus an applicable margin.

Additionally, upon the closing of the Acquisition of GeneDx on April 29, 2022, we received gross proceeds of \$200 million from the issuance of 50 million shares of our Class A common stock pursuant to the Acquisition PIPE Investment. The gross proceeds were partially used to pay for the cash consideration of the Acquisition and transaction costs incurred in connection with the Acquisition.

Accordingly, the condensed consolidated financial statements included in this Quarterly Report have been prepared on a basis that assumes we will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business. Nevertheless, we may also seek additional funding in the future through the sale of common or preferred equity or convertible debt securities, the entry into other credit facilities or another form of third-party funding or by seeking other debt financing.

Material Cash Requirements for Known Contractual Obligations and Commitments

The following is a description of commitments for known and reasonably likely cash requirements as of March 31, 2022 and December 31, 2021. We anticipate fulfilling such commitments with our existing cash and cash equivalents, which amounted to \$315.0 million and \$400.6 million as of March 31, 2022 and December 31, 2021, respectively, or through additional capital raised to finance our operations; see *"Liquidity and Capital Resources"*.

Our future minimum payments under non-cancellable operating lease agreements were \$74.3 million as of March 31, 2022 and \$68.3 million as of December 31, 2021. The timing of these future payments, by year, can be found in our audited financial statements in Note 9, "*Commitments and Contingencies*" included within our Annual Report on Form 10-K for the year ended December 31, 2021, and our unaudited condensed consolidated financial statements in Note 9, "*Leases,*" included within this Quarterly Report, respectively.

Our future payments under finance leases were \$64.5 million as of March 31, 2022. The timing of these future payments, by year, can be found in our audited financial statements in Note 9, "*Commitments and Contingencies*" included within our Annual Report on Form 10-K for the year ended December 31, 2021, and our unaudited condensed consolidated financial statements in Note 9, "*Leases,*" included within this Quarterly Report, respectively.

Cash Flows

	Three months ended March 31,		
		2022	2021
		(in thousands)	
Net cash used in operating activities	\$	(81,494) \$	(42,208)
Net cash used in investing activities		(3,913)	(4,994)
Net cash used in financing activities		(160)	(2,278)

Operating Activities

Net cash used in operating activities during the three months ended March 31, 2022 was \$81.5 million, which was primarily attributable to a net loss of \$76.9 million and a change in fair value of the warrant and earn-out liabilities of \$13.2 million, partially offset by non-cash depreciation and amortization of \$5.8 million and non-cash stock-based compensation expense of \$17.6 million. The net change in our operating assets and liabilities primarily reflected a \$11.1 million increase in accounts receivable primarily from institutional payors, a \$2.9 million increase in inventories driven by an increase in reagents, a \$1.6 million increase in prepaid expenses and other current assets mainly driven by new insurance policy premiums purchased during the current period, a \$3.9 million increase in accounts payable and accrued expenses due to the timing of vendor payments, and a \$6.6 million decrease in other current liabilities mainly driven by the decrease in employee payroll and compensation related accruals.

Net cash used in operating activities during the three months ended March 31, 2021 was \$42.2 million, which was primarily attributable to a net loss of \$191.8 million and a net change in our operating assets and liabilities of \$22.3 million, partially offset by non-cash depreciation and amortization of \$4.9 million and non-cash stock-based compensation expense of \$165.0 million. The net change in our operating assets and liabilities primarily reflected an \$9.8 million increase in inventories driven by a higher volume of purchases to support increasing testing volumes, a \$6.3 million increase in prepaid expenses and other current assets mainly driven by professional services costs directly related to our business combination with CMLS, a \$4.0 million increase in accounts payable and accrued expenses due to the timing of vendor payments, and a \$9.1 million decrease in other current liabilities mainly driven by a decline in our bonus accrual following bonus payments in March 2021.

Investing Activities

Net cash used in investing activities during the three months ended March 31, 2022 was \$3.9 million, which was attributable to \$1.4 million in purchases of property and equipment and \$2.5 million of costs related to development of internal-use software assets.

Net cash used in investing activities during the three months ended March 31, 2021 was \$5.0 million, which was attributable to \$2.1 million in purchases of property and equipment and \$2.9 million of costs related to development of internal-use software assets.

Financing Activities

Net cash used in financing activities during the three months ended March 31, 2022 was \$0.2 million, which was attributable to \$0.9 million of finance lease principal payments which was offset by proceeds of \$0.7 million from the exercise of stock options.



Net cash used in financing activities during the three months ended March 31, 2021 was \$2.3 million, which was attributable to \$1.3 million in payments for deferred transaction costs related to our business combination with CMLS, \$1.0 million in principal payments on our finance lease obligations and \$0.4 million in principal payments on our long-term debt obligations existed during the period, offset by \$0.4 million cash received from stock option exercise.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these unaudited 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 assets and liabilities at the date of the unaudited 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 various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about items that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Except as described in Note 2, "Summary of Significant Accounting Policies–Recent Accounting Pronouncement Issued but Not Yet Adopted," to our unaudited condensed consolidated financial statements included in this Quarterly Report, 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 audited consolidated financial statements and notes thereto included within our Annual Report on Form 10-K for the year ended December 31, 2021.

JOBS Act Accounting Election

We are considered an "emerging growth company" within the meaning of the JOBS Act. The JOBS Act allows an emerging growth company to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. We have elected to use this extended transition period and, as a result, our financial statements may not be comparable to companies that comply with public company effective dates. We also intend to rely on other exemptions provided by the JOBS Act, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

Following the completion of the Business Combination, we will remain an emerging growth company until the earliest of (1) September 1, 2025, (2) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our Class A common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

Recent Accounting Pronouncements

Additional information on recent accounting pronouncements can be found in the audited financial statements in Note 2, "Summary of Significant Accounting Policies" included within our Annual Report on Form 10-K for the year ended December 31, 2021, and our unaudited condensed consolidated financial statements in Note 2, "Summary of Significant Accounting Policies" included within this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. Our cash, cash equivalents, and restricted cash consists of bank deposits and money market funds, which totaled \$315.9 million at March 31, 2022 and \$401.5 million as of December 31, 2021. Such interest-bearing instruments carry a degree of risk; however, because our investments are primarily high-quality credit instruments with short-term durations with high-quality institutions, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A 100 basis point change in interest rates would not have a material effect on the fair market value of our cash, cash equivalents and restricted cash.

Our loan and financing obligation are recorded at amortized cost and include variable interest rate term. Therefore, change in interest rates can impact our interest payments we are obligated to pay. Additional information on our long-term debt can be found in Sema4's audited financial statements in Note 8, "Long-Term Debt" and Sema4's unaudited condensed consolidated financial statements in Note 8, "Long-Term Debt."

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

As required by Rules 13a-15 and 15d-15 under the Exchange Act, our Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2022. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of March 31, 2022 because of the material weaknesses in internal control over financial reporting as of December 31, 2021 that we previously identified in Item 9A. "Controls and Procedures" of our Annual Report on Form 10-K for the year ended December 31, 2021 and had not been fully remediated as of March 31, 2022.

Notwithstanding the identified material weaknesses in internal control over financial reporting, our management has concluded that our condensed consolidated financial statements included in the Quarterly Report on Form 10-Q are fairly stated in all material respects in accordance with accounting principles generally accepted in the United States of America.

Previously Reported Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis.

As described in more detail in Item 9A. "Controls and Procedures" of our Annual Report on Form 10-K for the year ended December 31, 2021, the material weaknesses identified related to the fact that we did not design and maintain accounting policies, procedures and controls to ensure complete, accurate and timely financial reporting in accordance with U.S. GAAP.

Remediation Plan

Our management is actively engaged and committed to taking the steps necessary to remediate the control deficiencies that constituted the material weaknesses, and these remediation activities are continuing in 2022. In addition to the remediation actions undertaken during 2021 and described in more detail in Item 9A. "Controls and Procedures" of our Annual Report on Form 10-K for the year ended December 31, 2021, we expect to engage in additional activities, including, but not limited to:

- Hiring more technical accounting resources to enhance our control environment;
- Engaging external consultants to provide support and to assist us in our evaluation of more complex applications of GAAP, and to assist us with
 documenting and assessing our accounting policies and procedures until we have sufficient technical accounting resources;
- Implementing business process-level controls across all significant accounts and information technology general controls across all relevant systems. This includes providing training for control owners that will present expectations as it relates to the control design, execution and monitoring of such controls, including enhancements to the documentation to evidence the execution of the controls; and
- Implementing improvements to our ERP system to enhance the accuracy of our financial records, enable the enforcement of systematic segregation of duties, and to improve our information technology general controls environment.

We continue to enhance corporate oversight over process-level controls and structures to ensure that there is appropriate assignment of authority, responsibility, and accountability to enable remediation of our material weaknesses. We believe that our remediation plan will be sufficient to remediate the identified material weaknesses and strengthen our controls. As we continue to evaluate, and work to improve our controls, management may determine that additional measures to address control deficiencies or modifications to the remediation plan are necessary.

While we have performed certain remediation activities to strengthen our controls to address the identified material weaknesses, control weaknesses are not considered remediated until new internal controls have been operational for a period of time, are tested, and management concludes that these controls are operating effectively. We will continue to monitor the effectiveness of our remediation measures in connection with our future assessments of the effectiveness of internal control over financial reporting and disclosure controls and procedures, and we will make any changes to the design of our plan and take such other actions that we deem appropriate given the circumstances.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the three months ended March 31, 2022 covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, other than as described herein. We are continuing to take steps to remediate the material weaknesses in our internal control over financial reporting, as discussed above.

Inherent Limitation on the Effectiveness of Internal Control

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures, or our internal controls, will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected.

Part II - Other Information

Item 1. Legal Proceedings

We, and our subsidiary, are currently not a party to, and our property is not currently the subject of, any material pending legal proceedings; however, we may become involved in various claims and legal actions arising in the ordinary course of business.

Item 1A. Risk Factors

You should carefully review and consider the following risk factors and the other information contained in this Quarterly Report on Form 10-Q before deciding whether to invest in our Class A common stock. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, financial condition, results of operations and prospects. Unless otherwise indicated, references to our business being harmed in these risk factors will include harm to our business, reputation, financial condition, results of operations, net revenue and future prospects. In such event, the trading price of our Class A common stock could decline, and you could lose all or part of your investment. We may face additional risks and uncertainties that are not presently known to us, or that we currently deem immaterial, which may also impair our business or financial condition. The following discussion should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included herein.

Risk Factors Summary

Our business is subject to a number of risks and uncertainties, including those risks discussed at length below. These risks include, among others, the following:

- The ongoing COVID-19 pandemic has affected and may further materially and adversely affect our business and financial results.
- We face intense competition. If we do not continue to innovate and provide products and services that are useful to users, we may not remain competitive, which could harm our business and operating results.
- If third-party payors, including managed care organizations, private health insurers and government health plans, do not provide adequate reimbursement for our tests, or seek to amend or renegotiate their fee reimbursement schedules, or if we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.
- We have limited experience with the development and commercialization of our databases and our health information and genomic platforms.
- If we fail to comply with federal and state laboratory licensing requirements or standards, we could lose the ability to perform our tests or experience disruptions to our business.
- We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.
- We need to scale our infrastructure in advance of demand for our products and services, and our failure to generate sufficient demand for our products and services would have a negative impact on our business and our ability to attain profitability.
- We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers or service providers.
- We rely on a limited number of product and service providers for data infrastructure and analytics capabilities, and any disruption of, or interference with, our use of data and workflow services could adversely affect our business, financial condition, and results of operations, and we may not be able to find replacements or immediately transition to alternative products or service providers.
- Our projections are subject to significant risks, assumptions, estimates and uncertainties, including assumptions regarding adoption of our products and services. As a result, our projected revenues, market share, expenses and profitability may differ materially from our expectations in any given quarter or fiscal year.

- Uncertainty in the development and commercialization of our enhanced or new tests or services could materially adversely affect our business, financial condition and results of operations.
- We currently use, and in the future expect to increase our use of, information and rights from customers, strategic partners, and collaborators for several aspects of our operations, and if we cannot maintain current and enter new relationships with these parties with adequate access and authorization to such information, our business will suffer.
- Our operating results could be subject to significant fluctuation, which could increase the volatility of our stock and warrant prices and cause losses to our stockholders.
- We may need to raise additional capital to fund our existing operations, develop additional products and services, commercialize new products and services or expand our operations and may have difficulties raising capital depending on financial market conditions.
- · We expect to make significant investments in our continued research and development of new products and services, which may not be successful.
- We have identified material weaknesses, some of which have a pervasive effect across the organization, and may identify additional material weaknesses or significant deficiencies, in our internal controls over financial reporting. Our failure to remedy these matters could result in a material misstatement of our financial statements and we will incur increased costs and demands on management as a result of compliance with internal control requirements, which could harm our operating results.
- We rely on third-party laboratories to perform certain elements of our service offerings.
- As a result of the Acquisition, OPKO became a substantial holder of shares of our Class A common stock and sales by OPKO into the market in the future could cause the market price of our Class A common stock to drop significantly, even if our business is doing well.
- Our ability to be successful following the Acquisition is dependent upon the efforts of our key personnel, including the key personnel of GeneDx. The loss of key personnel could negatively impact our operations and profitability our financial condition could suffer as a result.
- Future changes in FDA enforcement discretion for LDTs could subject our operations to much more significant regulatory requirements.
- · Compliance with the HIPAA security, privacy and breach notification regulations may increase our costs.
- We face uncertainty related to healthcare reform, pricing, coverage and reimbursement, which could reduce our revenue.
- Our inability to effectively protect our proprietary products, processes, and technologies, including the confidentiality of our trade secrets, could harm our competitive position.
- Security breaches, privacy issues, loss of data and other incidents could compromise sensitive, protected, or personal information related to our business, could prevent it from accessing critical information, and could expose it to regulatory liability, which could adversely affect our business.
- We will 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.

Risks Related to Our Business, Industry and Operations

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

The ongoing COVID-19 pandemic, together with related precautionary measures in response to the initial outbreak and resurgences, materially disrupted our business during certain periods in 2020 and 2021 and may continue to disrupt our business for an unknown period of time. Since the initial outbreak, we experienced a significant impact to our 2020 and 2021 operating results, including our order volumes, revenues, margins, and cash utilization, among other measures and may experience further impacts in future periods depending on the evolution of the COVID-19 pandemic.

Throughout 2020 and 2021, both we and our partners also undertook a number of precautionary measures in response to the virus, including requiring employees to work remotely, restricting travel and limiting interactions in person, and we



expect to adjust our precautionary measures at our various locations based on local recovery levels, vaccination rates and applicable governmental regulations. Our business could be negatively affected in the future if it takes excessive, ineffective or inadequate precautions.

The ongoing COVID-19 pandemic has materially impacted our business in 2020 and 2021 and may continue to impact our business for an unknown period of time. Such impacts have included and may include the following:

- Healthcare providers or patients have canceled or delayed scheduling, and for an extended period of time may continue to cancel or delay scheduling, standard wellness visits and other non-emergency appointments and procedures (including oncology and pregnancy-related screenings), contributing to a decline in orders for our products or services;
- Restrictions on travel, commerce and shipping may prevent patients and pathologists from shipping samples to our clinical laboratories;
- Illnesses, quarantines, financial hardships, restrictions on travel, commerce and shipping, or other consequences of the pandemic, may disrupt our supply chain or other business relationships, and we or other parties may assert rights under force majeure clauses to excuse performance;
- We have experienced, and for an extended period of time may continue to experience, reduced volumes at our clinical laboratories and we may need to suspend operations at some or all of our clinical laboratories;
- We have taken, and may take additional, cost cutting measures, which may hinder our efforts to commercialize our products or delay the development of future products and services. Further, we might not realize all of the cost savings we expect to achieve as a result of those efforts;
- We and our partners have postponed or cancelled clinical studies, which may delay or prevent our launch of future products and services;
- Some or all of our workforce, much of which continues to work remotely in an effort to reduce the spread of COVID-19, may be infected by the virus
 or otherwise distracted;
- A combination of factors, including infection from the virus, supply shortfalls, and inability to obtain or maintain equipment, could adversely affect our lab capacity and our ability to meet the demand for our testing services; and
- We may inaccurately estimate the duration or severity of the COVID-19 pandemic, which could cause us to misalign our staffing, spending, activities
 and precautionary measures with current or future market conditions.

Despite our efforts, the ultimate impact of the COVID-19 pandemic, or the impact of the emergence of new strains of the virus and any future resurgences of COVID-19 or variant strains, depends on factors beyond our knowledge or control, including availability and distribution of effective medical treatments and vaccines, the duration and severity of the pandemic, third-party actions taken to contain its spread and mitigate its public health effects and short- and long-term changes in the behaviors of medical professionals and patients resulting from the pandemic.

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

Due to the high degree of uncertainty regarding the implementation and impact of the CARES Act and other legislation related to COVID-19, there can be no assurance that we will be able to comply with the applicable terms and conditions of the CARES Act and retain such assistance.

On March 27, 2020, the CARES Act was signed into law, aimed at providing emergency assistance and health care for individuals, families, and businesses affected by the COVID-19 pandemic and generally supporting the U.S. economy. The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, and modifications



to the net interest deduction limitations. The CARES Act and similar legislation intended to provide assistance related to the COVID-19 pandemic also authorized \$175.0 billion in funding to be distributed by the U.S. Department of Health and Human Services (the "HHS"), to eligible health care providers. This funding, known as the Provider Relief Fund, is designated to fund eligible healthcare providers' healthcare-related expenses or lost revenues attributable to COVID-19. On December 27, 2020, the Consolidated Appropriations Act, 2021 was signed into law, which adds \$3.0 billion to the Provider Relief Fund. Payments from the Provider Relief Fund are subject to certain eligibility criteria, as well as reporting and auditing requirements, but do not need to be repaid to the U.S. government if recipients comply with the applicable terms and conditions.

In 2020, we received \$5.4 million as part of the stimulus, comprised of \$2.6 million received under the PRF and \$2.8 million received under the ERC. In 2021, we received an additional \$5.6 million under the PRF distribution. Funds provided under the PRF distributions to healthcare providers are not loans and will not be required to be repaid; however, as a condition to receiving these payments, providers must agree to certain terms and conditions and submit sufficient documentation demonstrating that the funds are being used for healthcare-related expenses or lost revenue attributable to the COVID-19 pandemic. Funds provided under the ERC distributions are refundable tax credits for 50% of qualified wages paid to employees during the pandemic. A company is eligible for the ERC if it has not received a Paycheck Protection Program loan under the Cares Act and (1) its operations have been fully or partially suspended because of COVID-19 or (2) its gross receipts in a calendar quarter in 2020 declined by more than 50% from the same period in 2019. At the time of applying for the ERC, we concluded that the eligibility requirements were met. However, subsequent to the filing of the application, our revenue was revised due to a change in estimate as a result of finalizing our accounting records, which impacted the applicable periods and calculations for determining eligibility, and may no longer meet the eligibility requirements. As such, we have deferred the recognition of the funds received under the ERC distribution and recorded the proceeds in other liabilities on the balance sheets as of March 31, 2022 and December 31, 2021.

Due to the high degree of uncertainty regarding the implementation of the CARES Act, the Consolidated Appropriations Act, 2021 and other stimulus legislation, and due to our revenue revisions, there can be no assurance that the terms and conditions of the PRF, ERC or other relief programs will not change or be interpreted in ways that affect our ability to comply with such terms and conditions in the future, which could affect our ability to retain such assistance. We will continue to monitor our compliance with the terms and conditions of the PRF, including demonstrating that the distributions received have been used for healthcare-related expenses or lost revenue attributable to COVID-19, and the ERC. If we are unable to comply with current or future terms and conditions, our ability to retain some or all of the distributions received may be impacted, and we may be subject to actions including payment recoupment, audits and inquiries by governmental authorities, and criminal, civil or administrative penalties.

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

We operate in a rapidly evolving and highly competitive industry. There are a number of private and public companies that offer products or services or have announced that they are developing products or services that compete, or may one day compete, with our products or services. Some of our current and potential competitors possess greater brand recognition, financial and other resources and development capabilities than we do. As the fields of genomic analysis and health information become more widely known to the public, we anticipate that competition will further increase. We expect to compete with a broad range of organizations in the U.S. and other countries that are engaged in the development, production and commercialization of genetic screening products, including women's health and oncology screening products, health information services, and analytics, and data science services, and other diagnostic products. These competitors include:

- companies that offer clinical, research and data clinical services, molecular genetic testing and other clinical diagnostics, life science research and drug discovery services, data services and healthcare analytics, and consumer genetics products;
- academic and scientific institutions;
- · governmental agencies; and
- public and private research organizations.

We may be unable to compete effectively against our competitors either because their products and services are superior or because they may have more expertise, experience, financial resources, or stronger business relationships. These competitors may have broader product lines and greater name recognition than we do. Furthermore, we must

compete successfully in our existing markets, including women's health and oncology, but also in any new markets we expand into. Even if we successfully develop new marketable products or services, our current and future competitors may develop products and services that are more commercially attractive than ours, and they may bring those products and services to market earlier or more effectively than we are able to. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for and sales of our tests and services, which could prevent us from increasing or sustaining our revenues or achieving sustained profitability.

We face intense competition. If we do not continue to innovate and provide products and services that are useful to users, we may not remain competitive, which could harm our business and operating results.

Our business environment is rapidly evolving and intensely competitive. Our businesses face changing technologies, shifting provider and patient needs, and frequent introductions of rival products and services. To compete successfully, we must accurately anticipate technology developments and deliver innovative, relevant and useful products, services, and technologies in a timely manner. As our businesses evolve, the competitive pressure to innovate will encompass a wider range of products and services. We must continue to invest significant resources in research and development, including through acquisitions and collaborations, joint ventures and partnerships, in order to enhance our current diagnostics and health information and data science technologies, and existing and new products and services based off these technologies.

We have many competitors in different industries. Our current and potential domestic and international competitors range from large and established companies to emerging start-ups in addition to academic and scientific institutions, and public and private research organizations. Some competitors have longer operating histories in various sectors. They can use their experience and resources in ways that could affect our competitive position, including by making acquisitions, continuing to invest heavily in research and development and in talent, initiating intellectual property claims (whether or not meritorious), and continuing to compete aggressively for our customers and partners in the market for health information and data science products and services. Our competitors may be able to innovate and provide products and services faster than we can or may foresee the need for products and services before we do.

Our operating results may also suffer if our products and services are not responsive to the needs of our customers and partners. As technologies continue to develop, our competitors may be able to offer products and services that are, or that are seen to be, substantially similar to or better than our current products and services. This may force us to compete in different ways and expend significant resources in order to remain competitive. If our competitors are more successful than us in developing compelling products and services for or in attracting and retaining customers or partners in the market for health information and data science products and services, our operating results could be harmed.

If third-party payors, including managed care organizations, private health insurers and government health plans, do not provide adequate reimbursement for our tests, or seek to amend or renegotiate their fee reimbursement schedules, or if we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.

Our ability to increase the number of billable tests and our revenue therefrom will depend on our success in achieving reimbursement for our tests from third-party payors. Reimbursement by a payor may depend on a number of factors, including a payer's determination that a test is appropriate, medically necessary, cost-effective and has received prior authorization. The commercial success of our current and future products, if approved, will depend on the extent to which our customers receive coverage and adequate reimbursement from third-party payors, including managed care organizations and government payers (e.g., Medicare and Medicaid).

Since each payer makes its own decision as to whether to establish a policy or enter into a contract to cover our tests, as well as the amount it will reimburse for a test, seeking these approvals is a time-consuming and costly process. In addition, the determination by a payer to cover and the amount it will reimburse for our tests will likely be made on an indication-by-indication basis and may consider our billing practices and reimbursements from other payors and from our patient billing programs. To date, we have obtained policy-level reimbursement approval or contractual reimbursement for some indications for our tests from most of the large commercial third-party payors in the United States, and the Centers for Medicare & Medicaid Services ("CMS") provides reimbursement for our multi-gene tests for hereditary breast and ovarian cancer-related disorders as well as other tests. We believe that establishing adequate reimbursement from Medicare is an important factor in gaining adoption from healthcare providers. Our claims for reimbursement from third-party payors may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive and may not result in payment. In cases where there is not a contracted rate for reimbursement, there is typically a greater coinsurance or copayment requirement from the patient, which may result in further delay or decreased likelihood of collection.

A significant portion of the payments for our tests are paid or reimbursed under insurance programs with third-party payors. To contain reimbursement and utilization rates, third-party payors often attempt to, or do in fact, amend or renegotiate their fee reimbursement schedules. Loss of revenue caused by third-party payor cost containment efforts or an inability to negotiate satisfactory reimbursement rates could have a material adverse effect on our revenue and results of operations.

Furthermore, in cases where we or our partners have established reimbursement rates with third-party payors, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements often vary from payer to payer and are reassessed by third party payors on a regular basis, and we have needed additional time and resources to comply with them. We have also experienced, and may continue to experience, delays in or denials of coverage if we do not adequately comply with these requirements. Our third-party payors have also requested, and in the future may request, audits of the amounts paid to us. We have been required to repay certain amounts to payers as a result of such audits, and we could be adversely affected if we are required to repay other payers for alleged overpayments due to lack of compliance with their reimbursement policies. In addition, we have experienced, and may continue to experience, delays in reimbursement when we transition to being an in-network provider with a payer.

We expect to continue to focus our resources on increasing adoption of, and expanding coverage and reimbursement for, our current tests and any future tests we may develop or acquire. If we fail to expand and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

We have limited experience with the development and commercialization of our databases and our health information and genomic platforms.

We have limited experience with the development or commercialization of clinical or research products in connection with the databases we manage and to which we have access, including our Centrellis and Traversa platforms. Our partners' usage of an advanced machine learning engine for therapeutic decision-making are at an early stage of development and usage under current and proposed collaborations, and we are continuing to develop new processes that may support the development of new therapeutics applications such as the delivery of personalized clinically actionable insights into clinical reports, clinical trial matching, real-world evidence trials, and clinical decision support, via an advanced programmable interface layer. Although our partners have invested significant financial resources to develop and utilize new technologies to support preclinical studies and other early research and development activities, and provide general and administrative support for these operations, our future success is dependent on our current and future partners' ability to successfully derive actionable insights from the database and our platform, and our partners' ability, where applicable, to obtain regulatory approval for new therapeutic solutions based off existing models or to obtain regulatory approval and marketing for, and to successfully commercialize, new therapeutics. The use of our platform and the databases it manages and to which it has access for these purposes will require additional regulatory investments for Centrellis, such as "good practice" quality guidelines and regulations ("GxP"), and data quality and integrity controls.

Ethical, legal and social concerns related to the use of genomic medicine and health information analysis could reduce demand for our tests.

Genomic medicine and health information analysis has raised ethical, legal and social issues regarding privacy rights and the appropriate uses of the resulting information. Domestic and international governmental and regulatory authorities could, for social or other purposes, such as data privacy, limit or regulate the use of health information or health information testing or prohibit testing for specific information derived from health information testing, including, for example, data on genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, genomic tests as part of health information assessment even if permissible, or lead patients to withhold or withdraw consent for our use of their data. These and other ethical, legal and social concerns may limit market acceptance of our tests, or services either of which could have an adverse effect on our business, research, financial condition or results of operations.

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

We are subject to Clinical Laboratory Improvement Amendments of 1988 ("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 establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. CLIA

certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payors, for our tests. We have current CLIA, CAP, and other certifications to conduct our tests at our laboratories in Connecticut. To renew these certifications, we are subject to survey and inspection on a regular basis and at the request of the certifying bodies. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories.

We would also be required to maintain in-state licenses if we were to conduct testing in other states. Several states require the licensure of out-of-state laboratories that accept specimens from certain states.

In addition to having laboratory licenses in New York, our clinical reference laboratories are approved on test-specific bases for the tests they run as laboratory-developed tests ("LDTs"), by the New York State Department of Health ("NYDOH"). Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of samples necessary for us to perform our tests that may limit our ability to make our tests available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays.

Failure to comply with applicable clinical laboratory licensure requirements or standards may result in a range of enforcement actions, including license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, and cancellation of the laboratory's approval to receive Medicare and Medicaid payment for our services, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure, or our failure to renew our CLIA certifications, a state or foreign license, or accreditation, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

The College of American Pathologists ("CAP"), maintains a clinical laboratory accreditation program. CAP asserts that its program is "designed to go well beyond regulatory compliance" and helps laboratories achieve the highest standards of excellence to positively impact patient care. While not required to operate a CLIA-certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. We have CAP accreditations for our laboratories. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

Additional Risks Related to GeneDx's Business and Operations

GeneDx needs to scale its infrastructure in advance of demand for its tests, and its failure to generate sufficient demand for its tests would have a negative impact on its business and its ability to attain profitability.

GeneDx's success depends in large part on its ability to extend its market position, to provide customers with high-quality test reports quickly and at a lower price than its competitors, and to achieve sufficient test volume to realize economies of scale. GeneDx's overall test volumes grew from approximately 134 thousand to 169 thousand tests processed during the years ended December 31, 2020 and 2021. In addition, GeneDx regularly evaluates and refines its testing process, often significantly updating its workflows, including with respect to exome sequencing and whole genome sequencing. In order to execute GeneDx's business model, it intends to continue to invest heavily in order to significantly scale its infrastructure, including GeneDx's testing capacity, particularly, with respect to exome sequencing and whole genome sequencing to supplement its panel testing capabilities, and information systems, expand its commercial operations, customer service, billing and systems processes and enhance its internal quality assurance program. GeneDx expects that much of this growth will be in advance of demand for its tests. GeneDx's and Sema4's current and future expense levels are to a large extent fixed and are largely based on investment plans and estimates of future revenue. Because the timing and amount of revenue from GeneDx's tests is difficult to forecast, when revenue does not meet expectations, GeneDx may not be able to adjust its spending promptly or reduce spending to levels commensurate with its revenue. Even if GeneDx's infrastructure. If GeneDx fails to generate demand commensurate with this growth or if it fails to scale its infrastructure sufficiently in advance of demand to successfully meet such demand, its business, prospects, financial condition and results of operations could be adversely affected.

If GeneDx is not able to continue to generate substantial demand of its tests, its commercial success will be negatively affected.

GeneDx's business model assumes that it will be able to generate significant test volume, particularly with respect to exome sequencing and whole genome sequencing in addition to its panel testing offerings, and it may not succeed in continuing to drive adoption of its tests to achieve sufficient volumes. Inasmuch as detailed genetic data from exome and whole genome sequencing has only recently become available at relatively affordable prices, the continued pace and degree of clinical acceptance of the utility of such testing is uncertain. Specifically, it is uncertain how much genetic data will be accepted as necessary or useful, as well as how detailed that data should be, particularly since medical practitioners may have become accustomed to genetic testing that is specific to one or a few genes and may not embrace the utility of exome sequencing and whole genome sequencing. Given the substantial amount of additional information available from a broad-based testing panel such as GeneDx's, there may be distrust as to the reliability of such information when compared with more limited and focused genetic tests. To generate further demand for GeneDx's tests, GeneDx will need to continue to make clinicians aware of the benefits of its tests, including the price, the breadth of its testing options, and the benefits of having additional genetic data available from which to make treatment decisions. A lack of or delay in clinical acceptance of GeneDx's tests and limit its revenue growth and potential profitability. Genetic testing is expensive and many potential customers may be sensitive to pricing. In addition, potential customers may not adopt GeneDx's tests if adequate reimbursement is not available, or if GeneDx is not able to maintain low prices relative to its competitors.

If GeneDx is not able to generate demand for its tests at sufficient volume, or if it takes significantly more time to generate this demand than GeneDx anticipates, GeneDx's business, prospects, financial condition and results of operations could be materially harmed.

GeneDx has devoted a portion of its resources to the development and commercialization of exome sequencing and whole genome sequencing, and to research and development activities related to such sequencing and the analysis thereof, including clinical and regulatory initiatives to obtain diagnostic clearance and marketing approval. The demand for these regulated products is relatively unproven, and GeneDx may not be successful in achieving market awareness and demand for these products through its and, following completion of the Acquisition, Sema4's sales and marketing operations.

If GeneDx's laboratories become inoperable due to disasters, health epidemics or for any other reasons, it will be unable to perform tests and its business will be harmed.

GeneDx performs all of its tests at its production facilities in Gaithersburg, Maryland. GeneDx's laboratories and the equipment it uses to perform its tests would be costly to replace and could require substantial lead time to replace and qualify for use. GeneDx's laboratories may be harmed or rendered inoperable by natural or man-made disasters, including flooding, fire and power outages, or by health epidemics, which may render it difficult or impossible for GeneDx to perform its tests for some period of time. The inability to perform GeneDx's tests or the backlog that could develop if its laboratories are inoperable for even a short period of time may result in the loss of customers or harm its reputation. Although GeneDx maintains insurance for damage to its property and the disruption of its business, this insurance may not be sufficient to cover all potential losses and may not continue to be available to GeneDx on acceptable terms, if at all.

Risks Related to Our Business Model

We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.

Our performance, including our research and development programs and laboratory operations, largely depends on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization, including software developers, geneticists, biostatisticians, bioinformaticians, data scientists, certified laboratory directors and technicians and other scientific and technical personnel to process and interpret our tests and related data. In addition, we may need to continue to expand our sales force with qualified and experienced personnel. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future due to the competition for qualified personnel among life science and technology businesses as well as universities and public and private research institutions, particularly in the New York City and the tristate area. Further, we may be unable to obtain the necessary visas for foreign personnel to work in the United States. In addition, our compensation arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating our



existing employees. 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 scale our business, support our research and development efforts and our clinical laboratories. We believe that our corporate culture fosters innovation, creativity and teamwork. However, as our organization grows, we may find it increasingly difficult to maintain the beneficial aspects of our corporate culture. This could negatively impact our ability to retain and attract employees and our future success.

The loss of any member or change in structure of our senior management team could adversely affect our business.

Our success depends in large part upon the skills, experience and performance of members of our executive management team and others in key leadership positions. The efforts of these persons will be critical to us as we continue to develop our technologies and test processes and focus on scaling our business. If we were to lose one or more key executives, including our Chief Executive Officer, Katherine Stueland, and our founder, President and Chief Research & Development Officer, Dr. Eric Schadt, we may experience difficulties in competing effectively, developing our tests and technologies and implementing our business strategy. Only certain of our executives have employment contracts, and the majority of our employees are at-will, which means that either we or any employee may terminate their employment at any time or in the notice period set forth in an executive's contract. In particular, in connection with the closing of the Acquisition, Dr. Schadt ceased serving as our Chief Executive Officer and we have not yet entered into a new employment agreement with Dr. Schadt. We also do not carry key person insurance for any of our executives or employees. In addition, we do not have long-term retention agreements in place with our executive officers. Furthermore, we compete against other leading companies in the diagnostics, health information, and data sciences markets for top talent. If such competitors offer better compensation or opportunities, there is no guarantee that we would be able to retain our key executives.

Our founder, President and Chief Research & Development Officer, Eric Schadt, and certain other of our employees have performed, and will continue to perform, duties for or on behalf of Mount Sinai.

Our founder, President and Chief Research & Development Officer, Eric Schadt, and certain of our other employees continue to perform duties for or on behalf of the Mount Sinai Health System, which refer to together with its related entities as Mount Sinai. In the case of Dr. Schadt, in addition to serving as our president and Chief Research & Development Officer and as a director, Dr. Schadt also serves as the Dean for Precision Medicine and a professor at Icahn School of Medicine at Mount Sinai ("ISMMS"). We expect Dr. Schadt to continue to devote a substantial amount of time to the research and development responsibilities for our company while maintaining certain duties for Mount Sinai. Though we do not expect Dr. Schadt's role as our President and Chief Research & Development Officer and a director to conflict with his roles at Mount Sinai, there can be no guarantee that such conflicts will not occur in the future.

We may not be able to manage our future growth effectively, which could make it difficult to execute our business strategy.

Our expected future growth could create a strain on our organizational, administrative and operational infrastructure, including data and laboratory operations, quality control, customer service, marketing and sales, and management. We may not be able to maintain the quality of or expected turnaround times for our products or services, or satisfy customer demand as it grows. We may need to continue expanding our sales force to facilitate our growth, and we may have difficulties locating, recruiting, training and retaining sales personnel. Our ability to manage our growth effectively will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. As we grow, any failure of our controls or interruption of our facilities or systems could have a negative impact on our business and financial operations. We plan to develop and launch new versions of our Centrellis and Traversa platforms and our core diagnostic products, which will affect a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain, and failure to complete these activities in a timely and efficient manner could adversely affect our operations. Future growth in our business could also make it difficult for it to maintain our corporate culture. 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.

We need to scale our infrastructure in advance of demand for our products and services, and our failure to generate sufficient demand for our products and services would have a negative impact on our business and our ability to attain profitability.

Our success depends in large part on our ability to extend our market position, to provide customers with high-quality health reports and health information and data science services in a manner that differentiates us from our competitors, and to deploy technologies and achieve sufficient volumes to realize economies of scale. In order to execute our business model, we intend to continue to invest heavily in order to significantly scale our infrastructure, including our lab infrastructure and testing capacity and our information and computing systems, expand our commercial operations,



customer service, billing and systems processes and enhance our internal quality assurance program. We will also need to enhance our capacity for data privacy management as we scale our infrastructure. We expect that much of this growth will be in advance of both demand for our products and services as well as our ability to diversify our offerings, including services related to Centrellis and Traversa and the databases we manage and to which we have access, and our ability to find appropriate partners through collaborations and acquisitions. Our current and future expense levels are to a large extent fixed and are largely based on our investment plans and our estimates of future revenue. Because the timing and amount of revenue from our products and services are difficult to forecast, when revenue does not meet our expectations, we may not be able to adjust our spending promptly or reduce our spending to levels commensurate with our revenue. Even if we are able to successfully scale our infrastructure and operations while successfully diversifying our offering, we cannot assure you that demand for our products and services, including our Centrellis platform, will increase at levels consistent with the growth of our infrastructure. If we fail to generate demand commensurate with this growth or if we fail to scale our infrastructure sufficiently in advance of demand to successfully meet such demand, our business, prospects, financial condition and results of operations could be adversely affected.

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

When cleared, authorized or approved, we and our collaborators may market, sell, and distribute our products and services outside of the United States, and our business would be subject to risks associated with doing business outside of the United States, including an increase in our expenses and diversion of our management's attention from the development of future products and services. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- multiple, conflicting and changing laws and regulations such as privacy, security and data use regulations, tax laws, export and import restrictions, economic sanctions and embargoes, employment laws, anticorruption laws, regulatory requirements, reimbursement or payer regimes and other governmental;
- approvals, permits and licenses;
- failure by us, our collaborators or our distributors to obtain regulatory clearance, authorization or approval for the use of our products and services in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining intellectual property protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations, including repatriating foreign earned profits;
- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- difficulties in negotiating favorable reimbursement negotiations with governmental authorities;
- logistics and regulations associated with shipping samples, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets if we are not able to conduct our clinical diagnostic services locally;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and services and exposure to foreign currency exchange rate fluctuations;
- international regulations and license requirements that may restrict foreign investment in and operation of the internet, IT infrastructure, data centers and other sectors, and international transfers of data;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, and outbreak of disease;
- boycotts, curtailment of trade and other business restrictions; and



regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within
the purview of the Foreign Corrupt Practices Act of 1977 ("FCPA"), its books and records provisions, or its anti-bribery provisions or laws similar to
the FCPA in other jurisdictions in which we may in the future operate, such as the United Kingdom's Bribery Act of 2010 and anti-bribery
requirements of member states in the European Union ("EU").

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

Unfavorable U.S. or global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn or increase in inflation rates 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 declining or inflationary economy could strain our collaborators and suppliers, 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.

We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers or service providers.

We have sourced and will continue to source components of our diagnostic testing workflow, including sequencers and other laboratory equipment, reagents, lab supplies and other laboratory services and materials and related services, from third parties.

Our failure to maintain a continued supply of our sequencers and other laboratory equipment, reagents, lab supplies and other laboratory services and materials, along with the right to use certain hardware and software and related services, would adversely impact our business, financial condition, and results of operations. In particular, while we are seeking to validate our tests on additional sequencing platforms we have not, to date, validated a viable alternative sequencing platform on which our testing could be run in a commercially viable manner. These efforts will require significant resources, expenditures and time and attention of management, and there is no guarantee that we will be successful in implementing any such sequencing platforms in a commercially sustainable way. We also cannot guarantee that we will appropriately prioritize or select alternative sequencing platforms on which to focus our efforts, in particular given our limited product and research and development resources and various business initiatives, which could result in increased costs and delayed timelines or otherwise adversely impact our business and results of operations.

Because we rely on third-party manufacturers, we do not control the manufacture of these components, including whether such components will meet our quality control requirements, nor the ability of our suppliers to comply with applicable legal and regulatory requirements. In many cases, our suppliers are not contractually required to supply these components to the quality or performance standards that we require. If the supply of components we receive does not meet our quality control or performance standards, we may not be able to use the components, or if we use them not knowing that they are of inadequate quality, which occasionally occurs with respect to certain reagents, our tests may not work properly or at all, or may provide erroneous results, and we may be subject to significant delays caused by interruption in production or manufacturing or to lost revenue from such interruption or from spoiled tests. In addition, any natural or other disaster, acts of war or terrorism, shipping embargoes, labor unrest, political instability, outbreak of disease or similar events at our third-party manufacturers' facilities that cause a loss of manufacturing capacity would heighten the risks that it faces.

In the event of any adverse developments with our sole suppliers, or if any of our sole suppliers modifies any of the components they supply to us, our ability to supply our products may be interrupted, and obtaining substitute components could be difficult or require us to re-design or re-validate our products. Our failure to maintain a continued supply of components, or a supply that meets our quality control requirements, or changes to or termination of our agreements or inability to renew our agreements with these parties or enter into new agreements with other suppliers could result in the loss of access to important components of our tests and impact our test performance or affect our ability to perform our tests in a timely manner or at all, which could impair, delay or suspend our commercialization activities. In the event that we transition to a new supplier from any of our sole suppliers, doing so could be time-consuming and expensive, may result in interruptions in our ability to supply our products to the market, could affect the performance of our tests or could

require that we re-validate our affected tests using replacement equipment and supplies, which could delay the performance of our tests, impact diagnostic solutions and heath information derived from such tests, and result in increased costs. Any of these occurrences could have a material adverse effect on our business, financial condition and results of operations.

We rely on a limited number of product and service providers for data infrastructure and analytics capabilities, and any disruption of, or interference with, our use of data and workflow services could adversely affect our business, financial condition, and results of operations, and we may not be able to find replacements or immediately transition to alternative products or service providers.

We currently rely upon third-party services for data storage and workflow management, including cloud storage solution providers, such as Amazon Web Services, or AWS, and Google Cloud Platform, or GCP. We rely on each of AWS and GCP features to complete several vital workflows in our health information and data science service delivery. To varying degrees some of those services are proprietary to how each platform performs in connection with our current usage of the services. Further, we have also built several proprietary workflows with our vendor and partner Command Health where we maintain versions of developed software on such platforms.

Nearly all of our data storage and analytics are conducted on, and the data and content we generate on our platforms are processed through, servers hosted by these providers, particularly AWS and GCP. We also rely on email service providers, bandwidth providers, internet service providers and mobile networks to deliver communications to patients, physicians and partners and to allow patients, physicians and our partners to access various offerings from our platforms. If our third-party vendors are unable or unwilling to provide the services necessary to support our business, or if our agreements with such vendors are terminated, our operations could be significantly disrupted. Some of our vendor agreements may be unilaterally terminated by the licensor for convenience, including with respect to AWS or GCP, and if such agreements are terminated, we may not be able to enter into similar relationships in the future on reasonable terms or at all.

Any damage to, or failure of, our systems or the systems of our third-party data centers or our other third-party providers could result in interruptions to the availability or functionality of database and platforms. As a result, we could lose health information data and miss opportunities to acquire and retain patients, physicians and partners including health systems and pharmaceutical and biotech companies, which could result in decreased revenue. If for any reason our arrangements with our data centers or third-party providers are terminated or interrupted, such termination or interruption could adversely affect our business, financial condition and results of operations. We exercise little control over these providers, which increases our vulnerability to problems with the services they provide. We could incur additional expense in arranging for new or redesigned facilities, technology, services and support. In addition, the failure of our third-party data centers or any other third-party providers to meet our capacity needs or any system failure as a result of reliance on third parties, including network, software or hardware failure, which causes a delay or interruption in our services and products, including our ability to handle existing or increased processing of data on our platforms, could have a material adverse effect on our business, revenues, operating results and financial condition.

Our current and future products and services may never achieve significant commercial market acceptance.

Our success depends on the market's confidence that we can provide data-driven research and diagnostic products and services that improve clinical outcomes, lower healthcare costs and enable better product development by Biopharma companies. Failure of our products and services, or those jointly developed with our collaborators, to perform as expected or to be updated to meet market demands could significantly impair our operating results and our reputation. We believe patients, health systems, clinicians, academic institutions and Biopharma companies are likely to be particularly sensitive to defects, errors, inaccuracies and delays with our products and services. Furthermore, inadequate performance of these products or services may result in lower confidence in our Centrellis platform in general.

We and our collaborators may not succeed in achieving significant commercial market acceptance for our current or future products and services due to a number of factors, including:

- Our ability to demonstrate the utility of our platforms including Centrellis and Traversa, and related products and services and their potential
 advantages over existing clinical artificial intelligence technology, life sciences research, clinical diagnostic and drug discovery technologies to
 academic institutions, Biopharma companies and the medical community;
- Our ability, and that of our collaborators, to perform clinical trials or other research to gather adequate evidence and/or to secure and maintain FDA and other regulatory clearance authorization or approval for our products or products developed based off our platform;



- the agreement by third-party payors to reimburse our products or services, the scope and extent of which will affect patients' willingness or ability to pay for our products or services and will likely heavily influence physicians' decisions to recommend our products or services;
- the rate of adoption of our platforms and related products and services by academic institutions, clinicians, patients, key opinion leaders, advocacy
 groups and Biopharma companies; and
- the impact of our investments in product and services, and technological innovation and commercial growth.

Additionally, our customers and collaborators, including Mount Sinai, may decide to decrease or discontinue their use of our products and services due to changes in their research and development plans, failures in their clinical trials, financial constraints, the regulatory environment, negative publicity about our products and services, competing products or the reimbursement landscape, all of which are circumstances outside of our control. We may not be successful in addressing these or other factors that might affect the market acceptance of our products, services and technologies. Failure to achieve widespread market acceptance of our platform and related products and services would materially harm our business, financial condition and results of operations.

Our projections are subject to significant risks, assumptions, estimates and uncertainties, including assumptions regarding adoption of our products and services. As a result, our projected revenues, market share, expenses and profitability may differ materially from our expectations in any given quarter or fiscal year.

We operate in rapidly changing and competitive industries and our projections are subject to the risks and assumptions made by our management with respect to these industries. Operating results are difficult to forecast as they generally depend on our assessment of the timing of adoption of our current and future products and services, which is uncertain. Furthermore, as we invest in the continued development of new businesses that have yet to achieve significant commercial success, whether because of competition or otherwise, we may not recover the often substantial up-front costs of developing and marketing those products and services or recover the opportunity cost of diverting management and financial resources away from other products or services. Additionally, our business may be affected by reductions in customer or partner demand as a result of a number of factors which may be difficult to predict. Similarly, our assumptions and expectations with respect to margins and the pricing of our products and services may not prove to be accurate as a result of competitive pressures or customer or partner demands. This may result in decreased revenue, and we may be unable to adopt measures in a timely manner to compensate for any unexpected shortfall in revenue. This inability could cause our operating results in a given quarter or year to be higher or lower than expected. Any failure to achieve our projected operating results could harm the trading price of our securities and our financial position.

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

Our estimates of the annual addressable markets for our current products and services and those under development are based on a number of internal and third-party estimates, including, without limitation, the number of patients who have developed one or more of a broad range of cancers, the number of individuals who are at a higher risk for developing one or more of a broad range of cancers, the number of individuals who have developed or are at a higher risk of developing certain disorders, the number of individuals with certain infectious diseases. The estimates also depend on whether we or our collaborators are able to engage, diagnose or treat patients through or using our products and services, the number of potential clinical tests utilized per treatment course per patient, the ongoing engagement by patients, physicians and health systems on our platforms, and the assumed prices at which we can sell our current and future products and services for markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual addressable market for our current or future products and services or services or the annual addressable market for our products or services is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

Uncertainty in the development and commercialization of our enhanced or new tests or services could materially adversely affect our business, financial condition and results of operations.

Our success will depend in part on our ability to effectively introduce enhanced or new offerings. The focus of our research and development efforts has expanded beyond our current products and services, focused substantially on women's health and oncology, as we are now also applying our expertise in processing and analyzing new areas, such as

rare diseases. In recent years we have developed and/or launched several new products or enhanced versions of existing products, including products leveraging alternative sequencing technologies, and we expect to continue our efforts in all of these areas and more. The development and launch of enhanced or new tests requires the completion of certain clinical development and commercialization activities that are complex, costly, time-intensive and uncertain, and requires us to accurately anticipate patients', clinicians', payors' and other counterparties' attitudes and needs as well as emerging technology and industry trends. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals.

We have relatively limited experience developing and commercializing products and services outside of the fields of women's health and oncology diagnostics, and we may not be successful in our current or future efforts to do so. We also have limited experience forecasting our future financial performance from our new products and services, and our actual results may fall below our financial guidance or other projections, or the expectations of analysts or investors, which could cause the price of our Class A common stock and warrants to decline. We may experience research and development, regulatory, marketing and other difficulties that could delay or prevent our introduction of enhanced or new tests and result in increased costs and the diversion of management's attention and resources from other business matters, such as from our current product and service offerings, which currently represent the significant majority of our current revenues. For example, any tests that we may enhance or develop may not prove to be clinically effective in clinical trials or commercially, or may not meet our desired target product profile, be offered at acceptable cost and with the sensitivity, specificity and other test performance metrics necessary to address the relevant clinical need or commercial opportunity; our test performance in commercial experience may be inconsistent with our validation or other clinical data; we may not be successful in achieving market awareness and demand, whether through our own sales and marketing operations or through collaborative arrangements; healthcare providers may not order or use, or third-party payors may not reimburse for, any tests that we may enhance or develop; or we may otherwise have to abandon a test or service in which we have invested substantial resources. For example, we are subject to the risk that the biological characteristics of the genetic mutations we seek to target, and upon which our technologies rely, are uncertain and difficult to predict. We may also experience

We cannot assure you that we can successfully complete the development of any new or enhanced product, or that we can establish or maintain the collaborative relationships that may be essential to our collaborators' goals, including clinical development or commercialization efforts. For example, clinical development requires large numbers of patient specimens and, for certain products, may require large, prospective, and controlled clinical trials. We may not be able to identify and help enroll patients or collect a sufficient amount of appropriate health data in a timely manner; or we may experience delays during data analysis process due to slower than anticipated supplies of patient data, or due to changes in study design or inputs, or other unforeseen circumstances; or we or our collaborators may be unable to afford or manage the large-sized clinical trials that some of our planned future products may require. Further, the publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for certain diagnostic solutions such as the ones offered by us, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any diagnostic solution that is the subject of or component in a study. Peer-reviewed publications regarding our products may be limited by many factors, including delays in the completion of, poor design of, or lack of compelling data from, clinical studies, as well as delays in the review, acceptance and publication process. If our diagnostic solutions or the technology underlying our current and future diagnostic solutions do not receive sufficient favorable exposure in peer-reviewed publications, the rate of clinician adoption of our diagnostic solutions and positive reimbursement coverage determinations for our diagnostic solutions could be negatively affected.

In addition, development of the data necessary to obtain regulatory clearance and approval of tests is time-consuming and carries with it the risk of not yielding the desired results. The performance achieved in published studies may not be repeated in later studies that may be required to obtain premarket clearance or approval from the U.S. Food and Drug Administration ("FDA"). Limited results from earlier-stage verification studies may not predict results from studies in larger numbers of subjects drawn from more diverse populations over longer periods of time. Unfavorable results from ongoing preclinical and clinical studies may delay, limit or prevent regulatory approvals or clearances or commercialization of our product candidates, or could result in delays, modifications or abandonment of ongoing analytical or future clinical studies, or abandonment of a product development program, any of which could have a material adverse effect on our business, operating results or financial condition.

These and other factors beyond our control could result in delays or other difficulties in the research and development, approval, production, launch, marketing or distribution of enhanced or new tests and could adversely affect our competitive position and results of operations.

We currently use, and in the future expect to increase our use of, information and rights from customers, strategic partners, and collaborators for several aspects of our operations, and if we cannot maintain current and enter new relationships with these parties with adequate access and authorization to such information, our business will suffer.

Accessing, combining, curating, and analyzing health information, including longitudinal patient medical history data and genetic data, are core features of the Centrellis platform and key elements of our long term business model. The regulatory landscape around the storage, processing and deidentification of genetic data is evolving globally and greatly impacts the ability of us, our strategic partners and collaborators to process and use the data in connection with our products and services.

We have limited resources to conduct our health information services, data analysis, life sciences research, clinical diagnostics and drug discovery operations and have not yet fully established infrastructure for sales, marketing or distribution in connection with our products and services. Accordingly, we have entered into service and collaboration agreements under which our partners, including health systems, have provided, and may in the future provide, funding, data access, and other resources for developing and potentially commercializing our products and services. These collaborations may result in us incurring significant expenses in pursuit of potential products and services, and we may not be successful in identifying, developing or commercializing any potential products or services.

Our future success depends in part on our ability to maintain and grow our existing relationships, including with Mount Sinai, and to establish new relationships. Many factors may impact the success of such collaborations, including our ability to perform our obligations, our collaborators' satisfaction with our products and services, our collaborators' performance of their obligations to us, our collaborators' internal priorities, resource allocation decisions and competitive opportunities, the ability to obtain regulatory approvals, disagreements with collaborators, the costs required of either party to the collaboration and related financing needs, and operating, legal and other risks in any relevant jurisdiction. Our ability to support such collaborations may also depend on factors outside of our control including the willingness of patients to engage with us and share their data, societal perspectives on privacy, and the willingness of health systems to establish collaborations, relationships may reduce our access to research, longitudinal patient health data, clinical trials or computing technologies that facilitate the collection and incorporation of new information into the databases we manage and to which we have access. All of the risks relating to product and service development, regulatory clearance, authorization or approval and commercialization described herein apply to us derivatively through the activities of our collaborators. We engage in conversations with companies regarding potential collaborations on an ongoing basis. These conversations may not result in a commercial agreement. Even if an agreement is reached, the resulting relationship may not be successful, and any products and services developed as part of the collaboration may not produce successful outcomes. Speculation in the industry about our existing or potential collaboration and our business.

If our products and services do not perform as expected, we may not realize the expected benefits of such products and services.

The success of our products depends on the market's confidence that we can provide reliable products and services that enable high quality diagnostic testing and health information services with high sensitivity and specificity and short turnaround times. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue as our product deliveries increase and our product and service portfolio expands.

Our products and services use a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors. An operational, technological or other failure in one of these complex processes or fluctuations in external variables may result in sensitivity or specificity rates that are lower than we anticipate or result in longer than expected turnaround times. In addition, labs are required to validate their processes before using our products for clinical purposes. These validations are outside of our control. If our products do not perform, or are perceived to not have performed, as expected or favorably in it to competitive products, our operating results, reputation, and business will suffer, and we may also be subject to legal claims arising from product limitations, errors, or inaccuracies.

If our sales and development or other collaborations and commercial relationships are not successful and we are not able to offset the resulting impact through our own efforts or through agreements with new partners, our commercialization activities may be impaired and our financial results could be adversely affected.

Part of our business strategy is to develop relationships with health systems, biopharma companies, and other partners to utilize our products and to provide access to data. Developing and commercializing products with third parties reduces our control over such development and commercialization efforts and subjects us to the various risks inherent in a joint effort with a third party, such as delays, operational issues, technical difficulties and other contingencies outside of our influence or control. The financial condition of these third parties could weaken, or they could terminate their relationship with us and/or stop sharing data or other information; reduce their marketing efforts relating to our products; develop and commercialize, or otherwise utilize competing products in addition to or in lieu of our tests; merge with or be acquired by a competitor of us or a company that chooses to de-prioritize the efforts to utilize our products or provide us with adequate data; or otherwise breach their agreements with us. Further, we must expend resources to operationalize our existing collaborations with our health system partners, which requires substantial effort in areas such as integrations for testing workflow, EMR, consents, marketing, and billing. To the extent, we are not successful at operationalizing existing collaborations with health partners, we may not be able to further improve or pursue new agreements with additional partners. Furthermore, our partners may misappropriate our trade secrets or use our proprietary information in such a way as to expose us to litigation and potential liability; and our compliance risk may increase to the extent that we are responsible for our partners' activities. Disagreements or disputes with our health systems and other partners, including disagreements over customers, proprietary or other rights or our or their compliance with financial or other contractual obligations, might cause delays or impair the development or commercialization of our products, services, and technologies, lead to additional responsibilities for us with respect to new products, services and technologies, or result in litigation or arbitration, any of which would divert management attention and resources and be time-consuming and expensive. As is typical for companies in our industry, it is continually evaluating and pursuing various strategic or commercial relationships, some of which may involve the sale and issuance of our Class A common stock, which could result in additional dilution of the percentage ownership of our stockholders and could cause the price of our Class A common stock and warrants to decline

If our relationships are not successful, our ability to develop and improve of products, services and technologies, and to successfully execute our commercial strategy regarding such products, services and technologies, could be compromised.

If we are unable to deploy and maintain effective sales, marketing and medical affairs capabilities, we will have difficulty achieving market awareness and selling our products and services.

To achieve commercial success for our tests and our future products and services, we must continue to develop and grow our sales, marketing and medical affairs organizations to effectively explain to healthcare providers the reliability, effectiveness and benefits of our current and future products and services as compared to alternatives. We may not be able to successfully manage our dispersed or inside sales forces or our sales force may not be effective. Because of the competition for their services, we may be unable to hire, partner with or retain additional qualified sales representatives or marketing or medical affairs personnel, either as our employees or independent contractors or through independent sales or other third-party organizations. Market competition for commercial, marketing and medical affairs talent is significant, and we may not be able to hire or retain such talent on commercially reasonable terms, if at all.

Establishing and maintaining sales, marketing and medical affairs capabilities will be expensive and time-consuming. Our expenses associated with maintaining our sales force may be disproportionate to the revenues we may be able to generate on sales of the certain tests or any future products or services.

We may never become profitable.

Sema4 has incurred losses since Sema4 was formed and we expect to continue to generate significant operating losses for the foreseeable future. As of March 31, 2022 and December 31, 2021, we have an accumulated deficit of approximately \$652.3 million and \$575.4 million, respectively. We expect to continue investing significantly toward development and commercialization of our health information technology and other products and services. If our revenue does not grow significantly, we will not be profitable. We cannot be certain that the revenue from the sale of any products or services based on our technologies will be sufficient to make us profitable.

Our operating results could be subject to significant fluctuation, which could increase the volatility of our stock and warrant prices and cause losses to our stockholders.

Our revenues and results of operations may fluctuate significantly, depending on a variety of factors, including the following:

- our success in marketing and selling, and changes in demand for, our tests, and the level of reimbursement and collection obtained for such tests;
- seasonal and environmental variations affecting healthcare provider recommendations for our tests and patient compliance with healthcare provider recommendations, including without limitation holidays, weather events, and circumstances such as the outbreak of coronavirus or influenza that may limit patient access to medical practices for diagnostic tests and preventive services;
- our success in collecting payments from third-party payors, patients and collaborative partners, variation in the timing of these payments and recognition of these payments as revenues;
- · the pricing of our tests, including potential changes in CMS or other reimbursement rates;
- circumstances affecting our ability to provide our tests, including weather events, supply shortages, or regulatory or other circumstances that
 adversely affect our ability to manufacture our tests or process tests in our clinical laboratories;
- circumstances affecting our ability to provide health information and data science services to biopharma partners, including software or hardware failures, insufficient capacity, regulatory changes or other circumstances that adversely affect the ability of us to deliver these services;
- fluctuations in the amount and timing of our selling and marketing costs and our ability to manage costs and expenses and effectively implement our business;
- · our research and development activities, including the timing of clinical trials; and
- our ability to collect, use, and commercialize data in a changing regulatory environment at a time when the public is growing increasingly concerned about privacy.

Our revenue growth rate could decline over time, and it may experience downward pressure on our operating margins in the future.

Our revenue growth rate could decline over time as a result of a number of factors, including increasing competition and the continued expansion of our business into a variety of new fields. Changes in geographic mix and product and service mix and an increasing competition for tests may also affect our revenue growth rate. We may also experience a decline in our revenue growth rate as our revenues increase to higher levels, if there is a decrease in the rate of adoption of our products, services, and technologies, among other factors.

In addition to a decline in our revenue growth rate, we may also experience downward pressure on our gross operating margins resulting from a variety of factors, such as the continued expansion of our business into new fields, including new products and services, as well as significant investments in new areas, all of which may have margins lower than those that we generate from testing. We may also experience downward pressure on our gross operating margins from increasing competition and increased costs for many aspects of our business. We may also pay increased fees to our partners as well as increased acquisition costs. We may also face an increase in infrastructure costs, supporting other businesses. Additionally, our expenditures to promote new products and services or to distribute certain products and services or increased investment in our innovation efforts across our Centrellis platform may affect our operating margins.

Due to these factors and the evolving nature of our business, our historical projected revenue growth rate and historical gross operating margins may not be indicative of our future performance.

We may need to raise additional capital to fund our existing operations, develop additional products and services, commercialize new products and services or expand our operations.

Sema4 has incurred net losses and negative cash flows from operations since its inception, including net losses of \$245.4 million, \$241.3 million and \$29.7 million for the years ended December 31, 2021, 2020 and 2019, respectively. The net loss was \$76.9 million for the three months ended March 31, 2022. As of March 31, 2022, we had an accumulated deficit of \$652.3 million. We expect to continue to generate significant operating losses for the foreseeable future, and we may therefore also seek to sell common or preferred equity or convertible debt securities, enter into a credit facility or another form of third-party funding or seek other debt financing.

We may also consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- increase our sales and marketing efforts to drive market adoption of our current and future products and services;
- · fund development efforts for our current and future products and services;
- expand our products and services into other disease indications and clinical applications;
- acquire, license or invest in technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth;
- our rate of progress in establishing payer coverage and reimbursement arrangements with commercial third-party payors and government payers;
- the cost of expanding our laboratory operations and offerings, including our sales and marketing efforts;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our Centrellis solution;
- · our rate of progress in, and cost of research and development activities associated with, products and services in research and early development;
- · the effect of competing technological, product and market developments;
- · costs related to international expansion; and
- the potential cost of and delays in product development as a result of any regulatory oversight applicable to our products and services.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any preferred equity securities issued also could provide for rights, preferences or privileges senior to those of holders of our Class A common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences and privileges senior to those of holders of our Class A common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products and services or grant licenses on terms that are not favorable to us.

We expect to make significant investments in our continued research and development of new products and services, which may not be successful.

We are seeking to leverage and deploy our Centrellis and Traversa platforms to develop a pipeline of future disease-specific research, diagnostic and therapeutic products and services. For example, we are attempting to extend current products into additional indications and sample types, and we are developing our population health program, and our pharmacogenomics solutions with a view toward advancing the development of tests designed to identify genetic variants for drug response that are associated with medically actionable and clinically relevant data to make more informed treatment decisions. We expect to incur significant expenses to advance these development efforts, but they may not be successful.

Developing new products and services is a speculative and risky endeavor. Products or services that initially show promise may fail to achieve the desired results or may not achieve acceptable levels of analytical accuracy or clinical utility. We may need to alter our products in development and repeat analysis or clinical studies before we identify a potentially successful product or service. Product development is expensive, may take years to complete and can have uncertain outcomes. Failure can occur at any stage of the development. If, after development, a product or service appears



successful, we or our collaborators may, depending on the nature of the product or service, still need to obtain FDA and other regulatory clearances, authorizations or approvals before we can market it. In the case of clinical products, the FDA's clearance, authorization or approval pathways are likely to involve significant time, as well as additional research, development and clinical study expenditures. The FDA may not clear, authorize or approve any future product or service we develop. Even if we develop a product or service that receives regulatory clearance, authorization or approval, or succeeds in initial product testing, we or our collaborators would need to commit substantial resources to commercialize, sell and market it before it could be profitable, and the product or service may never be commercially successful. Additionally, development of any product or service may be disrupted or made less viable by the development of competing products or services.

New potential products and services may fail at any stage of development or recalled after commercialization and if we determine that any of our current or future products or services are unlikely to succeed, we may abandon them without any return on our investment. If we are unsuccessful in developing additional products or services, our potential for growth may be impaired.

We have identified material weaknesses, some of which have a pervasive effect across the organization, and may identify additional material weaknesses or significant deficiencies, in our internal controls over financial reporting. Our failure to remedy these matters could result in a material misstatement of our financial statements.

In the course of preparing Legacy Sema4's financial statements for 2020, 2019 and 2018, we identified material weaknesses in our internal control over financial reporting as of December 31, 2020, which could, if not remediated, result in material misstatements in our financial statements. These material weaknesses had not been fully remediated as of March 31, 2022. In addition, during 2021, management identified a misclassification related to certain costs included within cost of services for the years ended December 31, 2021, 2020 and 2019. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses identified related to the fact that we did not design and maintain accounting policies, procedures and controls to ensure complete, accurate and timely financial reporting in accordance with U.S. GAAP. Specifically, the material weaknesses identified included the following:

- We did not design and maintain accounting policies, processes and controls to analyze, account for and report our revenue arrangements in accordance with ASC 606, Revenue from Contracts with Customers, and ASC 605, Revenue Recognition.
- We did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliations and journal entries; the accounting for cost capitalization policies in accordance with ASC 330, Inventory, and ASC 350-40, Intangibles Goodwill and Other Internal-Use Software; and the application of ASC 840, Leases.
- We had not developed and effectively communicated to our employees our accounting policies and procedures, which resulted in inconsistent practices. Since these entity level programs have a pervasive effect across the organization, management has determined that these circumstances constitute a material weakness.
- Our accounting and operating systems lacked controls over access, and program change management that are needed to ensure access to financial data is adequately restricted to appropriate personnel.
- We do not have sufficient, qualified finance and accounting staff with the appropriate U.S. GAAP technical accounting expertise to identify, evaluate
 and account for accounting and financial reporting, and effectively design and implement systems and processes that allow for the timely production
 of accurate financial information in accordance with internal financial reporting timelines, commensurate with our size and the nature and complexity
 of our operations. As a result, we did not design and maintain formal accounting policies, processes and controls related to complex transactions
 necessary for an effective financial reporting process.

Our management is in the process of implementing a remediation plan that is expected to include policies and procedures to support internal control over financial reporting for a public company as well as supplementing the accounting and finance function with robust technical accounting and financial reporting experience and training. However, we cannot guarantee that the steps we have taken or may subsequently take have been or will be sufficient to remediate the material weaknesses or ensure that our internal controls are effective. For a discussion of our remediation plan and actions, see "Item 4. Controls and Procedures." However, as noted above, as of March 31, 2022, the material weaknesses have not yet been fully remediated.

Furthermore, as a public company, we are required to comply with certain rules and requirements related to our disclosure controls and procedures and our internal control over financial reporting. Any failure to develop or maintain effective controls as a public company, any deficiencies found in the technology system we use to support our controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. For more information, see "*Risks Related to Being a Public Company—Our internal controls over financial reporting may not be effective and our independent registered public accounting firm may not be able to certify as to their effectiveness, which could have a significant and adverse effect on our business and reputation.*"

Our ability to use our net operating loss carry forwards and certain other tax attributes may be limited.

At December 31, 2021, our total gross deferred tax assets were \$160.5 million. Due to our lack of earnings history, future deductible temporary differences related to compensation and uncertainties surrounding our ability to generate future taxable income, our net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets are primarily comprised of federal and state tax net operating losses and tax credit carryforwards, stock-based compensation and other tax deductible temporary differences.

Furthermore, under Section 382 of the Internal Revenue Code of 1986, as amended ("Internal Revenue Code"), if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards ("NOLs"), and other pre-change tax attributes (such as research tax credits) to offset its future taxable income may be limited. In general, an "ownership change" occurs if there is a cumulative change in its ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Our existing NOLs and tax credit carryovers may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with completed acquisitions, including the business combination with CMLS or the Acquisition, or future transactions in our stock, our ability to utilize NOLs and tax credit carryovers could be further limited by Section 382 of the Internal Revenue Code. As a result, if we earn future taxable income, our ability to use our pre-change net operating loss and tax credit carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, the Tax Cuts and Jobs Act limits the deduction for NOLs to 80% of current year taxable income and eliminates NOL carrybacks. Further, there may also be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state liability.

Risks Related to Our Key Relationships

We rely on third-party laboratories to perform certain elements of our service offerings.

A limited but meaningful portion of our genomic analysis services is performed by third-party laboratories and service providers, while the remaining portion is performed in our laboratories. The third-party laboratories are subject to contractual obligations to perform these services for us, but are not otherwise under our control. We therefore do not control the capacity and quality control efforts of these third-party laboratories other than through our ability to enforce contractual obligations on volume and quality systems, and we have no control over such laboratories' compliance with applicable legal and regulatory requirements. We also have no control over the timeliness of such laboratories' performance of their obligations to us, and the third-party laboratories that we have contracted with have in the past had, and occasionally continue to have, issues with delivering results to us or resolving issues with us within the time frames we expected or established in our contracts with them, which sometimes results in longer than expected turnaround times for, or negatively impacts the performance of, these tests and services. In the event of any adverse developments with these third-party laboratories or their ability to perform their obligations in a timely manner and in accordance with the standards that we and our customers expect, our ability to service customers may be delayed, interrupted or otherwise adversely affected, which could result in a loss of customers and harm to our reputation. Furthermore, when these issues arise, we have had to expend time, management's attention and other resources to address and remedy such issues.

We may not have sufficient alternative backup if one or more of the third-party laboratories that we contract with are unable to satisfy their obligations to us with sufficient performance, quality and timeliness, including as a result of the ongoing COVID-19 pandemic. Any natural or other disaster, acts of war or terrorism, shipping embargoes, labor unrest, political instability, outbreaks of disease or similar events at one or more of these third-party laboratories' facilities that causes a loss of capacity would heighten the risks that we face. Changes to or termination of agreements or inability to renew agreements with these third-party laboratories or enter into new agreements with other laboratories that are able to perform such portions of our service offerings could impair, delay or suspend our efforts to market and sell these services.

In addition, certain third-party payors, including some state Medicaid payers, that we are under contract with may take the position that sending out testing to third-party laboratories and billing for such tests is contrary to the terms of its provider agreement and may refuse to pay us for the testing. If any of these events occur, our business, financial condition and results of operations could suffer. Further, some state laws impose anti-markup restrictions that prevent an entity from realizing a profit margin on outsourced testing. If we are unable to markup outsourced testing, our revenues and operating margins may suffer.

We rely on Mount Sinai, a related party, and its clinicians for a portion of our test volume in connection with our diagnostic solutions and for data programs, and we have entered into certain other arrangements with Mount Sinai.

We rely on Mount Sinai, which is a related party, and its clinicians for a portion of our test volumes in connection with our diagnostic solutions and for a significant portion of the de-identified clinical records in our databases. In addition, we sublease certain facilities from Mount Sinai, we provide certain research and data services to Mount Sinai, and we and Mount Sinai have entered into certain collaborative and commercial arrangements. Furthermore, we may in the future enter into other contracts for services or other engagements with Mount Sinai.

Mount Sinai is primarily made up of not-for-profit hospitals, a medical and graduate school and employed clinicians. The charitable missions of the Mount Sinai entities include patient care, teaching and research. As such, the Mount Sinai entities are required to deal with us strictly on an arms-length, fair market value basis, and the interests of Mount Sinai may not necessarily be aligned with our interests or those of our other stockholders.

We are subject to risks as a result of our reliance on Mount Sinai, and if our transactions and relationship with Mount Sinai were to cease, our business could be disrupted and it could have a material adverse effect on our business, research, financial condition and results of operations.

In addition, ISMMS is one of our significant stockholders. ISMMS may choose to dispose of some or all of the shares of our Class A common stock held by it. Any disposal of shares of Class A common stock by ISMMS, or the perception that these sales could occur, could cause the market price of our stock or warrants to decline.

We rely on commercial courier delivery services to transport samples to our facilities in a timely and cost-efficient manner and if these delivery services are disrupted, our business could be harmed.

Our core business depends on our ability to quickly and reliably deliver test results to our customers. We typically receive blood, saliva, or tissue samples for analysis at our laboratory facilities within days of collection from the patient. Disruptions and errors in these delivery service and accessioning errors and breaches, whether due to error by the courier service, labor disruptions, bad weather, natural disaster, terrorist acts or threats, outbreaks of disease or for other reasons, could adversely affect specimen integrity, our ability to process or store samples in a timely manner and to service our customers, and ultimately our reputation and our business. In addition, if we are unable to continue to obtain expedited delivery services on commercially reasonable terms, our operating results may be adversely affected.

Risks Related to Acquisitions

As a result of the Acquisition, OPKO became a substantial holder of shares of our Class A common stock and sales by OPKO into the market in the future could cause the market price of our Class A common stock to drop significantly, even if our business is doing well.

As a result of the Acquisition, OPKO became the owner of 80 million shares of Class A common stock as of the Closing Date. OPKO is subject to transfer restrictions and requirements to dispose of its shares in marketed sales processes under the shareholder agreements that were entered into in connection with the Acquisition, but those restrictions and requirements are finite and subject to exceptions.

If the shares held by OPKO or the other holders party such shareholder agreements are sold, or if it is perceived that they will be sold in the public market, the trading price of our Class A common stock could decline.

Our ability to be successful following the Acquisition is dependent upon the efforts of our key personnel, including the key personnel of GeneDx. The loss of key personnel could negatively impact our operations and profitability our financial condition could suffer as a result.

Our ability to be successful following the Acquisition is dependent upon the efforts of our key personnel, including the key personnel of GeneDx (who became our employees as of the closing of the Acquisition (the "Closing")). Although our

key personnel are expected to continue remain with the Company in their current roles, it is possible that we will lose some key personnel, the loss of which could negatively impact the operations and profitability of our business.

GeneDx's success depends to a significant degree upon the contributions of senior management, certain of whom would be difficult to replace. Departure by certain of GeneDx's officers could have a material adverse effect on GeneDx's business, financial condition, or operating results. The services of such personnel may not continue to be available to us.

We have incurred and will continue to incur significant transaction and transition costs in connection with the Acquisition.

We have incurred significant, non-recurring costs in connection with consummating the Acquisition. Furthermore, we expect to incur additional significant, non-recurring costs in connection with the integration of the businesses of our company and GeneDx. We may also incur additional costs to retain key employees.

The anticipated benefits of the Acquisition may not be realized fully or at all or may take longer to realize than expected.

The Acquisition involves the integration of two companies that have previously operated independently. Prior to the announcement, we and GeneDx did not conduct any integration planning for the two companies, and our ability to do so prior to consummation of the Acquisition was limited by applicable law. Following the Closing, we are devoting significant management attention and resources to integrating the two businesses. Delays in this process could adversely affect the combined company's business, financial results, financial condition and stock price. Even if we are able to integrate the two companies' business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, cost savings, innovation and operational efficiencies that we expected from this integration or that these benefits will be achieved within the anticipated time frame.

If the Acquisition's benefits do not meet the expectations of investors, stockholders or financial analysts, the market price of our securities may decline.

If the benefits of the Acquisition do not meet the expectations of investors or securities analysts, the market price of our securities may decline. For additional factors that may affect the trading price of our securities see "—*Risks Related to Being a Public Company*—*If we do not meet the expectations of investors, stockholders or financial analysts, the market price of our securities may decline.*"

We have been the target of transaction related lawsuits as result of the Acquisition, which could result in substantial costs, and we have also assumed GeneDx's risks arising from various legal proceedings.

In connection with the Acquisition, two lawsuits were filed in federal courts against us and our directors. The complaints assert claims under Section 14(a) and Section 20(a) of the Exchange Act, and Rule 14a-19 promulgated thereunder, generally allege that the proxy statement we mailed to our stockholders in connection with the approval of certain matters related to the Acquisition misrepresented and/or omitted certain purportedly material information, and seek a variety of equitable and injunctive relief. In addition, five purported stockholders of our company have sent us demand letters making similar allegations about the proxy statement and demanding we provide supplemental disclosures. Although we believe that these allegations, claims and demands are without merit, we cannot predict the outcome of these legal proceedings, or whether additional stockholders will file lawsuits.

In addition, as of the Closing, we assumed GeneDx's risks arising from legal proceedings. Furthermore, following the Closing of the Acquisition, the strategies or motivations of a party or parties with respect to actual or potential litigation against us may change. We cannot predict with certainty the eventual outcome of GeneDx's pending or future legal proceedings and the ultimate outcome of such matters could be material to our results of operations, cash flows and financial condition.

Finally, the Acquisition may result in post-transaction disputes with OPKO or the other counterparties to the Merger Agreement and the related agreements regarding a number of matters, including any post-closing adjustments to the Cash Consideration, the occurrence or non-occurrence of any Milestone Event (as defined in the Merger Agreement for the Acquisition) or payment of any Milestone Payment (as defined in the Merger Agreement) or any liabilities for which we or OPKO believes it was indemnified under the Merger Agreement.

We may seek to grow our business through additional acquisitions of complementary products or technologies, and the failure to manage these acquisitions, or the failure to integrate them with our existing business, could have a material adverse effect on our business, financial condition and operating results.

From time to time, we may consider additional opportunities to acquire other products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including:

- •problems assimilating the acquired products or technologies;
- •issues maintaining uniform standards, procedures, controls and policies;
- •unanticipated costs associated with acquisitions;
- •diversion of management's attention from our existing business;
- •risks associated with entering new markets in which we have limited or no experience; and
- •increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters.

We do not know if we will be able to identify any other acquisitions we deem suitable, whether we will be able to successfully complete any acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

Risks Related to Legal, Regulatory and Compliance

We may be subject to increased compliance risks as a result of our rapid growth, including our dependence on our sales, marketing and billing efforts.

We have had to expand our training and compliance efforts in line with our increasing reliance on personnel in our sales, marketing and billing functions, and our expansion of these functions in line with the overall growth in our business. We continue to monitor our personnel, but we have in the past experienced, and may in the future experience, situations in which employees fail to strictly adhere to our policies. In addition, sales and marketing activities in the healthcare space are subject to various rules and regulations. Moreover, our billing and marketing messaging can be complex and nuanced, and there may be errors or misunderstandings in our employees' communication of such messaging. Furthermore, we utilize text messaging, email, phone calls and other similar methods to communicate with patients who are existing or potential users of our products for various business purposes. These activities subject us to laws and regulations relating to communications with consumers, such as the CAN-SPAM Act and the Telephone Consumer Protection Act, violations of which could subject us to claims by consumers, who may seek actual or statutory damages, which could be material in the aggregate. As we continue to scale up our sales and marketing efforts in line with the growth in our business, in particular our increased pace of product launches as well as further geographical expansion, we face an increased need to continuously monitor and improve our policies, processes and procedures to maintain compliance with a growing number and variety of laws and regulations, including with respect to consumer marketing. To the extent that there is any violation, whether actual, perceived or alleged, of our policies or applicable laws and regulations, we may incur additional training and compliance costs, may receive inquiries from third-party payors or other third parties, or be held liable or otherwise responsible for such acts of non-compliance. Any of the foregoing could adversely affect our cash flow and financial condi

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

Our activities currently require the use of hazardous chemicals and biological material. 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, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. 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 and our partners will have to maintain compliance with FDA requirements for research, products and services and failure to maintain compliance with FDA requirements may prevent or delay the marketing of our products and services.



Even if we have obtained marketing authorization, we will have to comply with the scope of that clearance, authorization or approval. Failure to secure and to comply with clearance, authorization or approval or the additional, extensive and ongoing post-marketing obligations imposed by the FDA or other regulatory requirements of other regulatory agencies could result in unanticipated compliance expenditures, a range of administrative enforcement actions, injunctions and criminal prosecution. FDA post-market obligations include, among other things, compliance with the FDA QSR, establishing registration and device listings, labeling requirements, reporting of certain adverse events and malfunctions, and reporting of certain recalls. In addition, circumstances may arise that cause us to recall equipment used in connection with our research, products and services. Such recalls could have an adverse effect on our ability to provide those products and services, which in turn would adversely affect our financial condition. our collaborators will also be required to maintain FDA clearance, authorization or approval for the products and services that we jointly develop. Any failure by us or our collaborators to maintain such clearance, authorization or approval could impair or cause a delay in our ability to profit from these collaborations.

Future changes in FDA enforcement discretion for LDTs could subject our operations to much more significant regulatory requirements.

We currently offer a laboratory-develop test ("LDT"), version of certain tests. The FDA has a policy of enforcement discretion with respect to LDTs, whereby the FDA does not actively enforce its medical device regulatory requirements for such tests. However, in October 2014, the FDA issued two draft guidance documents stating that the FDA intended to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the existing classification of medical devices. Although the FDA halted finalization of the guidance in November 2016 to allow for further public discussion on an appropriate oversight approach to LDTs and to give Congressional authorizing committees the opportunity to develop a legislative solution, it is unclear if Congress or the FDA will modify the current approach to the regulation of LDTs in a way that would subject our current or future services marketed as LDTs to the enforcement of FDA regulatory requirements. The FDA Commissioner and the Director of the Center for Devices and Radiological Health ("CDRH"), have expressed significant concerns regarding disparities between some LDTs and in vitro diagnostics that have been reviewed, cleared, authorized or approved by the FDA. If the FDA were to determine that certain tests offered by us as LDTs are not within the policy for LDTs for any reason, including new rules, policies or guidance, or due to changes in statute, our tests may become subject to extensive FDA requirements or our business may otherwise be adversely affected. If the FDA were to disagree with our LDT status or modify our approach to regulating LDTs, we could experience reduced revenue or increased costs, which could adversely affect our business, prospects, results of operations and financial condition. If required, the regulatory marketing authorization process required to bring our current or future LDTs into compliance may involve, among other things, successfully completing additional clinical validations and submitting to and obtaining clearance from the FDA for a premarket clearance (510(k)) submission or authorization for a de novo or approval of a PMA. Furthermore, pending legislative proposals, if passed, such as the VALID Act, could create new or different regulatory and compliance burdens on us and could have a negative effect on our ability to keep products on the market or develop new products, which could have a material effect on our business. In the event that the FDA requires marketing authorization of our LDTs in the future, the FDA may not ultimately grant any clearance, authorization or approval requested by us in a timely manner, or at all. In addition, if the FDA inspects our laboratory in relation to the marketing of any FDA-authorized test, any enforcement action the FDA takes might not be limited to the FDA-authorized test carried by us and could encompass our other testing services.

Recently, the FDA has also taken a more active role in certain diagnostic areas, including the oversight of pharmacogenetic ("PGx"), and COVID-19 tests. In 2019, the FDA contacted several laboratories to demand changes to PGx test reports and marketing materials. In February 2020, the FDA issued a statement indicating that it continues to have concerns about the claims that certain clinical laboratories make with respect to their PGx tests, and published tables that list PGx associations for which the FDA has determined that the data support therapeutic management recommendations, a potential impact on safety or response, or a potential impact on pharmacokinetic properties only, respectively. To date, however, the FDA has not provided any general guidance on the types of claims or other characteristics that will cause a PGx test to fall outside FDA's enforcement discretion. As such, the extent to which the FDA will allow any laboratory to offer PGx tests in their current form without meeting FDA regulatory requirements for medical devices is unclear at this time.

For each product and service we are developing that may require FDA premarket review prior to marketing, the FDA may not grant clearance, authorization or premarket approval and failure to obtain necessary approvals for our future products and services would adversely affect our ability to grow our business.

Before we begin to manufacture, label and market additional clinical diagnostic products for commercial diagnostic use in the United States, we may be required to obtain either clearance, marketing authorization or approval from the FDA,

unless an exemption applies or the FDA exercises its enforcement discretion and refrains from enforcing its requirements. For example, the FDA currently has a policy of refraining from enforcing its medical device requirements with respect to LDTs, which the FDA considers to be a type of *in vitro* diagnostic test that is designed, manufactured and used within a single properly licensed laboratory.

The process of obtaining PMA is much more rigorous, costly, lengthy and uncertain than the 510(k) clearance process. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. Conversely, in the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a legally marketed "predicate" device in order for the product to be cleared for marketing. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics or if it has different technological characteristics as the predicate device, the proposed device must be as safe and effective as, and not raise different questions of safety or effectiveness than, the predicate device. Clinical data is sometimes required to support substantial equivalence. For lower-risk devices that would otherwise automatically be placed into Class III, which require a PMA because no predicate device is available and the devices do not fall within an existing 510(k)-exempt classification, an applicant may submit a *de novo* request to down classify the device into Class II or Class I, which would not require a PMA. In the *de novo* process, the FDA must determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness of a device, which is low to moderate risk and has no predicate. In other words, the applicant must justify the "down-classification" to Class I or II for a new product type that would otherwise automatically be placed into Class III, but is lower risk. Clinical data may be required. For laboratory tests for which FDA clearance, authorization or approval is required, the FDA may also require data to support analytical and clinical validity.

The 510(k), *de novo* and PMA processes can be expensive and lengthy and require the payment of significant fees, unless an exemption applies. The FDA's 510(k) clearance pathway usually takes from three to nine months from submission, but it can take longer for a novel type of product. The FDA's *de novo* classification pathway usually takes from six to 12 months, but for many applicants can take up to 18 months or more.

The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory clearances, authorizations or approvals would have a material adverse effect on our business, financial condition and prospects.

The FDA can delay, limit or deny clearance, authorization or approval of a device for many reasons, including:

- the inability to demonstrate to the satisfaction of the FDA that the products are safe or effective for their intended uses;
- the disagreement of the FDA with the design, conduct or implementation of the clinical trials or the analysis or interpretation of data from preclinical studies, analytical studies or clinical trials;
- · serious and unexpected adverse device effects experienced by participants in clinical trials;
- the data from preclinical studies, analytical studies and clinical trials may be insufficient to support clearance, authorization or approval, where
 required;
- the inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- an advisory committee, if convened by the FDA, may recommend against approval of a PMA or other application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee makes a favorable recommendation, the FDA may still not approve the product;
- the FDA may identify deficiencies in our marketing application;
- the FDA may identify deficiencies in our or our collaborators' manufacturing processes, facilities or analytical methods;
- the potential for policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering clinical data or regulatory filings insufficient for clearance, authorization or approval; and

the FDA or foreign regulatory authorities may audit clinical trial data and conclude that the data is not sufficiently reliable to support a PMA.

There are numerous FDA personnel assigned to review different aspects of marketing submissions, which can present uncertainties based on their ability to exercise judgment and discretion during the review process. During the course of review, the FDA may request or require additional data and information, and the development and provision of these data and information may be time-consuming and expensive. The process of obtaining regulatory clearances, authorizations or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances, authorizations or approvals on a timely basis, or at all for our products in development. If we are unable to obtain clearance, authorization or approval for any products for which it plans to seek clearance, authorization or approval, our business may be harmed.

Modifications to our products with FDA marketing authorization may require new FDA clearances, authorizations or approvals, or may require it to cease marketing or recall the modified clinical diagnostic products or future clinical products until clearances are obtained.

Any modification to a 510(k)-cleared device that significantly affects its safety or effectiveness, or that constitutes a major change in its intended use, could require a new 510(k) clearance, a new *de novo* authorization or approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances, authorizations or approvals are necessary.

For any product approved pursuant to a PMA, we would be required to seek supplemental approval for many types of modifications to the approved product. The FDA requires manufacturers in the first instance to determine whether a PMA supplement or other regulatory filing is needed or whether the change may be reported via the PMA Annual Report, but may disagree with a company's assessment.

If the FDA disagrees with our determination, which it may not review until we submit an annual report or the FDA conducts an inspection or other inquiry, and requires us to seek new clearances, authorizations or approvals for modifications to our previously cleared, authorized or approved clinical diagnostic products for which we have concluded new clearances, authorizations or approvals are unnecessary, we may be required to cease marketing or distribution of these clinical diagnostic products or to recall the modified products until we obtain clearance, authorization or approval. We may also be subject to enforcement action, including, among other things, significant regulatory fines or penalties.

In addition, for example, we plan to match our test reports for certain indications to identified mutations with FDA-approved targeted therapies or relevant clinical trials of targeted therapies. If a patient or physician who orders a test using one of our products is unable to obtain, or be reimbursed for the use of, targeted therapies because they are not indicated in the FDA-approved label for treatment, the patient is unable to enroll in an identified clinical trial due to the enrollment criteria of the trial, or some other reason, the ordering physician may conclude the test report does not contain actionable information. If physicians do not believe our products consistently generate actionable information about their patients' disease or condition, they may be less likely to use our products.

Furthermore, we cannot provide assurance that customers will always use these products in the manner in which they are intended. Any intentional or unintentional misuse of these products by customers could lead to substantial civil and criminal monetary and non-monetary penalties, and could result in significant legal and investigatory fees.

Our business is subject to various complex laws and regulations applicable to clinical diagnostics. We could be subject to significant fines and penalties if we or our partners fail to comply with these laws and regulations.

As a provider of clinical diagnostic products and services, we and our partners are subject to extensive and frequently changing federal, state, local and foreign laws and regulations governing various aspects of our business.

In particular, the clinical laboratory and healthcare industry is subject to significant governmental certification and licensing regulations, as well as federal, state and foreign laws regarding:

- test ordering and billing practices;
- marketing, sales and pricing practices;
- health information privacy and security, including HIPAA and comparable state laws;



- insurance;
- anti-markup legislation;
- fraud and abuse; and
- consumer protection.

We are also required to comply with FDA regulations, including with respect to our labeling and promotion activities. In addition, advertising and marketing of our clinical products are subject to regulation by the Federal Trade Commission ("FTC"), and advertising of laboratory services is regulated by certain state laws. Violation of any FDA requirement could result in enforcement actions, such as seizures, injunctions, civil penalties and criminal prosecutions, and violation of any FTC or state law requirement could result in injunctions and other remedies, all of which could have a material adverse effect on our business. Most states also have similar regulatory and enforcement authority for devices. Additionally, most foreign countries have authorities comparable to the FDA and processes for obtaining marketing approvals. Obtaining and maintaining these approvals, and complying with all laws and regulations, may subject us to similar risks and delays as those we could experience under FDA, FTC and state regulation. We incur various costs in complying and overseeing compliance with these laws and regulations. The growth of our business and sales organization, the acquisition of additional businesses or products and services and our expansion outside of the U.S. may increase the potential of violating these laws, regulations or our internal policies and procedures.

Healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments and healthcare laws and regulations are subject to change. Development of the existing commercialization strategy for our tests and planned development of products in our pipeline has been based on existing healthcare policies. We cannot predict what additional changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition and results of operations.

If we or our partners, fail to comply with these laws and regulations, it could incur significant fines and penalties and our reputation and prospects could suffer. Additionally, any such partners could be forced to cease offering our products and services in certain jurisdictions, which could materially disrupt our business. An adverse outcome could include us being required to pay treble damages, incur civil and criminal penalties, paying attorneys' fees, entering into a corporate integrity agreement, being excluded from participation in government healthcare programs, including Medicare and Medicaid, and other adverse actions that could materially and adversely affect our business, financial condition and results of operations.

Compliance with the HIPAA security, privacy and breach notification regulations may increase our costs.

The HIPAA privacy, security and breach notification regulations, including the expanded requirements under HITECH, establish comprehensive federal standards with respect to the uses and disclosures of protected health information ("PHI"), by health plans, healthcare providers and healthcare clearinghouses, in addition to setting standards to protect the confidentiality, integrity and security of PHI. The regulations establish a complex regulatory framework on a variety of subjects, including:

- the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient, including but not
 limited to treatment purposes, activities to obtain payments for our services, and our healthcare operations activities;
- a patient's rights to access, amend and receive an accounting of certain disclosures of PHI;
- requirements to notify individuals if there is a breach of their PHI;
- the contents of notices of privacy practices for PHI;
- · administrative, technical and physical safeguards required of entities that use or receive PHI;
- deidentification of PHI; and
- the protection of computing systems maintaining electronic PHI.

We have implemented practices intended to meet the requirements of the HIPAA privacy, security and breach notification regulations, as required by law. We are required to comply with federal privacy, security and breach notification regulations as well as varying state privacy, security and breach notification laws and regulations, which may be more stringent than federal HIPAA requirements. In addition, for healthcare data transfers from other countries relating to citizens and/or residents of those countries, we must comply with the laws of those countries. The federal privacy regulations under HIPAA restrict our ability to use or disclose patient identifiable data, without patient authorization, for purposes other than payment, treatment, healthcare operations and certain other specified disclosures such as public health and governmental oversight of the healthcare industry.

HIPAA provides for significant fines and other penalties for wrongful use or disclosure of PHI, including potential civil and criminal fines and penalties. Computer networks are always vulnerable to breach and unauthorized persons may in the future be able to exploit weaknesses in the security systems of our computer networks and gain access to PHI. Additionally, we share PHI with third-parties who are legally obligated to safeguard and maintain the confidentiality of PHI. Unauthorized persons may be able to gain access to PHI stored in such third-parties computer networks. Any wrongful use or disclosure of PHI by us or such third-parties, including disclosure due to data theft or unauthorized access to us or our third-parties computer networks, could subject it to fines or penalties that could adversely affect our business and results of operations. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we could also be liable for damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

Some of our activities may subject it to risks under federal and state laws prohibiting 'kickbacks' and false or fraudulent claims.

In addition to FDA marketing and promotion restrictions, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the healthcare product and service industry and to regulate billing practices and financial relationships with healthcare providers, hospitals and other healthcare providers. These laws include a federal law commonly known as the Medicare/Medicaid anti-kickback law, and several similar state laws, which prohibit payments intended to induce healthcare providers or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. While the federal law applies only to referrals, products or services for which payment may be made by a federal healthcare program, state laws often apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices and providers of laboratory services by limiting the kinds of financial arrangements, including sales programs, that may be used with hospitals, healthcare providers, laboratories and other potential purchasers or prescribers of medical devices and laboratory services. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services that were not provided as claimed.

In 2018, Congress passed the Eliminating Kickbacks in Recovery Act ("EKRA"), as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. Similar to the Medicare/Medicaid anti-kickback law, EKRA imposes criminal penalties for knowing or willful payment or offer, or solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing (among other healthcare services) unless a specific exception applies. However, unlike the Medicare/Medicaid anti-kickback law, EKRA is not limited to services covered by federal or state healthcare programs but applies more broadly to services covered by "healthcare benefit programs," including commercial insurers. As currently drafted, EKRA potentially expands the universe of arrangements that could be subject to government enforcement under federal fraud and abuse laws. In addition, while the Medicare/Medicaid anti-kickback law includes certain exceptions that are widely relied upon in the healthcare industry, including compensating employees on a percentage basis, not all of those same exceptions apply under EKRA. EKRA expressly does not protect employee compensation that varies by the number of individuals referred to a laboratory, the number of tests performed by a laboratory, or the amount billed to or received from a health benefit program from individuals referred to a laboratory. Because EKRA is a relatively new law, there is no agency guidance and only one court has addressed the application of EKRA. That case was decided by the United States District Court of Hawaii and involved a lawsuit between a laboratory and an employee. The Court ruled that the commission-based compensation provisions of the laboratory employee's contract did not violate EKRA. Although this may be a favorable interpretation of EKRA for laboratory compensation structures. we cannot be assured that courts in our jurisdiction will reach the same conclusion or that the decision will not be overturned if there is an appeal. Because EKRA is a relatively new law, there is no agency guidance or court precedent to indicate how and to what extent it will be applied and enforced. We cannot assure you that our relationships with healthcare providers, hospitals, customers, our own sales representatives, or any other party will not be subject to scrutiny or will survive regulatory challenge under EKRA.

Additionally, to avoid liability under federal false claims laws, we or our partners must carefully and accurately code claims for reimbursement, proactively monitor the accuracy and appropriateness of claims and payments received, diligently investigate any credible information indicating that we or our partners may have received an overpayment, and promptly return any overpayments. Medicare payments are subject to audit, including through the Comprehensive Error Rate Testing ("CERT"), program, and payments may be recouped by CMS if it is determined that they were improperly made. Currently, a small percentage of our revenues are generated by payments from Medicare. The federal anti-kickback statute and certain state-level false claims laws prescribe civil and criminal penalties (including fines) for noncompliance that can be substantial. In addition, various states have enacted false claim laws analogous to the federal laws that apply where a claim is submitted to any third-party payor and not only a governmental payer program. While we continually strive to comply with these complex requirements, interpretations of the applicability of these laws to marketing and billing practices are constantly evolving and even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could harm our business and prospects. Our failure to comply with applicable laws could result in various adverse consequences that could have a material adverse effect upon our business, including the exclusion of our products and services from government programs and the imposition of civil or criminal sanctions.

Our business could be harmed by the loss, suspension or other restriction on a license, certification or accreditation, or by the imposition of a fine or penalties, under CLIA, our implementing regulations or other state, federal and foreign laws and regulations affecting licensure or certification, or by future changes in these laws or regulations.

Federal law requires virtually all clinical laboratories to comply with CLIA, which generally involves becoming certified by the federal and state government for the testing that will be performed and complying with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that testing services are accurate and reliable. CLIA certification is also a prerequisite to be eligible to bill state and federal healthcare programs, as well as many private third-party payors, for laboratory research and clinical diagnostic testing services. For example, as a condition of our CLIA certification, a laboratory may be subject to survey and inspection every other year, additional random inspections and surprise inspections based on complaints received by state or federal regulators. The biennial survey and inspection is conducted by CMS, a CMS agent or, if the laboratory holds a CLIA certificate of accreditation, a CMS-approved accreditation organization, such as CAP. Sanctions for failure to comply with CLIA requirements, including proficiency testing violations, may include suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as the imposition of significant civil, administrative or criminal sanctions against the lab, its owners and other individuals. In addition, we are subject to regulation under certain state laws and regulations governing laboratory licensure. Some states have enacted laboratory licensure and compliance laws that affect our ability to offer and provide research and diagnostic products and services across state or foreign country lines could materially and adversely affect our business. In addition, state and foreign requirements for laboratory certification may be costly or difficult to meet and could affect our ability to receive specimens from certain states or foreign countries.

Any sanction imposed under CLIA, its implementing regulations or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license or accreditation, could have a material adverse effect on our business.

We may never obtain approval in the EU or in any other foreign country for any of our products or services and, even if we do, we or our partners and collaborators may never be able to commercialize them in another jurisdiction, which would limit our ability to realize their full market potential.

In order to eventually market any of our current or future products and services in any particular foreign jurisdiction, we must establish compliance with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding quality, safety, performance, privacy and efficacy. In addition, clinical trials or clinical investigations conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory clearance, authorization or approval in one country does not guarantee regulatory clearance, authorization or approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking foreign regulatory clearance, authorization or approval could result in difficulties and costs for us and our collaborators and require additional preclinical studies, clinical trials or clinical investigations which could be costly and time-consuming. Regulatory requirements and ethical approval obligations can vary widely from country to country and could delay or prevent the introduction of our products and services in those countries. The foreign regulatory clearance, authorization or approval process involves all of the risks and uncertainties associated with FDA clearance, authorization or approval. We currently have limited experience in obtaining regulatory clearance, authorization or approval in international

markets. If we or our collaborators fail to comply with regulatory requirements in international markets or to obtain and maintain required regulatory clearances, authorizations or approvals in international markets, or if those approvals are delayed, our target market will be reduced and our ability to realize the full market potential of our products and services will be unrealized.

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:

- HIPAA, which establishes comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions;
- amendments to HIPAA under HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators and expand vicarious liability, extend enforcement authority to state attorneys general, and impose requirements for breach notification;
- the General Data Protection Regulation ("GDPR"), which imposes strict privacy and security requirements on controllers and processors of European
 personal data, including enhanced protections for "special categories" of personal data, including sensitive information such as health and genetic
 information of data subjects;
- the CCPA, which, among other things, regulates how subject businesses may collect, use, disclose and/or sell the personal information of consumers who reside in California, affords rights to consumers that they may exercise against businesses that collect their information, and requires implementation of reasonable security measures to safeguard personal information of California consumers;
- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual, for the furnishing of or arrangement for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering, arranging for, or recommend purchasing, leasing or ordering, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program;
- EKRA, which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories and reaches beyond federal health care programs, to include private insurance;
- the federal physician self-referral law, known as the Stark Law, which prohibits a physician from making a referral to an entity 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 unless an exception applies, and prohibits an entity from billing for designated health services furnished pursuant to a prohibited referral;
- the federal false claims law, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare 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 healthcare program, unless an exception applies;
- the HIPAA fraud and abuse provisions, which create new federal criminal statutes that prohibit, among other things, defrauding health care benefit
 programs, willfully obstructing a criminal investigation of a healthcare offense and falsifying or concealing a material fact or making any materially
 false statements in connection with the payment for healthcare benefits, items or services;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests 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 21st Century Cures Act information blocking prohibition, which prohibits covered actors from engaging in certain practices that are likely to interfere with the access, exchange, or use of electronic health information;
- the Physician Payments Sunshine Act and similar state laws that require reporting of certain payments and other transfers of value made by
 applicable manufacturers, directly or indirectly, to or on behalf of covered recipients including physicians (defined to include doctors, dentists,
 optometrists, podiatrists and chiropractors) and teaching hospitals as well as ownership and investment interests held by physicians and their
 immediate family members.
- Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- state laws that limit or prohibit the provision of certain payments and other transfers of value to certain covered healthcare providers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- state laws that prohibit other specified practices, such as billing clinicians for testing that they order; waiving coinsurance, copayments, deductibles
 and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payers;
- similar foreign laws and regulations that may apply to us in the countries in which we operate or may operate in the future; and
- laws that relate to maintaining accurate information and control over activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions, or anti-bribery provisions.

We have adopted policies and procedures designed to comply with these laws and regulations. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance may also be subject to governmental review. The growth of our business and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of us being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. 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 significant administrative, civil and criminal penalties, damages, fines, imprisonment, exclusion from participation in Federal healthcare programs, refunding of payments received by us and curtailment or cessation of our operations, which may impact existing contracts with key payors, collaborators, health systems, and commercial partners. Any of the foregoing consequences could seriously harm our business and our financial results.

We face uncertainty related to healthcare reform, pricing, coverage and reimbursement, which could reduce our revenue.

Healthcare reform laws, including the Patient Protection and Affordable Care Act ("ACA"), and the Protecting Access to Medicare Act of 2014 ("PAMA"), are significantly affecting the U.S. healthcare and medical services industry. Existing legislation, and possible future legal and regulatory changes, including potential repeal or modification of the ACA, elimination of penalties regarding the individual mandate for coverage, or approval of health plans that allow lower levels of coverage for preventive services, could materially change the structure and finances of the health insurance system and the methodology for reimbursing medical services, drugs and devices, including our current and future products and services. The ACA has also been the subject of various legal challenges and in December 2018, a federal district court in Texas found that the ACA's "individual mandate" was unconstitutional such that the whole of the ACA is invalid. The decision was appealed, and in December 2019, the Fifth Circuit Court of Appeals affirmed certain portions of the district court's decision but remanded to the district court to determine if any portions of the ACA may still be valid. If the plaintiffs in this case, or in any other case challenging the ACA, are ultimately successful, insurance coverage for our tests could be materially and adversely affected. Any change in reimbursement policy could result in a change in patient cost-sharing, which could adversely affect a provider's willingness to prescribe and patient's willingness and ability to use our tests and any other product or service we may develop. Healthcare reforms, which may intend to reduce healthcare costs, may have the effect of discouraging third-party payors from covering certain kinds of medical products and services,

particularly newly developed technologies, or other products or tests we may develop in the future. We cannot predict whether future healthcare reform initiatives will be implemented at the federal or state level or the effect any such future legislation or regulation will have on it. The taxes imposed by new legislation, cost reduction measures and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, which may adversely affect our business, financial condition and results of operations.

PAMA presents significant uncertainty for future CMS reimbursement rates for our tests. Because Medicare currently covers a significant number of patients, any reduction in the CMS reimbursement rate for our tests would negatively affect our revenues and our business prospects. Under PAMA, CMS reimbursement rates for clinical diagnostic laboratory tests are updated every three years, or annually for clinical laboratory tests that are considered "advanced diagnostic laboratory tests". The CMS reimbursement rates for clinical diagnostic laboratory tests are updated based on the volume-weighted median of private payer rates for each clinical diagnostic laboratory tests based on data submitted by certain applicable laboratories. Further, laboratories that fail to report or erroneously report required payment information may be subject to substantial civil money penalties. There can be no assurance under PAMA that adequate CMS reimbursement rates will continue to be assigned to our tests. Congress could modify or repeal PAMA in the future or CMS could modify regulations under PAMA, and any such action could have the effect of reducing the CMS reimbursement rate for our tests. Further, it is possible that Medicare or other federal payers that provide reimbursement for our tests may suspend, revoke or discontinue coverage at any time, may require co-payments from patients, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues.

Coverage of our screening products that we may develop may also depend, in whole or in part, on whether payers determine, or courts and/or regulatory authorities determine, coverage is required under applicable federal or state laws mandating coverage of certain cancer screening services.

Several states have laws mandating coverage for preventive services, such as certain cancer screening services, applicable to certain health insurers. However, not all of these laws apply to our current tests and not all of these laws presently mandate coverage for patients within the certain age ranges. We and payers may disagree about how these mandates apply to our tests and we may find the mandates difficult to enforce. Further, if the ACA is repealed, replaced or overturned, or even if it is not, states may decide to modify their laws, which may include repeal of those coverage mandates that we believe currently apply to our oncology tests.

Outside of the U.S., we would largely depend on public or government-controlled payers for coverage of our oncology tests. As compared to many more routine diagnostic tests, our oncology tests are more complicated, expensive and are performed in a central, specialized lab. In order to accommodate the unique characteristics of our diagnostic products, public payers in certain non-U.S. markets have designed reimbursement frameworks specifically for each test type. These payers could decide to modify or discontinue these special frameworks, potentially leading to lower reimbursement prices or the impossibility of providing the test in the market. These changes could also impose additional administrative burdens on us, if it were to ever sell our tests in foreign jurisdictions, including complex public tendering procedures, or on ordering physicians, which could adversely affect the number of payers covering the test or the number of orders placed. Public payers could condition reimbursement of our tests upon performance of our tests locally or, even in laboratories owned or operated by the payers. Any such change would adversely affect our ability to continue to serve those patients through our labs. We may develop future oncologic tests that could be performed locally by laboratory partners and in hospitals around the world, however those developments efforts may be unsuccessful and any such tests that we may develop may not be approved by regulators or accepted by payers or patients.

Product and professional liability suits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.

The sale and use of our solutions, products and services could lead to product or professional liability claims, including class action lawsuits. We may also be subject to liability for errors in the test results including health information it provides to healthcare providers or patients or for a misunderstanding of, or inappropriate reliance upon, the information it provides. Claims could also arise out of clinical studies we may conduct or any of our other activities. A product or professional liability claim could result in substantial damages, be costly and time consuming to defend, and cause material harm to our business, reputation or financial condition. We cannot assure you that our liability insurance would protect our assets from the financial impact of defending a product or professional liability claim. Any claim brought against us, with or without merit, could increase our liability insurance rates or prevent it from securing insurance coverage in the future.

Errors, defects, or mistakes in our products or services, and operations could harm our reputation, decrease market acceptance of our products or services.



We are creating new products and services, many of which are initially based on largely untested technologies. As all of our products and services progress, we or others may determine that it made product or service-level scientific or technological mistakes. The diagnostic and testing processes utilize a number of complex and sophisticated molecular, biochemical, informatics, and mechanical processes, many of which are highly sensitive to external factors. An operational or technological failure in one of these complex processes or fluctuations in external factors may result in less efficient processing or variation between testing runs. Refinements to our processes may initially result in unanticipated issues that reduce the efficiency or increase variability. In particular, sequencing, which is a key component of these processes, could be inefficient with higher than expected variability thereby increasing total sequencing costs and reducing the number of samples we can process in a given time period. Therefore, inefficient or variable processes can cause variability in our operating results and damage our reputation.

In addition, our laboratory operations could result in any number of errors or defects. Our quality assurance system may fail to prevent it 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. In addition, 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. If we provide products or services with undiscovered errors to our customers, our clinical diagnostics may falsely indicate a patient has a disease or genetic variant, fail to assess a patient's risk of getting a disease or having a child with a disease, or fail to detect disease or variant in a patient who requires or could benefit from treatment or intervention. We believe our customers are likely to be particularly sensitive to product and service defects, errors and delays, including if our products and services fail to indicate the presence of residual disease with high accuracy from clinical specimens or if we fail to list or inaccurately indicate the presence or disease in our test report or analysis. In drug discovery, such errors may interfere with our collaborators' clinical studies or result in adverse safety or efficacy profiles for their products in development. This may harm our customers' businesses and may cause it to incur significant costs, divert the attention of key personnel, encourage regulatory enforcement action against it, create a significant customer relations problem for us and cause our reputation to suffer. We may also be subject to warranty and liability claims for damages related to errors or defects in our products or services. Any of these developments could harm our business and operating results.

We are subject to increasingly complex taxation rules and practices, which may affect how we conduct our business and our results of operations.

As our business grows, we are required to comply with increasingly complex taxation rules and practices. We are subject to tax in multiple U.S. tax jurisdictions and may be subject to foreign tax jurisdictions in the future. The development of our tax strategies requires additional expertise and may impact how we conduct our business. Our future effective tax rates could be unfavorably affected by changes in, or interpretations of, tax rules and regulations in the jurisdictions in which we do business or by changes in the valuation of our deferred tax assets and liabilities. Furthermore, we provide for certain tax liabilities that involve significant judgment. We are and may be subject to the examination of our tax returns by federal, state and foreign tax authorities. If our tax strategies are ineffective or it is not in compliance with domestic and international tax laws, as applicable, our financial position, operating results and cash flows could be adversely affected.

Risks Related to Our Intellectual Property and Trade Secrets

Our inability to effectively protect our proprietary products, processes, and technologies, including the confidentiality of our trade secrets, could harm our competitive position.

We currently rely upon trade secret protection and copyright, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, and to a limited extent patent protection, to protect our confidential and proprietary information. Although our competitors have utilized and are expected to continue utilizing similar methods and have aggregated and are expected to continue to aggregate similar databases of genetic testing information, our success will depend upon our ability to develop proprietary methods and databases and to defend any advantages afforded by our methods and databases relative to our competitors. If we do not protect our intellectual property adequately, competitors may be able to use our methods and databases and thereby erode any competitive advantages we may have.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. In this regard, we have applied, and we intend to continue applying, for patents covering such aspects of our technologies as it

deems appropriate. However, we expect that potential patent coverage we may obtain will not be sufficient to prevent substantial competition. In this regard, we believe it is probable that others will independently develop similar or alternative technologies or design around those technologies for which we may obtain patent protection. In addition, any patent applications we file may be challenged and may not result in issued patents or may be invalidated or narrowed in scope after they are issued. Questions as to inventorship or ownership may also arise. Any finding that our patents or applications are unenforceable could harm our ability to prevent others from practicing the related technology, and a finding that others have inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms, if at all. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, which would be expensive, and we lose, we may lose some of our intellectual property rights. Furthermore, these lawsuits may divert the attention of our management and technical personnel.

We expect to rely substantially upon trade secrets and proprietary know-how protection for our confidential and proprietary information, and we have taken security measures to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how or other confidential information. Among other things, we seek to protect our trade secrets and confidential information by entering into confidentiality agreements with employees and consultants. There can be no assurance that any confidentiality agreements that we have with our employees and consultants will provide meaningful protection for our trade secrets and confidential information or will provide adequate remedies in the event of unauthorized use or disclosure of such information. Accordingly, there also can be no assurance that our trade secrets will not otherwise become known or be independently developed by competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

Any inability to effectively protect our proprietary technologies under certain jurisdictions and legal regimes could harm our competitive position.

Our success and ability to compete in certain jurisdictions and under certain legal regimes depend to a large extent on our ability to develop proprietary products and technologies and to maintain adequate protection of our intellectual property in the United States and other countries; this becomes increasingly important as we expand our operations and enter into strategic collaborations with partners to develop and commercialize products. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and we may encounter difficulties in establishing and enforcing its proprietary rights outside of the United States. In addition, the proprietary positions of companies developing and commercializing tools for molecular diagnostics, including our own, generally are uncertain and involve complex legal and factual questions. This uncertainty may materially affect our ability to defend or obtain patents or to address the patents and patent applications owned or controlled by our collaborators and licensors.

Any of these factors could adversely affect our ability to obtain commercially relevant or competitively advantageous patent protection for our products.

If patent regulations or standards are modified, such changes could have a negative impact on our business.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability and validity of patents within the cancer screening and diagnostics space, and any such changes could have a negative impact on our business.

There have been several cases involving "gene patents" and diagnostic claims that have been considered by the U.S. Supreme Court. In March 2012, the Supreme Court *in Mayo Collaborative Services v. Prometheus Laboratories, Inc,* found a patented diagnostic method claim unpatentable because the relationship between a metabolite concentration and optimized dosage was a patent-ineligible "law of nature." In June 2013, the Supreme Court ruled in *ACLU v. Myriad Genetics, Inc,* that an isolated genomic DNA sequence is not patent eligible while cDNA is eligible. The *Prometheus and Myriad* decisions, as well as subsequent case law, affect the legal concept of subject matter eligibility by seemingly narrowing the scope of the statute defining patentable inventions.

In December 2014 and again in 2019, the USPTO published revised guidelines for patent examiners to apply when examining process claims for patent eligibility in view of several recent Supreme Court decisions, including *Mayo, Association for Molecular Pathology v. Myriad Genetics, Inc.*, and *Alice Corporation Pty. Ltd. v. CLS Bank International*, and others. The guidance indicates that claims directed to a law of nature, a natural phenomenon, or an abstract idea that do

not meet the eligibility requirements should be rejected as non-statutory, patent ineligible subject matter. While these guidelines may be subject to review and modification by the USPTO over time, we cannot assure you that our intellectual property strategy or patent portfolio will not be negatively impacted by the decisions described above, rulings in other cases or changes in guidance or procedures issued by the USPTO.

Additional substantive changes to patent law, whether new or associated with the America Invents Act — which substantially revised the U.S. patent system — may affect our ability to obtain, enforce or defend our patents. Accordingly, it is not clear what, if any, impact these substantive changes will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents, all of which could have a material adverse effect on our business.

If we are not able to adequately protect our trade secrets and other proprietary information, including the databases we manage and to which we have access, the value of our technology and products could be significantly diminished.

We rely on trade secret and proprietary know-how protection for our confidential and proprietary information and have taken security measures to protect this information. These measures, however, may not provide adequate protection. For example, we have a policy of requiring our consultants, advisors and collaborators, including, for example, our strategic collaborators with whom we seek to develop and commercialize products, to enter into confidentiality agreements and our employees to enter into invention, non-disclosure and in certain cases non-compete agreements. However, breaches of our physical or electronic security systems, or breaches caused by our employees who failing to abide by their confidentiality obligations during or upon termination of their employment with us, could compromise these protection efforts. Any action we take to enforce our rights may be time-consuming, expensive, and possibly unsuccessful. Even if successful, the resulting remedy may not adequately compensate us for the harm caused by the breach. These risks are heightened in countries where laws or law enforcement practices may not protect proprietary rights as fully as in the United States or Europe. Any unauthorized use or disclosure of, or access to, our trade secrets, know-how or other proprietary information, whether accidentally or through willful misconduct, could have a material adverse effect on our programs and our strategy, and on our ability to compete effectively.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.

Failure to maintain our trademark registrations, or to obtain new trademark registrations in the future, could limit our ability to protect our trademarks and impede our marketing efforts in the countries in which we operate. We may not be able to protect our rights to trademarks and trade names which we may need to build name recognition with potential partners or customers in our markets of interest. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, and possibly unsuccessful. our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to infringe on other marks.

Our pending trademark applications in the United States and in other foreign jurisdictions where we may file may not be successful. Even if these applications result in registered trademarks, third parties may challenge these trademarks in the future. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

Litigation or other proceedings resulting from either third-party claims of patent infringement, or asserting infringement by third parties of our technology, could be costly, time-consuming, and could limit our ability to commercialize our products or services.

Our success depends in part on our non-infringement of the patents or intellectual property rights of third parties, and our ability to successfully prevent third parties from infringing our intellectual property. We operate in a crowded technology area in which there has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the genetic diagnostics industry. Third parties, including our competitors, have asserted and may in the future assert that we are infringing their intellectual property rights. We may also become subject to and/or initiate future intellectual property litigation as our product portfolio and the level of competition in our industry grow.

Because the U.S. Patent & Trademark Office ("USPTO"), maintains patent applications in secrecy until a patent application publishes or the patent is issued, we have no way of knowing if others may have filed patent applications covering technologies used by it or our partners. Additionally, there may be third-party patents, patent applications and other intellectual property relevant to our technologies that may block or compete with our technologies. From time-to-time we have received correspondence from third parties alleging to hold intellectual property rights that could block our

development or commercialization of products. While none of these inquiries to date have had any material effect on it, we may receive inquiries in the future that could have a material effect on our business. Even if third-party claims are without merit, defending a lawsuit may result in substantial expense to us and may divert the attention of management and key personnel. In addition, we cannot provide assurance that it would prevail in any such suits to the extent necessary to conduct our business according to our strategic plan or that the damages or other remedies, if any, awarded against it would not be substantial. Claims of intellectual property infringement may require that we, or our strategic partners, enter into unsustainably high royalty or license agreements with third parties that may only be available on unacceptable terms, if at all. In addition, we could experience delays in product introductions or sales growth while we attempt to develop non-infringing alternatives. These claims could also result in injunctions against the further development and commercial sale of services or products containing our technologies, which would have a material adverse effect on our business, financial condition and results of operations.

Further, patents and patent applications owned by us may become the subject of interference proceedings in the USPTO to determine priority of invention, which could result in substantial cost to us as well as a possible adverse decision as to the priority of invention of the patent or patent application involved. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application subject to such a proceeding. We cannot predict whether, or offer any assurance that, the patent infringement claims may initiate in the future will be successful. We are and may become subject to counterclaims by patent infringement defendants. Our patents may be declared invalid or unenforceable, or narrowed in scope. Even if we prevail in an infringement action, we cannot assure you that it would be adequately compensated for the harm to our business. If we are unable to enjoin third-party infringement, our revenues may be adversely impacted and we may lose market share; and such third-party product may continue to exist in the market, but fail to meet our regulatory or safety standards, thereby causing irreparable harm to our reputation as a provider of quality products, which in turn could result in loss of market share and have a material adverse effect on our business, financial condition and our results of operations.

In addition, our agreements with some of our customers, suppliers, and other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in patent infringement claims, including the types of claims described in this risk factor. We have agreed, and may in the future agree, to defend or indemnify third parties if we determine it to be in the best interests of our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, financial condition and results of operations.

Our use of open-source software could subject our business to possible litigation or cause us to subject our platform to unwanted open-source license conditions that could negatively impact our sales.

A limited but meaningful portion of our platforms and products incorporate open-source software, and we will incorporate open-source software into other offerings or products in the future. Such open-source software is generally licensed by its authors or other third parties under open-source licenses. There is little legal precedent governing the interpretation of certain terms of these licenses, and therefore the potential impact of these terms on our business is unknown and may result in unanticipated obligations regarding our products and technologies. If an author or other third party that distributes such open-source software were to allege that we had not complied with the conditions of one or more of these licenses, we could be required to incur significant legal expenses defending against such allegations. In addition, if we combine our proprietary software with open-source software in a certain manner, under some open-source licenses, we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than our products.

We rely on strategic collaborative and licensing arrangements with third parties to develop critical intellectual property. We may not be able to successfully establish and maintain such intellectual property.

The development and commercialization of our products and services rely, directly or indirectly, upon strategic collaborations and licensing agreements with third parties. Such arrangements provide us with intellectual property and other business rights crucial to our product development and commercialization. We have incorporated licensed technology into our tests. Our dependence on licensing, collaboration and other similar agreements with third parties may subject it to a number of risks. There can be no assurance that any current contractual arrangements between us and third parties or between our strategic partners and other third parties will be continued on materially similar terms and will not be breached or terminated early. Any failure to obtain or retain the rights to necessary technologies on acceptable commercial terms could require us to re-configure our products and services, which could negatively impact their commercial sale or increase the associated costs, either of which could materially harm our business and adversely affect our future revenues and ability to achieve sustained profitability.

We expect to continue and expand our reliance on collaborative and licensing arrangements. Establishing new strategic collaborations and licensing arrangements is difficult and time-consuming. Discussions with potential collaborators or licensors may not lead to the establishment of collaborations on favorable terms, if at all. To the extent we agree to work exclusively with one collaborator in a given area, our opportunities to collaborate with other entities could be limited. Potential collaborators or licensors may reject collaborations with it based upon their assessment of our financial, regulatory or intellectual property position or other factors. Even if we successfully establish new collaborations, these relationships may never result in the successful commercialization of any product or service. In addition, the success of the projects that require collaboration with third parties will be dependent on the continued success of such collaborators. There is no guarantee that our collaborators will continue to be successful and, as a result, we may expend considerable time and resources developing products or services that will not ultimately be commercialized.

Risks Related to Cybersecurity, Privacy and Information Technology

Interruption, interference with, or failure of our information technology and communications systems could hurt our ability to effectively provide our products and services, which could harm our reputation, financial condition, and operating results.

The availability of our products and services and fulfillment of our customer contracts depend on the continuing operation of our information technology and communications systems. Our systems are vulnerable to damage, interference, or interruption from terrorist attacks, natural disasters, the effects of climate change (such as sea level rise, drought, flooding, wildfires, and increased storm severity), power loss, telecommunications failures, computer viruses, ransomware attacks, computer denial of service attacks, phishing schemes, or other attempts to harm or access our systems. Some of our data centers are located in areas with a high risk of major earthquakes or other natural disasters. Our data centers are also subject to break-ins, sabotage, and intentional acts of vandalism, and, in some cases, to potential disruptions resulting from problems experienced by facility operators. Some of our systems are not fully redundant, and disaster recovery planning cannot account for all eventualities.

The occurrence of a natural disaster, closure of a facility, or other unanticipated problems at our data centers could result in lengthy interruptions in our service. In addition, our products and services are highly technical and complex and may contain errors or vulnerabilities, which could result in interruptions in or failure of our services or systems.

Security breaches, privacy issues, loss of data and other incidents could compromise sensitive, protected, or personal information related to our business, could prevent it from accessing critical information, and could expose it to regulatory liability, which could adversely affect our business.

In the ordinary course of our business, we collect and store sensitive data, including PHI, personally identifiable information, genetic information, credit card information, intellectual property and proprietary business information owned or controlled by us or our customers, payers and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based systems. We also communicate PHI and other sensitive patient data through our various customer tools and platforms. In addition to storing and transmitting sensitive data that is subject to multiple legal protections, these applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure, inappropriate modification, and the risk of our being unable to adequately monitor and modify our controls over our critical information. Any technical problems that may arise in connection with the data that we access and our systems, including those that are hosted by third-party providers, could result in interruptions to our business and operations or exposure to security vulnerabilities. These types of problems may be caused by a variety of factors, including infrastructure changes, intentional or accidental human actions or omissions, software errors, malware, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have experienced outages or other problems that have resulted in their systems being offline and inaccessible. Such outages could materially impact our business and operations.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take what we believe to be reasonable and appropriate measures, including a formal, dedicated enterprise security program, to protect sensitive information from various compromises (including unauthorized access, disclosure, or modification or lack of availability), our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. Any such breach or interruption could compromise our networks and the information stored therein could be accessed by unauthorized parties, altered, publicly disclosed, lost or stolen.



Further, some of our customer tools and platforms are currently accessible through a portal and there is no guarantee that we can protect our portal from a security breach. Unauthorized access, loss or dissemination could also disrupt our operations (including our ability to conduct our analyses, provide test results, bill payers or patients, process claims and appeals, provide customer assistance, 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) and damage our reputation, any of which could adversely affect our business. In addition to data security risks, we also face privacy risks. Should we actually violate, or be perceived to have violated, any privacy promises our business makes to patients or consumers, it could be subject to a complaint from an affected individual or interested privacy regulator, such as the FTC, a state Attorney General, an EU Member State Data Protection Authority, or a data protection authority in another international jurisdiction. This risk is heightened given the sensitivity of the data we collect.

Any security compromise that causes an apparent privacy violation could also result in legal claims or proceedings; liability under federal, state, foreign, or multinational laws that regulate the privacy, security, or breach of personal information, such as but not limited to the HIPAA, HITECH, state data security and data breach notification laws, the EU's GDPR, the UK Data Protection Act of 2018; and related regulatory penalties. Penalties for failure to comply with a requirement of HIPAA or HITECH vary significantly, and, depending on the knowledge and culpability of the HIPAA-regulated entity, may include civil monetary penalties of up to \$1.5 million per calendar year for each provision of HIPAA that is violated. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to \$50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. Penalties for unfair or deceptive acts or practices under the FTC Act or state Unfair and Deceptive Acts and Practices ("UDAP"), statutes may also vary significantly.

There has been unprecedented activity in the development of data protection regulation around the world. As a result, 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. The GDPR took effect on May 25, 2018. The GDPR took effect on May 25, 2018. The GDPR applies to any entity established in the EU as well as extraterritorially to any entity outside the EU that offers goods or services to, or monitors the behavior of, individuals who are located in the EU. The GDPR imposes strict requirements on controllers and processors of personal data, including enhanced protections for "special categories" of personal data, which includes sensitive information such as health and genetic information of data subjects. The GDPR also grants individuals various rights in relation to their personal data, including the rights of access, rectification, objection to certain processing and deletion. The GDPR provides an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR or the related national data protection laws of the member states of the EU, which may deviate from or be more restrictive than the GDPR, may result in significant administrative fines issued by EU regulators. Maximum penalties for violations of the GDPR are capped at 20 million euros or 4% of an organization's annual global revenue, whichever is greater.

Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. The relationship between the United Kingdom and the EU remains uncertain, for example how data transfers between the United Kingdom and the EU and other jurisdictions will be treated and the role of the United Kingdom's supervisory authority. For example, on June 28, 2021, the European Commission adopted the adequacy decision (the "UK Adequacy Decision") in the wake of a non-binding vote by the European Parliament against the thendraft UK Adequacy Decision the month prior. Consequently, personal data can continue to flow from the EEA to the United Kingdom without the need for appropriate safeguards. The UK Adequacy Decision includes a "sunset clause", rendering the decision valid for four years only, after which it will be reviewed by the European Commission and renewed only if the European Commission considers that the United Kingdom continues to ensure an adequate level of data protection. The European Commission also stated that it would intervene at any point within the four years if the United Kingdom deviates from the level of protection presently in place. If this adequacy decision reversed by the European Commission, it would require that companies implement protection measures such as the standard contractual clauses for data transfers between the EU and the United Kingdom.

Additionally, the implementation of GDPR has led other jurisdictions to either amend or propose legislation to amend their existing data privacy and cybersecurity laws to resemble the requirements of GDPR. For example, on June 28, 2018, California adopted the CCPA. The CCPA regulates how certain for-profit businesses that meet one or more CCPA applicability thresholds collect, use, and disclose the personal information of consumers who reside in California. Among other things, the CCPA confers to California consumers the right to receive notice of the categories of personal information that will be collected by a business, how the business will use and share the personal information, and the third parties who

will receive the personal information; the CCPA also confers rights to access, delete, or transfer personal information; and the right to receive equal service and pricing from a business after exercising a consumer right granted by the CCPA. In addition, the CCPA allows California consumers the right to opt out of the "sale" of their personal information, which the CCPA defines broadly as any disclosure of personal information to a third party in exchange for monetary or other valuable consideration. The CCPA also requires a business to implement reasonable security procedures to safeguard personal information against unauthorized access, use, or disclosure. California amended the law in September 2018 to exempt all PHI collected by certain parties subject to HIPAA, and further amended the law in September 2020 to clarify that de-identified data as defined under HIPAA will also be exempt from the CCPA. The California Attorney General's final regulations implementing the CCPA took effect on August 14, 2020. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches resulting from a business's failure to implement and maintain reasonable data security procedures that is expected to increase data breach litigation. In addition, California voters recently approved the California Privacy Rights Act of 2020 ("CPRA"), that is scheduled to go into effect on January 1, 2023. The CPRA would, among other things, amend the CCPA to give California residents the ability to limit the use of their sensitive information, provide for penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the law. Other jurisdictions in the United States are beginning to propose laws similar to CCPA. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation, which could increase our potential liability and adversely affect our bu

It is possible the GDPR, CCPA and other emerging United States and international data protection laws may be interpreted and applied in manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy laws and regulations may differ from country to country and state to state, and our obligations under these laws and regulations vary based on the nature of our activities in the particular jurisdiction, such as whether we collect samples from individuals in the local jurisdiction, perform testing in the local jurisdiction, or process personal information regarding employees or other individuals in the local jurisdiction. Complying with these various laws and regulations could cause us to incur substantial costs or require it to change our business practices and compliance procedures in a manner adverse to our business. We can provide no assurance that it is or will remain in compliance with diverse privacy and data security requirements in all of the jurisdictions in which we do business. Failure to comply with privacy and data security requirements could result in a variety of consequences, or damage to our reputation, any of which could have a material adverse effect on our business.

Data privacy and security concerns relating to our technology and our practices could damage our reputation, subject it to significant legal and financial exposure, and deter current and potential users or customers from using our products and services. Software bugs or defects, security breaches, and attacks on our systems could result in the improper disclosure and use of user data and interference with our users and customers' ability to use our products and services, harming our business operations and reputation.

Concerns about our practices with regard to the collection, use, disclosure, or security of personal information or other data-privacy-related matters, even if unfounded, could harm our reputation, financial condition, and operating results. Our policies and practices may change over time as expectations regarding privacy and data change.

Our products and services involve the storage and transmission of protected health information and other personal information, proprietary information, and bugs, theft, misuse, defects, vulnerabilities in our products and services, and security breaches expose it to a risk of loss of this information, improper use and disclosure of such information, litigation, and other potential liability. Systems and control failures, security breaches, failure to comply with our privacy policies, and/or inadvertent disclosure of user data could result in government and legal exposure, seriously harm our reputation and brand and, therefore, our business, and impair our ability to attract and retain users or customers. We expect to continue to expend significant resources to maintain security protections that shield against bugs, theft, misuse, or security vulnerabilities or breaches.

We experience cyber-attacks and other attempts to gain unauthorized access to our systems on a regular basis. We may experience future security issues, whether due to employee error or malfeasance or system errors or vulnerabilities in our or other parties' systems, which could result in significant legal and financial exposure. Government inquiries and enforcement actions, litigation, and adverse press coverage could harm our business. We may be unable to anticipate or detect attacks or vulnerabilities or implement adequate preventative measures. Attacks and security issues could also compromise trade secrets and other sensitive information, harming our business.

While we have dedicated significant resources to privacy and security incident response capabilities, including dedicated worldwide incident response teams, our response process may not be adequate, may fail to accurately assess the severity of an incident, may not respond quickly enough, or may fail to sufficiently remediate an incident. As a result, we may suffer significant legal, reputational, or financial exposure, which could harm our business, financial condition, and operating results.

We depend on our scientific computing and information technology and management systems and any failure of these systems could harm our business.

We depend on scientific computing and information technology and management systems, including third-party cloud computing infrastructure, operating systems and artificial intelligence platforms, for significant elements of our operations, including our laboratory information management system, clinical database, analytical platform, laboratory workflow tools, customer and collaborator reporting and related functions. We also depend on our proprietary workflow software to support new product and service launches and regulatory compliance.

We use complex software processes and bioinformatic pipelines to manage samples and evaluate sequencing result data. These are subject to initial design or ongoing modifications which may result in unanticipated issues that could cause variability in patient results, leading to service disruptions or errors, resulting in liability.

We have installed, and expects to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including systems laboratory operations, handling human resources, financial controls and reporting, contract management, regulatory compliance and other infrastructure operations, and patient consent and information management. In addition to these business systems, we have installed, and intends to extend, the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design and the automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation and general administrative activities. In addition, our third-party billing and collections provider depends upon technology and telecommunications systems provided by outside vendors.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious internal or external human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of these systems or those used by our collaborators or subcontractors could prevent it from conducting our comprehensive screening analysis, clinical diagnostics and drug discovery, preparing and providing reports to researchers, clinicians and our collaborators, billing payers, handling physician inquiries, conducting research and development activities and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and our reputation, and we may be unable to regain or repair our reputation in the future.

Our ability to transfer data stored outside of the United States could be limited by international regulations or other action by foreign governments, which could adversely affect our business.

Some of the data we process in the ordinary course of our business may be stored outside of the United States. In order to process such data, we may need to transfer them to countries other than those where they are stored. Should a foreign government adopt a regulation restricting the international transfer of such data, we may not be able to process them, which could adversely impact our business.

Risks Related to Being a Public Company

We will 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 incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") as well as rules implemented by the SEC and the Nasdaq Stock Market ("Nasdaq") impose a number of requirements on public companies, including with respect to corporate governance practices. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require the company's compliance. In addition, the

Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), enacted in 2010, includes significant corporate governance and executive-compensation-related provisions. Our management and other personnel will need to devote a substantial amount of time to these compliance and disclosure obligations. If these requirements divert the attention of our management and personnel from other aspects of our business concerns, they could have a material adverse effect on our business, financial condition and results of operations. Moreover, these rules and regulations applicable to public companies substantially could increase our legal, accounting and financial compliance costs, require that we hire additional personnel and make some activities more time consuming and costly.

A market for our securities may not continue, which would adversely affect the liquidity and price of our securities.

The price of our securities may fluctuate significantly due to general market and economic conditions. An active trading market for our securities may not be sustained. In addition, the price of our securities can vary due to general economic conditions and forecasts, our general business condition and the release of our financial reports. You may be unable to sell your securities when desired or at an acceptable price unless an active trading market can be sustained.

If we do not meet the expectations of investors, stockholders or financial analysts, the market price of our securities may decline.

If we do not meet the expectations of investors or securities analysts, the market price of our securities may decline. In addition, fluctuations in the price of our securities could contribute to the loss of all or part of your investment. If an active market for our securities does not continue, the trading price of our securities could be volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. Any of the factors listed below could have a material adverse effect on your investment in our securities and our securities may trade at prices significantly below the price you paid for them. In such circumstances, the trading price of our securities may not recover and may experience a further decline.

Factors affecting the trading price of our securities may include:

- actual or anticipated fluctuations in our quarterly financial results or the quarterly financial results of companies perceived to be similar to us;
- changes in the market's expectations about our operating results;
- the public's reaction to our press releases, our other public announcements and our filings with the SEC;
- speculation in the press or investment community;
- announcements of technological innovation, new products, acquisitions, strategic alliances, significant agreements by us or competitors;
- success of competitors;
- our operating results falling below our financial guidance or other projections or failing to meet the expectation of securities analysts or investors in a
 particular period;
- changes in financial estimates and recommendations by securities analysts concerning us or the market in general;
- operating and stock price performance of other companies that investors deem comparable to us;
- our ability to market new and enhanced products on a timely basis;
- · changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- · risks that the Acquisition disrupts our current plans and operations or affects our ability to retain or recruit key employees;
- risks related to the Acquisition diverting management's or employees' attention from ongoing business operations;

- the effect of the Acquisition on our business relationships (including, without limitation customers, strategic partners, collaborators and suppliers), operating results and business generally;
- the amount of the costs, fees, expenses and charges related to the Acquisition;
- the volume of shares of our Class A common stock available for public sale;
- any major change in our Board or management;
- sales of substantial amounts of Class A common stock by our directors, officers or significant stockholders or the perception that such sales could occur;
- the expiration of the market stand-off or contractual lock-up agreements;
- the realization of any of the risk factors described herein;
- additions or departures of key personnel;
- failure to comply with the requirements of the Nasdaq;
- failure to comply with the Sarbanes-Oxley Act or other laws or regulations;
- actual, potential or perceived control, accounting or reporting problems;
- · changes in accounting principles, policies and guidelines; and
- general economic and political conditions such as recessions, inflation and interest rates, fuel prices, international currency fluctuations and acts of war or terrorism.

Broad market and industry factors may materially harm the market price of our securities irrespective of our operating performance. The stock market in general and Nasdaq have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the particular companies affected. The trading prices and valuations of these stocks, and of our securities, may not be predictable. A loss of investor confidence in the market for the stocks of other companies which investors perceive to be similar to us could depress our stock price regardless of our business, prospects, financial conditions or results of operations. A decline in the market price of our securities also could adversely affect our ability to issue additional securities and our ability to obtain additional financing in the future.

In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

If securities or industry analysts cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding our Class A common stock adversely, then the price and trading volume of our Class A common stock could decline.

The trading market for our Class A common stock is influenced by the research and reports that industry or securities analysts publish about us, our business, our market, or our competitors. If any of the analysts who cover us change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, the price of our Class A common stock would likely decline. If any analyst who covers us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

Changes in laws, regulations or rules, or a failure to comply with any laws, regulations or rules, may adversely affect our business, investments and results of operations.

We are subject to laws, regulations and rules enacted by national, regional and local governments and Nasdaq. In particular, we are required to comply with certain SEC, Nasdaq and other legal or regulatory requirements. Compliance with, and monitoring of, applicable laws, regulations and rules may be difficult, time consuming and costly. Those laws, regulations or rules and their interpretation and application may also change from time to time and those changes could have a material adverse effect on our business, investments and results of operations. In addition, a failure to comply with

applicable laws, regulations or rules, as interpreted and applied, could have a material adverse effect on our business and results of operations.

Anti-takeover provisions contained in our Charter and Restated Bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

Our Amended and Restated Certificate of Incorporation (which we refer to as our "Charter") contains provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. We are also subject to anti-takeover provisions under Delaware law, which could delay or prevent a change of control. Together, these provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities. These provisions will include:

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority
 of the Board;
- the requirement that directors may only be removed from the Board for cause;
- the right of our Board to elect a director to fill a vacancy created by the expansion of our Board or the resignation, death or removal of a director in certain circumstances, which prevents stockholders from being able to fill vacancies on our Board;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- a prohibition on stockholders calling a special meeting and the requirement that a meeting of stockholders may only be called by a majority of the board, our chairman of the board or our chief executive officer and may not be called by any other person, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement that changes or amendments to certain provisions of our Charter must be approved by holders of at least two-thirds of our Class A common stock; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our Board or to propose matters to be acted upon at
 a meeting of stockholders, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own
 slate of directors or otherwise attempting to obtain control of us.

The JOBS Act permits "emerging growth companies" like us to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies.

We currently qualify as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the JOBS Act. As such, we take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including: (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act; (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements; and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports. As a result, our stockholders may not have access to certain information they deem important. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year: (a) following September 1, 2025, the fifth anniversary of the initial public offering of CMLS; (b) in which we have total annual gross revenue of at least \$1.07 billion; or (c) in which we are deemed to be a large accelerated filer, which means the market value of our Class A common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the exemption from complying with new or revised accounting standards provided in Section 7(a)(2)(B) of the Securities Act as long as we are an emerging growth company. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The JOBS Act provides that a

company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies, but any such election to opt out is irrevocable. We have elected to avail ourselves of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company that is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited consolidated financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our Class A common stock held by non-affiliates exceeds \$250 million as of the prior June 30, or (ii) our annual revenues exceeded \$100 million during such completed fiscal year and the market value of our Class A common stock held by non-affiliates exceeds \$700 million as of the prior June 30.

We cannot predict if investors will find our Class A common stock less attractive because we rely on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

Our internal controls over financial reporting may not be effective and our independent registered public accounting firm may not be able to certify as to their effectiveness, which could have a significant and adverse effect on our business and reputation.

As a public company, we are required to comply with the SEC's rules implementing Sections 302 and 404 of Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. To comply with the requirements of being a public company, we are required to provide management's assessment on internal controls, and we may need to undertake various actions, such as implementing additional internal controls and procedures and hiring additional accounting or internal audit staff. Further, as an emerging growth company, our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 until the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm may issue a report that is adverse in the event that it is not satisfied with the level at which the controls of the company are documented, designed or operating.

Testing and maintaining these controls can divert our management's attention from other matters that are important to the operation of our business. If we identify material weaknesses in the internal control over financial reporting of the company or are unable to comply with the requirements of Section 404 or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting when we no longer qualify as an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our Class A common stock could be negatively affected, and we could become subject to investigations by the SEC or other regulatory authorities, which could require additional financial and management resources.

Our Charter designates the Court of Chancery of the State of Delaware and federal court within the State of Delaware as the exclusive forum for certain types of actions and proceedings that our stockholders may initiate, which could limit a stockholder's ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Charter designates the Court of Chancery of the State of Delaware and federal court within the State of Delaware as the exclusive forum for certain types of actions and proceedings that our stockholders may initiate, which could limit a stockholder's ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Charter provides that, subject to limited exceptions, the Court of Chancery of the State of Delaware and federal court within the State of Delaware will be exclusive forums for any:

- · derivative action or proceeding brought on our behalf;
- action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our directors, officers, stockholders, employees or agents to us or our stockholders;



- action asserting a claim against the us or any of our directors, officers, stockholders, employees or agents arising pursuant to any provision of the General Corporation Law, our Charter or our Restated Bylaws or as to which the General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware:
- action to interpret, apply, enforce or determine the validity of our Charter or our Bylaws; or
- other action asserting a claim against us or any of our directors, officers, stockholders, employees or agents that is governed by the internal affairs doctrine.

This choice of forum provision does not apply to actions brought to enforce a duty or liability created under the Exchange Act or any other claim for which federal courts have jurisdiction. Furthermore, in accordance with our Bylaws, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be, to the fullest extent permitted by law, the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provision in our Bylaws and the choice of forum provision in our Charter.

These provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our Charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

The stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the choice of forum provision. These provisions may limit a stockholders' ability to bring a claim, and may result in increased costs for a stockholder to bring a claim in a judicial forum of their choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees.

Risks Related to Our Common Stock and Warrants

We may amend the terms of the public warrants in a manner that may be adverse to holders with the approval by the holders of at least 50% of the thenoutstanding public warrants. As a result, the exercise price of a holder's public warrants could be increased, the exercise period could be shortened and the number of shares of our common stock purchasable upon exercise of a public warrant could be decreased, all without the approval of that warrant holder.

Our public warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and us. The warrant agreement provides that the terms of the public warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval by the holders of at least 50% of the then-outstanding public warrants to make any change that adversely affects the interests of the registered holders. Accordingly, we may amend the terms of the public warrants in a manner adverse to a holder if holders of at least 50% of the then-outstanding public warrants approve of such amendment. Although our ability to amend the terms of the public warrants with the consent of at least 50% of the then-outstanding public warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the public warrants, convert the warrants into cash or stock, shorten the exercise period or decrease the number of shares of common stock purchasable upon exercise of a public warrant.

We may redeem unexpired public warrants prior to their exercise at a time that is disadvantageous to warrant holders, thereby making their public warrants worthless.

We have the ability to redeem outstanding public warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.01 per public warrant; provided that the last reported sales price of our common stock equals or exceeds \$18.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading-day period ending on the third trading day prior to the date on which we give notice of such redemption to the warrant holders. If and when the public warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. We will use our best efforts to register or qualify such shares of common stock under the blue sky laws of



the state of residence in those states in which the warrants were offered by us. Redemption of the outstanding public warrants could force the warrant holders: (i) to exercise their public warrants and pay the exercise price therefor at a time when it may be disadvantageous for them to do so; (ii) to sell their public warrants at the then-current market price when they might otherwise wish to hold their public warrants; or (iii) to accept the nominal redemption price which, at the time the outstanding public warrants are called for redemption, is likely to be substantially less than the market value of their public warrants. None of the private placement warrants will be redeemable by us so long as they are held by CMLS Holdings LLC, or the Former Sponsor, or its permitted transferees.

Our warrants are exercisable for our Class A common stock, which will increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

As of March 31, 2022, our public warrants are exercisable for 14,758,305 shares of Class A common stock at \$11.50 per share. Our private warrants are exercisable for 7,236,667 shares of Class A common stock at \$11.50 per share. The additional shares of our Class A common stock issuable upon exercise of our warrants will result in dilution to the then existing holders of our Class A common stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of our Class A common stock.

Our warrants are accounted for as liabilities and the changes in value of our warrants could have a material effect on our financial results.

Included on our balance sheet as of March 31, 2022 are derivative liabilities related to our warrants. Accounting Standards Codification 815, Derivatives and Hedging ("ASC 815"), provides for the remeasurement of the fair value of such derivatives at each balance sheet date, with a resulting non-cash gain or loss related to the change in the fair value being recognized in earnings in the statement of operations. As a result of the recurring fair value measurement, our financial statements and results of operations may fluctuate quarterly, based on factors, which are outside of our control. Due to the recurring fair value measurement, we expect that we will recognize non-cash gains or losses on our warrants each reporting period and that the amount of such gains or losses could be material.

Future resales of our Class A common stock could cause the market price of our Class A common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our Class A common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our Class A common stock.

We had outstanding 377,249,186 shares of Class A common stock as of April 30, 2022. We have filed a registration statement which registers the offer and sale from time to time by certain selling stockholders of up to 160,864,198 shares of our Class A common stock, although the 110,864,198 shares registered on behalf of OPKO pursuant to this registration statement will be subject to transfer restrictions pursuant to the shareholder agreements that were entered into in connection with the Acquisition. In addition, we have filed a separate registration statement that the registers the offer and sale from time to time by certain selling security holders of up to an additional 229,657,978 shares of our Class A common stock. Furthermore, beginning on July 29, 2022, Rule 144 will become available for the resale of any shares that are restricted or control securities, subject to volume and other restrictions as applicable under Rule 144. To the extent shares are sold into the market pursuant to this prospectus, under Rule 144 or otherwise, particularly in substantial quantities and including following the end of the transfer restrictions provided for in the shareholder agreements in the case of OPKO and the other holders party such shareholder agreements, the market price of our Class A common stock could decline.

There is no guarantee that the public warrants will ever be in the money, and they may expire worthless and the terms of our public warrants may be amended.

The exercise price for the public warrants is \$11.50 per share of Class A common stock. There is no guarantee that the public warrants will ever be in the money prior to their expiration, and as such, the public warrants may expire worthless.



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

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

The following exhibits are filed as part of, or incorporated by reference into this Quarterly Report.

No.	Description of Exhibit	Form	Exhibit	Filing Date	Filed Herewith
2.1+	Agreement and Plan of Merger and Reorganization, dated as of January 14, 2022, by and among, Orion Merger Sub I, Inc., Orion Merger Sub II, LLC, GeneDx, Inc., GeneDx Holding 2, Inc. and OPKO Health, Inc.	8-K	2.1	01/18/2022	
3.1	Third Amended and Restated Certificate of Incorporation of Sema4 Holdings Corp.	8-K	3.1	07/28/2021	
3.2	Restated Bylaws of Sema4 Holdings Corp.	8-K	3.2	07/28/2021	
10.1	Form of Subscription Agreement.	8-K	10.1	01/18/2022	
10.2	Form of Shareholder Agreement.	8-K	10.2	01/18/2022	
10.3	Form of Support Agreement.	8-K	10.3	01/18/2022	
10.4	Form of Lock-Up Agreement.	8-K	10.4	01/18/2022	
10.5	Separation Agreement with James Coffin dated as of January 25, 2022.	8-K	10.1	01/31/2022	
10.6	Executive Chairman Agreement, dated as of January 17, 2022, by and between the Company and Jason Ryan.	10-K	10.31	03/14/2022	
31.1*	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				Х
31.2*	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				Х
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				Х
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				Х
101.INS	XBRL Instance Document				Х
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				Х
101.SCH	XBRL Taxonomy Extension Schema Document				Х
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				Х
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document				Х
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				Х
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.)				Х

- * Filed herewith.
- ** Furnished.
- + Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Company agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

Signatures

Pursuant to the requirements of 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 12, 2022

Date: May 12, 2022

SEMA4 HOLDINGS CORP.

	/s/ Katherine Stueland
Name:	Katherine Stueland
Title:	Chief Executive Officer and Director (Principal Executive Officer)
	/s/ Isaac Ro
Name:	Isaac Ro

Chief Financial Officer (Principal Financial Officer)

95

Title: