UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 June 30, 2021

OR

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

For the transition period from

Commission File Number: 001-40047

Talis Biomedical Corporation

(Exact Name of Registrant as Specified in its Charter)

Delaware (State or other jurisdiction of incorporation or organization)	**46-3122255** (I.R.S. Employer Identification No.)
230 Constitution Drive Menlo Park, California 94025 (Address of principal executive officers)	**94025** (Zip Code)

Registrant's telephone number, including area code:
(650) 433-3000

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	TLIS	The Nasdaq Stock Market LLC

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

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

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

As of August 6, 2021, there were 55,554,597 shares of the Registrant's common stock and preferred stock outstanding, consisting of 25,690,923 shares of common stock and 29,863,674 shares of Series 1 convertible preferred stock, which is a voting common stock equivalent, subject to certain limitations.

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Special note regarding forward-looking statements

This Quarterly Report on Form 10-Q (this Quarterly Report) contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Risk factors,” and “Management’s discussion and analysis of financial condition and results of operations.” These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our expectations regarding our revenue, expenses and other operating results;
- the timing or outcome of any of our domestic and international regulatory submissions;
- our expectations of the reliability, accuracy and performance of our products and services, as well as expectations of the benefits to patients, clinicians and providers of our products and services;
- future investments in our business, our anticipated capital expenditures and our estimates regarding our capital requirements, future revenues, expenses, reimbursement rates and needs for additional financing;
- impact from future regulatory, judicial, and legislative changes or developments in the United States and foreign countries;
- our ability to establish a sales force and acquire customers;
- our expectations regarding our sales models;
- the costs and success of our marketing efforts, and our ability to promote our brand;
- our ability to increase demand for our products and services, obtain favorable coverage and reimbursement determinations from third-party payers and expand geographically;
- our efforts to successfully develop and commercialize our products and services, including our ability to successfully conduct clinical trials;
- our ability to successfully develop additional revenue opportunities and expand our product and service offerings, including our recently launched offerings;
- the performance of our third-party suppliers and manufacturers;
- our ability to effectively manage our growth, including our ability to retain and recruit personnel, and maintain our culture;
- our ability to compete effectively with existing competitors and new market entrants;
- the impact on our business of economic or political events or trends;
- the size and growth potential of the markets for our products and services, and our ability to serve those markets; and
- the rate and degree of market acceptance of our products and services.

In some cases, you can identify these statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expects,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. These forward-looking statements reflect our management’s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Quarterly Report and are subject to risks and uncertainties. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. We discuss many of the risks associated with the forward-looking statements in this Quarterly Report in greater detail under the heading “Risk factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. You should carefully read this Quarterly Report and the documents that we reference in this Quarterly Report and have filed as exhibits to the registration statement, of which this Quarterly Report is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this Quarterly Report by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

Summary of Risk Factors

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under "Risk Factors" in Part II, Item 1A of this Quarterly Report. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should carefully consider the risks and uncertainties described under "Risk Factors" in Part II, Item 1A of this Quarterly Report as part of your evaluation of an investment in our common stock.

- There can be no assurance that the COVID-19 test we are developing for the detection of the SARS-CoV-2 virus will be granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA). If no EUA is granted or, once granted, it is revoked or the emergency declaration is terminated, we will be unable to sell this product in the near future and will be required to pursue 510(k) clearance or other marketing authorization, which would likely be a lengthy and expensive process.
- We may not be able to obtain marketing authorization for our Talis One system or for any test.
- We contract with a significant number of third parties for the manufacturing and supply of products, which supply may become limited or interrupted or may not be of satisfactory quality and quantity.
- We have no products approved for commercial sale. We have no or limited experience in developing, marketing and commercializing diagnostic platforms and tests, and we are continuing to evaluate the sales model for the Talis One system which may make it difficult to evaluate the success of our business and to assess our future viability.
- The COVID-19 pandemic could materially adversely affect our business, financial condition and results of operations.
- If our products do not perform as expected, including due to errors, defects or reliability issues, our reputation and market acceptance of our products could be harmed, and our operating results, reputation and business will suffer.
- We may be unable to manage our growth effectively, which could make it difficult to execute our business strategy.
- We may rely on a small number of customers for a significant portion of our revenue, which may materially adversely affect our financial condition and results of operations.
- Our commercial success could be compromised if our customers do not receive coverage and adequate reimbursement for our products, if approved.
- Modifications to our marketed products may require new EUAs, 510(k) clearances, pre-market approvals, or other marketing authorizations, or may require us to cease marketing or recall the modified products until clearances, approvals or other marketing authorizations are obtained. If we are not able to obtain, maintain, defend or enforce patent and other intellectual property protection for products, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.
- Some of our intellectual property has been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies, and compliance with such regulations may limit our exclusive rights and our ability to contract with non-U.S. manufacturers.
- We have incurred significant losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future, which could harm our future business prospects.
- We may need to raise additional capital to fund our existing operations, further develop our diagnostic platform, commercialize new products and expand our operations.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Talis Biomedical Corporation
Condensed Balance Sheets
(in thousands, except for shares and par value)

	June 30, 2021 (unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 313,458	$ 138,483
Restricted cash	34,650	34,650
Grants receivable	—	238
Unbilled grants receivable	117	233
Prepaid research and development expenses	2,431	12,014
Prepaid expenses and other current assets	3,209	3,106
Total current assets	353,865	188,724
Property and equipment, net	10,178	9,114
Operating lease right-of-use-assets	13,747	567
Other long-term assets	1,748	—
Total assets	$ 379,538	$ 198,405
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 11,695	$ 4,906
Accrued compensation	5,291	2,738
Accrued liabilities	54,761	7,694
Operating lease liabilities, current portion	882	693
Total current liabilities	72,629	16,031
Operating lease liabilities, long-term portion	13,177	—
Total liabilities	$ 85,806	$ 16,031
Commitments and contingencies (Note 6)		
Convertible preferred stock, $0.0001 par value—no shares authorized as of June 30, 2021 and 229,296,908 shares authorized as of December 31, 2020; no shares issued and outstanding as of June 30, 2021 and 53,509,351 shares issued and outstanding as of December 31, 2020; no aggregate liquidation preference of as of June 30, 2021 and $475,617 as of December 31, 2020	—	290,945
Stockholders' equity (deficit):		
Series 1 convertible preferred stock, $0.0001 par value—60,000,000 and 57,324,227 shares authorized as of June 30, 2021 and December 31, 2020, respectively; 29,863,674 and no Series 1 convertible preferred stock issued and outstanding as of June 30, 2021 and December 31, 2020, respectively; aggregate liquidation preference of $3 as of June 30, 2021 and none as of December 31, 2020	3	—
Common stock, $0.0001 par value; 200,000,000 and 230,000,000 shares authorized at June 30, 2021 and December 31, 2020, respectively; 25,690,373 and 2,126,254 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	2	—
Additional paid-in capital	591,597	64,335
Accumulated deficit	(297,870)	(172,906)
Total stockholders' equity (deficit)	293,732	(108,571)
Total liabilities, convertible preferred stock and stockholders' equity	$ 379,538	$ 198,405

See accompanying notes to the unaudited condensed financial statements

Talis Biomedical Corporation
Condensed Statements of Operations and Comprehensive Loss (Unaudited)
(in thousands, except for share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Grant revenue	$ 117	$ 820	$ 7,117	$ 1,219
Operating expenses:				
Research and development	54,495	8,184	114,688	13,898
Selling, general and administrative	9,983	2,660	17,310	4,740
Total operating expenses	64,478	10,844	131,998	18,638
Loss from operations	(64,361)	(10,024)	(124,881)	(17,419)
Other expense, net	(111)	(22)	(83)	(1)
Net loss and comprehensive loss	$ (64,472)	$ (10,046)	$ (124,964)	$ (17,420)
Net loss per share, basic and diluted	$ (2.51)	$ (4.75)	$ (6.44)	$ (8.23)
Weighted average shares used in the calculation of net loss per share, basic and diluted	25,648,151	2,116,623	19,414,066	2,116,437

See accompanying notes to the unaudited condensed financial statements

Talis Biomedical Corporation
Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) (Unaudited)
(in thousands, except for share amounts)

	Convertible Preferred Stock		Series 1 Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Value	Shares	Value	Shares	Value			
Balance at December 31, 2020	53,509,351	$ 290,945	—	—	2,126,254	$ —	$ 64,335	$ (172,906)	$ (108,571)
Issuance of Common Stock upon exercise of stock options	—	—	—	—	85,895	—	131	—	131
Issuance of Common Stock upon initial public offering, net of issuance costs of $21,349	—	—	—	—	15,870,000	2	232,546	—	232,548
Conversion of convertible preferred stock into common stock and Series 1 convertible preferred stock upon initial public offering	(53,509,351)	(290,945)	29,863,674	3	7,555,432	—	290,942	—	290,945
Stock-based compensation expense	—	—	—	—	—	—	1,772	—	1,772
Net loss	—	—	—	—	—	—	—	(60,492)	(60,492)
Balance at March 31, 2021	—	$ —	29,863,674	$ 3	25,637,581	$ 2	$ 589,726	$ (233,398)	$ 356,333
Issuance of Common Stock upon exercise of stock options	—	—	—	—	52,792	—	80	—	80
Stock-based compensation expense	—	—	—	—	—	—	1,791	—	1,791
Net loss	—	—	—	—	—	—	—	(64,472)	(64,472)
Balance at June 30, 2021	—	$ —	29,863,674	$ 3	25,690,373	$ 2	$ 591,597	$ (297,870)	$ 293,732

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Deficit
	Shares	Value	Shares	Value			
Balance at December 31, 2019	37,871,430	$ 42,755	2,115,583	$ —	$ 60,636	$ (81,776)	$ (21,140)
Issuance of Common Stock upon exercise of stock options	—	—	483	—	5	—	5
Stock-based compensation expense	—	—	—	—	681	—	681
Net loss	—	—	—	—	—	(7,374)	(7,374)
Balance at March 31, 2020	37,871,430	$ 42,755	2,116,066	$ —	$ 61,322	$ (89,150)	$ (27,828)
Issuance of Common Stock upon exercise of stock options	—	—	2,557	—	1		1
Proceeds from second tranche of Series C-1 convertible preferred stock, net of issuance costs of $24	—	18,333	—	—	—	—	—
Proceeds from second tranche of Series D-1 convertible preferred stock, net of issuance costs of $3	—	1,884	—	—	—	—	—
Proceeds from second tranche of Series D-2 convertible preferred stock, net of issuance costs of $6	—	4,710	—	—	—	—	—
Cancellation of third tranche of Series C-1 convertible preferred stock	(9,314,766)	—	—	—	—	—	—
Cancellation of third tranche of Series D-1 convertible preferred stock	(955,666)	—	—	—	—	—	—
Cancellation of third tranche of Series D-2 convertible preferred stock	(2,387,171)	—	—	—	—	—	—
Issuance of Series E-1 convertible preferred stock, net of issuance costs of $48	513,746	3,831	—	—	—	—	—
Issuance of Series E-2 convertible preferred stock, net of issuance costs of $233	11,187,189	82,776	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	407	—	407
Net loss	—	—	—	—	—	(10,046)	(10,046)
Balance at June 30, 2020	36,914,762	$ 154,289	2,118,623	$ —	$ 61,730	$ (99,196)	$ (37,466)

See accompanying notes to the unaudited condensed financial statements

Talis Biomedical Corporation
Condensed Statements of Cash Flows (Unaudited)
(in thousands)

	Six Months Ended June 30,	
	2021	**2020**
Operating activities		
Net loss	$ (124,964)	$ (17,420)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,563	1,088
Depreciation and amortization	410	378
Non-cash lease expense	528	278
Changes in operating assets and liabilities:		
Unbilled grants receivable	116	1,213
Grants receivable	238	—
Prepaid expenses and other current assets	(103)	119
Prepaid research and development	9,583	(3,422)
Other long-term assets	(981)	(249)
Accounts payable	6,633	4,012
Accrued expenses and other liabilities	49,428	(3,141)
Lease liabilities	(346)	(391)
Net cash used in operating activities	$ (55,895)	$ (17,535)
Investing activities		
Purchase of property and equipment	(1,120)	(337)
Net cash used in investing activities	$ (1,120)	$ (337)
Financing activities		
Proceeds from initial public offering, net of issuance costs	232,546	—
Proceeds from stock option exercises	211	6
Proceeds from the issuance of preferred stock, net of issuance costs	—	111,534
Net cash provided by financing activities	$ 232,757	$ 111,540
Net increase in cash, cash equivalents and restricted cash	175,742	93,668
Cash, cash equivalents and restricted cash at beginning of period	173,133	21,604
Cash, cash equivalents and restricted cash at end of period	$ 348,875	$ 115,272
Supplemental disclosure of noncash investing and financing activities		
Property and equipment purchases included in accounts payable and accrued expenses	$ 354	$ 301
Right-of-use assets obtained in exchange for operating lease liabilities	$ 13,499	$ 743
Remeasurement of operating lease right-of-use asset for lease modification	$ 208	$ 417

The following table provides a reconciliation of the cash and restricted cash balances as of each of the periods shown above:

	Six Months Ended June 30,	
	2021	**2020**
Cash and cash equivalents	$ 313,458	$ 115,272
Restricted cash	34,650	—
Restricted cash equivalent - other long-term assets	767	—
Total cash, cash equivalents and restricted cash	$ 348,875	$ 115,272

See accompanying notes to the unaudited condensed financial statements

1. Organization and nature of business

Talis Biomedical Corporation (the Company) is a molecular diagnostic company focused on transforming diagnostic testing through innovative molecular diagnostic products that enable customers to deploy accurate, reliable, low cost and rapid point-of-care testing for infectious diseases and other conditions. The Company was incorporated in 2013 under the general laws of the State of Delaware and is based in Menlo Park, California (CA) and Chicago, Illinois (IL).

Initial Public Offering and Reverse Stock Split

In February 2021, the Company amended and restated its amended and restated certificate of incorporation to effect a 1-for-1.43 reverse split (2021 Reverse Split) of shares of the Company's common stock. The par value and authorized shares of common stock were not adjusted as a result of the 2021 Reverse Split. Shares of the Company's convertible preferred stock were not subject to the 2021 Reverse Split but have been converted at the same rate as the reverse split. All of the share and per share information included in the accompanying condensed financial statements has been retroactively adjusted to reflect the 2021 Reverse Split.

In February 2021, the Company completed an initial public offering (IPO) in which the Company issued and sold 13,800,000 shares of common stock at a public offering price of $16.00 per share, with an additional 2,070,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares. The aggregate proceeds received by the Company from the IPO was $232.5 million after deducting underwriting discounts, commissions and offering expenses of approximately $21.3 million. Upon the closing of the IPO, convertible preferred stock held by Baker Bros. Advisors LP, a related party, and its affiliates, were converted into 29,863,674 Series 1 convertible preferred stock. The remaining outstanding convertible preferred stock were converted into 7,555,432 shares of common stock.

Liquidity

The Company has incurred significant losses and negative cash flows since inception, including net losses of $125.0 million for the six months ended June 30, 2021. As of June 30, 2021, the Company had unrestricted cash and cash equivalents of $313.5 million and $35.4 million of restricted cash. In July 2021, the Company paid $29.6 million to a contract manufacturing organization and was relieved of the standby letter of credit (LOC), releasing $34.7 million of collateral (see Note 11).

Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities. The Company's activities are subject to significant risks and uncertainties, including failing to secure additional funding to continue to operationalize the Company's current technology and to advance the development of its products. The Company expects its existing unrestricted cash and cash equivalents as of June 30, 2021 will be sufficient to fund its operations through at least one year from the date these condensed financial statements are issued. The Company expects to finance its future operations with its existing restricted and unrestricted cash and through strategic financing opportunities that could include, but are not limited to, future offerings of its equity, grant agreements, or the incurrence of debt. However, there is no guarantee that any of these strategic or financing opportunities will be executed or realized on favorable terms, if at all, and some could be dilutive to existing stockholders. The Company's ability to raise additional capital through either the issuance of equity or debt, is dependent on a number of factors including, but not limited to, the demand for the Company, which itself is subject to a number of development and business risks and uncertainties, as well as the uncertainty that the Company would be able to raise such additional capital at a price or on terms that are favorable to the Company.

2. Summary of significant accounting policies

Basis of presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for interim financial reporting. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. These unaudited condensed financial statements include all adjustments necessary to fairly state the financial position and the results of our operations and cash flows for interim periods in accordance with GAAP. All such adjustments are of a normal, recurring nature. The results for any interim period are not necessarily indicative of the results that may be expected for the year ending December 31, 2021 or for any future period.

The condensed balance sheet presented as of December 31, 2020, has been derived from the audited financial statements as of that date. The condensed financial statements and notes are presented do not contain all information that is included in the annual financial

statements and notes thereto of the Company. The condensed financial statements and notes included in this report should be read in conjunction with the financial statements and notes included in the Company's 2020 Annual Report on Form 10-K filed with the SEC.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. These estimates form the basis for judgments the Company makes about the carrying values of assets and liabilities that are not readily apparent from other sources. The Company bases its estimates and judgments on historical experience and on various other assumptions that the Company believes are reasonable under the circumstances. These estimates are based on management's knowledge about current events and expectations about actions the Company may undertake in the future. Significant estimates include, but are not limited to, recovery of long-lived assets, stock-based compensation expense, research and development accruals, the measurement of right-of-use assets and lease liabilities, uncertain tax positions, and the fair value of common stock prior to the Company's IPO. Actual results could vary from the amounts derived from management's estimates and assumptions.

Reclassifications

The accompanying condensed balance sheet as of June 30, 2021 and December 31, 2020 reflects the Company's reclassification of accrued compensation out of accrued expenses and other liabilities to conform with current year presentation.

Cash and cash equivalents

The Company considers cash equivalents to be highly liquid investments with an original maturity at purchase of three months or less. These cash equivalents include holdings in money market funds that are invested in U.S. Treasury obligations which are stated at fair value. Prior to April 1, 2021, the Company only carried cash on its condensed balance sheets.

Deferred initial public offering costs

The Company capitalizes certain direct incremental legal, consulting, banking, and accounting fees primarily relating to the Company's IPO. After consummation of the IPO, which closed on February 17, 2021, these costs were recorded in stockholders' equity as a reduction of additional paid-in capital. As of December 31, 2020, the Company recorded deferred offering costs of $2.4 million recorded within other current assets on the balance sheet.

Restricted cash

Restricted cash consists of cash that serves as collateral for the Company's standby letters of credit (see Note 6). Any cash that is legally restricted from use is classified as restricted cash. If the purpose of restricted cash relates to acquiring a long-term asset, liquidating a long-term liability, or is otherwise unavailable for a period longer than one year from the balance sheet date, the restricted cash is classified as a long-term asset, otherwise, restricted cash is included in current assets in the balance sheet.

Concentration of credit risk and other risks and uncertainties

Financial instruments which potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, restricted cash, and grant receivables. The Company's cash is deposited in accounts at large financial institutions and its cash equivalents are primarily held in prime and United States government money market funds. The Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash is held and government grant funded nature of the Company's grant receivables.

The Company is subject to risks common to companies in the diagnostics industry including, but not limited to, uncertainties related to commercialization of products, regulatory approvals, and protection of intellectual property rights.

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 coronavirus has spread globally. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The COVID-19 pandemic has and may continue to impact the Company's third-party manufacturers and suppliers, which could disrupt its supply chain or the availability or cost of materials. The effects of the public health directives and the Company's work-from-home policies may negatively impact productivity, disrupt its business and delay clinical programs and timelines and future clinical trials, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on the Company's ability to conduct business in the ordinary course. These and similar, and perhaps more severe, disruptions in the Company's operations could negatively impact business, results of operations and financial condition, including its ability to obtain financing. To date, the Company has not incurred impairment losses in the carrying values of its assets as a result of the pandemic and is not aware of any specific related event or circumstance that would require the Company to revise its estimates reflected in these condensed financial statements.

The Company has developed its COVID-19 test in direct response to the pandemic and has been awarded a contract from the NIH for Phase 2 of its Rapid Acceleration of Diagnostics (RADx) initiative. These developments may mitigate risks that could affect the Company's ability to complete its clinical trials in a timely manner, delay the initiation and/or enrollment of any future clinical trials, disrupt regulatory activities or have other adverse effects on its business and operations.

The Company cannot be certain what the overall impact of the COVID-19 pandemic will be on its business and prospects. The extent to which the COVID-19 pandemic will further directly or indirectly impact its business, results of operations, financial condition and liquidity, including planned and future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, the actions taken to contain or treat it, and the duration and intensity of the related effects. In addition, the Company could see some limitations on employee resources that would otherwise be focused on its operation, including but not limited to sickness of employees or their families, the desire of employees to avoid contact with large groups of people, and increased reliance on working from home. If the financial markets and/or the overall economy are impacted for an extended period, the Company's business, financial condition, results of operations and prospects may be adversely affected.

Income taxes

On March 11, 2021, the President signed the American Rescue Plan Act of 2021 (ARPA) into law. ARPA includes several provisions, such as measures that extend and expand the employee retention credit, previously enacted under the Coronavirus Aid, Relief and Economic Security Act (CARES Act), through December 31, 2021. The enactment of ARPA did not have a material impact on our condensed financial statements.

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses include certain payroll and personnel expenses, laboratory supplies, consulting costs, external contract research and development expenses, allocated overhead and facility occupancy costs. Costs to develop the Company's technologies, including software, are recorded as research and development expense except for costs that meet the criteria to be capitalized as internal-use software costs.

The Company does not capitalize pre-launch inventory costs until future commercialization is considered probable and the future economic benefit is expected to be realized. Capitalizing pre-launch inventory costs will not occur prior to obtaining an Emergency Use Authorization (EUA) or other U.S Food and Drug Administration (FDA) marketing authorization unless the regulatory review process has progressed to a point that objective and persuasive evidence of regulatory approval is sufficiently probable, and future economic benefit can be asserted. The Company records such costs as research and development expenses, or if used in marketing evaluations records such costs as selling, general and administrative expenses.

In 2020, the Company began developing production lines to automate the production of its Talis One cartridges for the COVID-19 assay with the intention to scale-up its manufacturing capabilities to meet the high demand expected in response to the COVID-19 pandemic. Approximately $92.8 million of the high capacity production equipment acquired as part of the Company's effort to scale-up its manufacturing capacity, is highly specialized for the manufacturing of the Company's Talis One cartridges and was determined not to have an alternative future use, of which $51.9 million had been incurred in the six months ended June 30, 2021. All materials, equipment, and external consulting costs associated with developing aspects of the production line that do not have an alternative future use are expensed as research and development costs until regulatory approval is obtained. Materials, equipment, and external consulting costs associated with developing aspects of the production line that are deemed to have an alternative future use are capitalized as property and equipment, assessed for impairment and depreciated over their related useful lives. These research and development costs, including expenditures for property and equipment with no alternative future use, are classified as operating cash outflows within the Company's statements of cash flows.

The Company makes estimates of its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances at that time. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments if necessary. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to the Company's prior estimates of accrued research and development expenses.

Convertible preferred stock

The Company records convertible preferred stock at fair value on the dates of issuance, net of issuance costs. The Company has classified its historical convertible preferred stock, which are redeemable, as temporary equity in the accompanying balance sheets due to terms that allow for redemption of the shares into the Company's common stock. The Company has classified Series 1 convertible preferred stock and Series 2 non-voting convertible preferred stock as permanent equity in the accompanying condensed balance sheets, as they meet the criteria for permanent equity classification and the liquidation value is de minimis. The Company also

evaluates the features of its convertible preferred stock to determine if the features require bifurcation from the underlying shares by evaluating if they are clearly and closely related to the underlying shares and if they do, or do not, meet the definition of a derivative.

Net loss per share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration of potential dilutive securities. The convertible preferred stock are participating securities but because they do not have the obligation to share in the loss of the Company, are excluded from the calculation of basic earnings per share. Stock options, convertible preferred stock, and shares estimated to be purchased under the Company's employee stock purchase plan (ESPP) are considered potentially dilutive common stock. The Company computes diluted net loss per share after giving consideration to all potentially dilutive common stock outstanding during the period, determined using the treasury-stock and if-converted methods, except where the effect of including such securities would be antidilutive.

For the three and six month period ended June 30, 2021 and 2020, the Company reported a net loss. The potentially dilutive common stock would have been anti-dilutive and therefore basic and diluted loss per share attributable to common stockholders were the same.

Comprehensive loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company did not have any other comprehensive income or loss for either period presented, and therefore comprehensive loss was the same as the Company's net loss.

New accounting pronouncements

Recently adopted accounting standards

In August 2020, the FASB issued Accounting Standards Update No. 2020-06 (ASU 2020-06) *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)*. ASU 2020-06 removes certain bifurcation models for convertible debt instruments and convertible preferred stock. ASU 2020-06 eliminates certain models that require separate accounting for embedded conversion features, in certain cases. In addition, the amendments expand disclosure requirements for convertible instruments and simplify areas of the guidance for diluted earnings-per-share calculations that are impacted by the amendments. For public business entities, the guidance is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The guidance is to be applied using either a full retrospective or modified retrospective method. The Company early adopted ASU 2020-06 on January 1, 2021 under the modified retrospective approach, with no impact on its financial position, results of operations or cash flows.

Accounting standards issued but not yet adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses* (ASU 2016-13) to require the measurement of expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. As a result of the Company having elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the Jumpstart Our Business Startups Act of 2021 (JOBS Act), and assuming the Company continues to be considered an emerging growth company, ASU 2016-13 will be effective for the Company on January 1, 2023. The Company has not yet determined the potential effects of ASU 2016-13 on its financial statements and disclosures.

In May 2021, the FASB issued ASU 2021-04, *Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options* (ASU 2021-04), which requires issuers to account for a modification or exchange of freestanding equity-classified written call options that remain equity classified after the modification or exchange based on the economic substance of the modification or exchange. Specifically, under ASU 2021-04, an issuer determines the accounting for the modification or exchange based on whether the transaction was done to issue equity, issue and or modify debt, or for other reasons. The result is a change in the fair value of the written call option dependent on the reason for the modification. ASU 2021-04 is effective for interim and annual periods beginning after December 15, 2021, with early adoption permitted. Adoption of ASU 2021-04 can be applied on a prospective basis. The Company has not yet determined the potential effects of ASU 2021-04 on its financial statements and disclosures.

3. Fair value measurement

The Company determine the fair value of an asset or liability based on the assumptions that market participants would use in pricing the asset or liability in an orderly transaction between market participants at the measurement date. The identification of market participant assumptions provides a basis for determining what inputs are to be used for pricing each asset or liability. A fair value

hierarchy has been established which gives precedence to fair value measurements calculated using observable inputs over those using unobservable inputs. This hierarchy prioritizes the inputs into three broad levels as follows:

- Level 1: Quoted prices in active markets for identical instruments
- Level 2: Other significant observable inputs (including quoted prices in active markets for similar instruments)
- Level 3: Significant unobservable inputs (including assumptions in determining the fair value of certain investments)

Financial assets carried at fair value and measured on a recurring basis as of June 30, 2021 are classified in the hierarchy as follows (in thousands):

	June 30, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents (money market funds)	$ 275,018	$ —	$ —	$ 275,018
Total assets measured at fair value	$ 275,018	$ —	$ —	$ 275,018

There were no assets or liabilities measured at fair value as of December 31, 2020.

There were no transfers of assets or liabilities between Level 1, Level 2, and Level 3 categories of the fair value hierarchy during the six months ended June 30, 2021. Cash equivalents consistent of funds held in money market accounts that are valued using quoted prices in active markets for identical instruments.

4. Balance sheet components

Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Accrued research and development costs	$ 53,664	$ 6,360
Professional fees	388	608
Other liabilities	709	726
	$ 54,761	$ 7,694

Due to the delayed submission of the Company's EUA for the Talis One system for COVID-19, the Company determined that certain components procured, or expected to be procured, and other costs for the Talis One system will be in excess of expected demand or usage. Although the Company will be taking steps to minimize the adverse impact on the Company's business, based on information available as of June 30, 2021, the Company had accrued $3.6 million within accrued research and development costs on the condensed balance sheet and within research and development expenses on the condensed statement of operations and comprehensive loss for modifying one of the agreements with its suppliers.

5. Grant revenue and receivables

NIH Rapid Acceleration of Diagnostics - Advanced Technology Platforms (RADx) Initiative contracts

During the six months ended June 30, 2021, the Company recognized as revenue, and received, $7.0 million in relation to the RADx initiative. The Company received $1.2 million relating to completing the second stage of the contract and $5.8 million relating to completing the third stage of the contract during the six months ended June 30, 2021. There were no unbilled receivables recorded for this contract as of June 30, 2021 or December 31, 2020.

NIH grant

During the six months ended June 30, 2021, the Company recognized $0.1 million of revenue related to efforts incurred under its NIH grant for Diagnostics via Rapid Enrichment, Identification, and Phenotypic Antibiotic Susceptibility Testing of Pathogens from Blood project. This amount was included in unbilled receivables as of June 30, 2021.

During the six months ended June 30, 2020, the Company recognized $0.3 million, $0.6 million and $0.3 million of grant revenue related to efforts incurred under its RADx, NIH and CARB-X grants, respectively.

6. Commitments and contingencies

Operating leases

In January 2021 the Company entered a new operating lease for laboratory and office space in Chicago, IL. The Company received access to the premises and the lease commenced in May 2021. As of June 30, 2021, the Company had recorded a right-of-use asset and lease liability of $13.2 million. The lease is classified as an operating lease and will continue for an initial term of 11 years, with options to extend the term for two successive five-year periods after the initial expiration date. The Company's minimum commitment under the new lease is approximately $1.7 million annually with fixed escalations of 2.5% per annum.

In January 2021, the Company entered a new operating lease for laboratory and office space in Redwood City, CA. As of June 30, 2021, the Company did not have access to the space, concluded that the leasehold improvements were lessor owned and determined that the lease had not yet commenced for accounting purposes. The lease will continue for an initial term of 10.5 years, with options to extend the term for two successive five-year periods after the initial expiration date. The Company's minimum commitment under the new lease is approximately $2.6 million annually with fixed escalations of 3.0% per annum. The Company has included $1.0 million of security deposit to secure the lease within other long-term assets on the condensed balance sheet.

The components of the lease costs and supplemental cash flow information relating to the Company's leases were as follows (in thousands):

	Three Months Ended June 30,	Six Months Ended June 30,
Lease Costs	**2021**	**2021**
Operating lease costs	$ 478	$ 648
Variable lease costs	35	52
Total operating lease costs	$ 513	$ 700
Cash Flows		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows used for operating leases	$ 261	$ 466

Weighted-average remaining lease terms and discount rates were as follows:

	June 30, 2021
Weighted-average remaining lease term	10.4 years
Weighted-average discount rate	5.1%

The undiscounted future lease payments for operating leases as of June 30, 2021 were as follows (in thousands):

(in thousands)	Operating Leases
2021 (remainder)	$ 579
2022	1,125
2023	1,644
2024	1,684
2025	1,724
2026 and thereafter	12,102
Total future minimum lease payments	18,858
Less: imputed interest	(4,799)
Present value of operating lease liabilities	14,059
Less: current portion of lease liabilities	(882)
Noncurrent portion of lease liabilities	$ 13,177

Standby letter of credit

Between June 2020 and August 2020, the Company executed and amended a $33.0 million standby LOC with JPMorgan Chase (JPMC) as terms of collateral that were required by one of the Company's contract manufacturing organizations. The Company is required to maintain a cash balance of $34.7 million as collateral for the LOC for the term of the contract, which is for a period less than one year from the balance sheet date. The collateral for the LOC is classified as restricted cash on the condensed balance sheets as of June 30, 2021. In July 2021, the Company paid $29.6 million to the contract manufacturing organization and was relieved of the LOC, releasing all $34.7 million of collateral held by JPMC (see Note 11).

In conjunction with the Chicago laboratory lease entered into in January 2021, the Company is required to hold an additional LOC in the amount of $0.8 million to secure this lease through its expiration. The Company is required to maintain a cash balance of $0.8 million as collateral for the LOC, which is classified in other long-term assets on the condensed balance sheet as of June 30, 2021 because it is unavailable for a period longer than one year from the balance sheet date.

Neither LOC had been drawn upon through June 30, 2021.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, customers and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. The Company also provides indemnifications to directors and officers of the Company to the maximum extent permitted under applicable Delaware law. The maximum potential amount of future payments that the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

Unconditional purchase obligations

In the normal course of business, the Company enters into various firm purchase commitments. As of June 30, 2021, these commitments total approximately $64.1 million in aggregate and are primarily related to the build out of manufacturing capacity of $2.2 million and purchase of certain inventory related items of $61.9 million, all of which are expected to be incurred in 2021.

7. Convertible preferred stock and stockholders' equity (deficit)

Amended and Restated Certificate of Incorporation

Immediately prior to the closing of the Company's IPO in February 2021, the Company's Board of Directors approved and the Company filed its Amended and Restated Certificate of Incorporation, which authorized the issuance of up to 170,000,000 of convertible preferred stock with a par value of $0.0001 per share, of which 60,000,000 shares have been designated as Series 1 convertible preferred stock and 60,000,000 shares have been designated Series 2 non-voting convertible preferred stock.

Convertible preferred stock

The Company had an aggregate 53,509,351 shares of convertible preferred stock issued and outstanding as of December 31, 2020. Upon the closing of the IPO, 42,705,056 affiliated convertible preferred stock with a carrying value of $225.4 million were converted into 29,863,674 Series 1 convertible preferred stock. The remaining 10,804,295 outstanding convertible preferred stock were converted into 7,555,432 shares of common stock. As of June 30, 2021, there were no shares of Series 2 non-voting convertible preferred stock outstanding.

The Company's convertible preferred stock consisted of the following (in thousands, except share amounts):

June 30, 2021	Preferred authorized	Preferred shares issued and outstanding	Carrying Value	Liquidation Preference	Common shares issuable upon conversion
Series 1 convertible preferred stock	60,000,000	29,863,674	$ 225,383	$ 3	29,863,674
Series 2 non-voting convertible preferred stock	60,000,000	—	—	—	—
Undesignated	50,000,000	—	—	—	—
	170,000,000	29,863,674	$ 225,383	$ 3	29,863,674

December 31, 2020	Preferred authorized	Preferred shares issued and outstanding	Carrying Value	Liquidation Preference	Common shares issuable upon conversion
Series C-1 convertible preferred stock	13,404,197	13,404,197	$ 39,756	$ 105,041	9,373,556
Series C-2 convertible preferred stock	13,404,197	—	—	—	—
Series D-1 convertible preferred stock	11,809,630	1,437,178	3,561	5,631	1,005,013
Series D-2 convertible preferred stock	11,809,630	10,372,452	24,365	40,641	7,253,461
Series E-1 convertible preferred stock	13,477,088	2,289,899	16,943	24,319	1,601,316
Series E-2 convertible preferred stock	13,477,088	11,187,189	82,766	118,808	7,823,208
Series F-1 convertible preferred stock	18,633,312	4,859,897	38,496	59,420	3,398,514
Series F-2 convertible preferred stock	18,633,312	9,958,539	85,058	121,758	6,964,012
Series 1 convertible preferred stock	57,324,227	—	—	—	—
Series 2 non-voting convertible preferred stock	57,324,227	—	—	—	—
	229,296,908	53,509,351	$ 290,945	$ 475,617	37,419,080

The Series 1 convertible preferred stock and Series 2 non-voting convertible preferred stock have various rights, privileges and features. The Company determined that none of the features required bifurcation from the underlying shares, either because they are clearly and closely related to the underlying shares or because they do not meet the definition of a derivative. The rights, preferences, and privileges of the Company's Series 1 and Series 2 convertible preferred stock are as follows:

Voting

The holders of our Series 1 convertible preferred stock are entitled to one vote per share. Holders of shares of our common stock and Series 1 convertible preferred stock will vote together as a single class on all matters (including the election of directors) submitted to a vote of stockholders, subject to the limitations described above. The Series 1 convertible preferred stock does not have cumulative voting rights.

Holders of our Series 2 convertible preferred stock have no voting rights except as required by law or as set forth in our amended and restated certificate of incorporation.

Conversion

The Series 1 convertible preferred stock is convertible, at the election of the holder, into Series 2 convertible preferred stock on a one-for-one basis at any time following the third anniversary of the closing of the IPO. Shares of Series 1 convertible preferred stock automatically convert to common stock on a one-for-one basis at any time at the discretion of the holder, or upon any sale or transfer of such shares of Series 1 convertible preferred stock.

Conversion of the Series 2 convertible preferred stock is prohibited if the holder exceeds a specified threshold of voting security ownership. The Series 2 convertible preferred stock is convertible into common stock on a one-for-one basis, subject to adjustment for events such as stock splits, combinations and the like; provided that such holder shall not be entitled to convert the Series 2 convertible preferred in excess of that number of convertible preferred stock which upon giving effect or immediately prior to such conversion would cause the holder to exceed 4.99% ownership or voting power individually or in aggregate with its affiliated holders. The 4.99% can be increased to up to 19.99% by the holders of such shares with 61 days' notice to the Company. Shares of Series 2 convertible preferred stock automatically convert to common stock on a one-for-one basis upon any sale or transfer of such shares of Series 2 convertible preferred stock.

Dividends

The Series 1 convertible preferred stock and Series 2 non-voting convertible preferred stock have the right to receive dividends first or simultaneously with payment of dividends on common stock.

Liquidation preference

In the event of any liquidation or dissolution of the company, holders of the Series 1 convertible preferred stock and Series 2 non-voting convertible preferred stock are entitled to receive $0.0001 per share prior to the payment of any amount to any holders of our capital stock ranking junior to the Series 1 convertible preferred stock and Series 2 non-voting convertible preferred stock and thereafter shall participate on an as-if-converted-to-common-stock basis.

Protective provisions

Consent of the holders of a majority of the voting rights of the outstanding Series 1 convertible preferred stock and Series 2 non-voting convertible preferred stock is required for any amendment or change of the rights, preferences, privileges, or powers of, or the restrictions provided for the benefit of, the Series 1 convertible preferred stock and Series 2 non-voting convertible preferred stock.

Registration rights

In March 2021, the Company entered into a registration rights agreement (the Registration Rights Agreement) with Baker Brothers Life Sciences, L.P. and 667, L.P. (the Baker Funds), holders of the Company's Series 1 convertible preferred stock and related parties. The obligations of the Company regarding such registration rights include, but are not limited to, file a registration statement with the SEC for the registration of registrable securities, reasonable efforts to cause such registration statement to become effective, keep such registration statement effective for up to 30 days, prepare and file amendments and supplements to such registration statement and the prospectus used in connection with such registration statement, and notify each selling holder, promptly after the Company receives notice thereof, of the time when such registration statement has been declared effective or a supplement to any prospectus forming a part of such registration statement has been filed. The terms of the registration rights provide for the payment of certain expenses related to the registration of the shares, including a capped reimbursement of legal fees of a single special counsel for the holders of the shares, but do not impose any obligations for the Company to pay additional consideration to the holders in case a registration statement is not declared effective. Under the Registration Rights Agreement, the Baker Funds also have the right to one underwritten offering per calendar year, but no more than two underwritten offerings or block trades in any twelve month period, to effect the sale or distribution of their registrable securities, subject to specified exceptions, conditions and limitations. The Registration Rights Agreement also includes customary indemnification obligations in connection with registrations conducted pursuant to the Registration Rights Agreement.

Common stock

The Company's February 2021 Amended and Restated Certificate of Incorporation authorized the issuance of up 200,000,000 shares of common stock, each having a par value of $0.0001 and entitled to one vote per share.

In February 2021, the Company issued and sold 15,870,000 shares of the Company's common stock including 2,070,000 shares pursuant to the full exercise of the underwriter' option to purchase additional shares, at a public offering price of $16.00 per share, for aggregate net proceeds of $232.5 million after deducting underwriting discounts, commissions and offering expenses.

The Company has reserved the following shares of common stock for future issuances:

	As of June 30, 2021
Shares reserved for conversion of outstanding Series 1 convertible preferred stock	29,863,674
Shares reserved for options to purchase Common Stock under the 2013 Equity Incentive Plan	7,233,974
Shares reserved for options to purchase Common Stock under the 2021 Equity Incentive Plan	640,160
Shares reserved for issuance under the 2021 Equity Incentive Plan	4,966,770
Shares reserved for issuance under the 2021 Employee Stock Purchase Plan	550,000
Total	43,254,578

8. Stock-based compensation

2013 Equity Incentive Plan

The 2013 Equity Incentive Plan (2013 Plan) provides the Board the discretion to grant stock options and other equity-based awards to employees, directors, and consultants of the Company. The Board administers the 2013 Plan and has discretion to delegate some or all of the administration of the 2013 Plan to a committee or committees or an officer. To date, the Company has only granted Incentive Stock Options (ISOs) and Non-statutory Stock Options (NSOs) to employees, consultants, and directors. Following the completion of the Company's IPO no additional shares will be granted under the 2013 Plan. However, the 2013 Plan will continue to govern outstanding equity awards granted thereunder. To the extent outstanding options granted under the 2013 Plan are cancelled, forfeited or otherwise terminated without being exercised and would otherwise have been returned to the share reserve under the 2013 Plan, the number of shares underlying such awards will be available for future grant under the 2021 Equity Incentive Plan. As of June 30, 2021, there were 7,233,974 shares of common stock reserved by the Company for options to purchase common stock under the 2013 Plan and no shares of common stock remained available for future grants.

2021 Equity Incentive Plan

In February 2021, the Company's Board of Directors adopted our 2021 Equity Incentive Plan (2021 Plan), and our stockholders approved our 2021 Plan. Our 2021 Plan is a successor to and continuation of our 2013 Plan. To date, the Company has only granted Incentive Stock Options (ISOs) and Non-statutory Stock Options (NSOs) to employees and directors. Therefore, the below discussion is limited to the terms applicable to ISOs and NSOs (collectively, stock options or options). As of June 30, 2021, there were 5,606,930 shares of common stock reserved by the Company for grant under the 2021 Plan and an aggregate of 4,966,770 shares of common stock remained available for future grants.

2021 Employee Stock Purchase Plan (ESPP)

In February 2021, the Company's Board of Directors adopted our ESPP, and our stockholders approved our ESPP. The price at which stock is purchased under the ESPP is equal to 85% of the fair market value of the Company's common stock on the first or the last day of the offering period, whichever is lower. Generally, each offering under the ESPP will be for a period of six months as determined by the Company's Board of Directors. Employees may invest up to 15% of their qualifying gross compensation through payroll deductions. In no event may an employee purchase more than 4,750 shares of common stock during any six-month offering period. As of June 30, 2021, there were 550,000 shares of common stock available for issuance under the ESPP and no shares issued under the ESPP. The ESPP is a compensatory plan as defined by the authoritative guidance for stock compensation; therefore, stock-based compensation expense of $0.3 million related to the ESPP has been recorded during the six months ended June 30, 2021.

Stock option activity

A summary of stock option activity during the six months ended June 30, 2021 is as follows:

	Number of Units Outstanding	Weighted Average Strike Price per Unit	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	7,737,095	$ 4.22	9.3	$ 16,374
Granted	640,160	$ 13.90		
Exercised	(138,687)	$ 1.50		
Forfeited/Expired	(364,434)	$ 4.18		
Outstanding at June 30, 2021	7,874,134	$ 5.06	8.9	$ 48,993
Exercisable at June 30, 2021	1,413,820	$ 1.89	8.1	$ 12,949
Nonvested at June 30, 2021	6,460,314	$ 5.75	9.1	$ 36,044

As of June 30, 2021, the total unrecognized stock-based compensation related to stock options, excluding the stock option granted to the Company's Chief Executive Officer (CEO) with the performance condition (discussed further below), was $20.4 million, which is expected be recognized over a weighted-average period of approximately 2.9 years.

During 2020, the Chief Executive Officer of the Company received stock options for the purchase of 241,958 shares of common stock that vest upon the first sale by the Company of a regulatory authorized product. As of June 30, 2021, there was $1.4 million of unrecognized compensation expense related to these stock options as the achievement of the performance condition was not yet deemed probable.

Stock-based compensation expense

The following table summarizes the components of stock-based compensation expense recorded in the Company's statement of operations and comprehensive loss (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 558	$ 163	$ 1,181	$ 462
Selling, general and administrative	1,233	244	2,382	626
Total stock-based compensation	$ 1,791	$ 407	$ 3,563	$ 1,088

9. Related-party transactions

Research and development consulting services agreement

The Company has a service agreement with a major stockholder, director and member of its Scientific Advisory Board, under which, the individual is compensated for providing the Company with research and development consulting services. Under the agreement,

the Company has made payments of less than $0.1 million for services rendered during each of the six months ended June 30, 2021 and 2020.

Financing activity

During the six months ended June 30, 2021, the company received proceeds of $106.2 million from the issuance of common stock to related parties as part of the Company's IPO, including the Company's majority shareholder, Baker Bros. Advisors LP, six officers and two members of the Company's Board of Directors.

Registration rights

In March 2021, the Company entered into a registration rights agreement (the Registration Rights Agreement) with Baker Brothers Life Sciences, L.P. and 667, L.P. (the Baker Funds), holders of our Series 1 convertible preferred stock and related parties (see Note 7).

10. Net loss per share

Net loss per share

The following table sets forth the computation of the basic and diluted net loss per share (in thousands, except for share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Numerator:				
Net loss - basic and diluted	$ (64,472)	$ (10,046)	$ (124,964)	$ (17,420)
Denominator:				
Weighted-average number of shares of common stock outstanding - basic and diluted	25,648,151	2,116,623	19,414,066	2,116,437
Net loss per share - basic and diluted	$ (2.51)	$ (4.75)	$ (6.44)	$ (8.23)

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all potential common shares outstanding would have been anti-dilutive. The Company's Series 1 convertible preferred stock are participating securities but because they do not have the obligation to share in the loss of the Company, they are excluded from the calculation of basic net loss per share. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	As of June 30,	
	2021	2020
Convertible preferred stock	—	36,914,762
Series 1 convertible preferred stock	29,863,674	—
Options to purchase Common Stock	7,874,134	5,421,804
Shares estimated to be purchased under 2021 ESPP	77,727	—
Total	37,815,535	42,336,566

11. Subsequent events

In July 2021, the Company made a payment of $29.6 million to one of the Company's contract manufacturing organizations in connection with the purchase of certain instrument components. The Company's $33.0 million standby letter of credit that was required to be held as collateral by the contract manufacturing organization was concurrently terminated, releasing $34.7 million of collateral. All of the $29.6 million was included in accrued liabilities as of June 30, 2021.

In July 2021, the Company and the NIH agreed to an amended contract for the completion of the RADx initiative. The amendment extended contract to October 31, 2021, and decreased the potential milestone payments from $7.9 million to $4.0 million. The remaining $4.0 million available under the amended RADx contract is contingent upon the Company meeting the agreed-upon contractual milestone.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read together with our condensed financial statements and related notes elsewhere in this Quarterly Report and our audited financial statements and the related notes and the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed with the SEC on March 30, 2021 (Annual Report). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk factors" section of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the "Risk factors" section of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special note regarding forward-looking statements."

Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is designed to provide material information relevant to an assessment of our financial condition and results of operations, including an evaluation of the amounts and certainty of cash flows from operations and from outside sources. This section is designed to focus on material events and uncertainties known to management that are reasonably likely to cause reported financial information not to be necessarily indicative of future operating results or of future financial condition. This includes descriptions and amounts of matters that have had a material impact on reported operations, as well as matters that are reasonably likely based on management's assessment to have a material impact on future operations.

Overview

Our primary focus is to transform diagnostic testing through innovative molecular diagnostic products that enable customers to deploy accurate, reliable, low-cost and rapid molecular testing at the point-of-care for infectious diseases and other conditions.

We are developing the Talis One system which leverages expertise across chemistry, biology, engineering and software to create a fully integrated, cloud-enabled and portable molecular diagnostic solution that customers can rapidly deploy when and where needed. The Talis One system incorporates core proprietary technologies into a compact, easy-to-use instrument, that utilizes single use test cartridges and software, including a central cloud database, which are designed to work together to provide levels of testing accuracy equivalent to a central laboratory. We intend to commercialize the Talis One system as an integrated solution comprising single use consumables, an instrument and software. Our commercial strategy will focus on building and expanding an installed base of Talis One instruments and driving utilization of our Talis One assay kits to generate revenue from the purchase of such products. Subject to marketing authorization, our first commercial test will be a rapid point-of-care molecular diagnostic to detect SARS-CoV-2 directly from a patient sample in less than 30 minutes (COVID-19 test). We are also developing assays for the detection of other respiratory infections that could be included as a panel test with our COVID-19 test as well as tests for infections related to women's health and sexually transmitted infections.

Our products will require marketing authorization from the FDA prior to commercialization. Due to the COVID-19 global pandemic, we are pursuing marketing authorization for our COVID-19 test under an emergency use authorization (EUA) rather than initially pursuing 510(k) clearance or other forms of marketing authorization under the FDA's standard medical device authorities.

We have invested in automated cartridge manufacturing lines capable of producing one million Talis One cartridges per month. The first of such lines was delivered in the first quarter of 2021, and we expect will scale to meet demand through 2021. These manufacturing lines are located at our contract manufacturers' sites and are operated by our contract manufacturing partners. We have also ordered 5,000 Talis One instruments from our instrument contract manufacturer.

Since our inception in 2013, we have devoted substantially all our efforts to research and development activities, manufacturing capabilities, raising capital, building our intellectual property portfolio and providing general and administrative support for these operations. We have principally financed our operations through the issuance and sale of shares of our convertible preferred stock to outside investors in private equity financings as well as the issuance of convertible promissory notes and receipts from government grants. Prior to our initial public offering we received $351.5 million from investors in our preferred stock financings and the sale of convertible promissory notes that converted in such financings. Additionally, on February 17, 2021, we raised $232.5 million through an initial public offering (IPO) to finance operations going forward.

We have incurred recurring losses since our inception, including net losses of $125.0 million for the six months ended June 30, 2021 and $17.4 million for the six months ended June 30, 2020. As of June 30, 2021, we had an accumulated deficit of $297.9 million. We expect to continue to generate operating losses and negative operating cash flows for the foreseeable future if and as we:

- continue the research and development of our platform and assays for additional diseases;
- initiate clinical trials for, or additional preclinical development of, our platform;
- further develop and refine the manufacturing processes for our platform;
- change or add manufacturers or suppliers of materials used for our platform;
- seek marketing authorizations;
- seek to identify and validate diagnostic assays for other disease states;
- obtain, maintain, protect and enforce our intellectual property portfolio;
- hire and deploy a salesforce;
- seek to attract and retain new and existing skilled personnel;
- create additional infrastructure to support our operations as a public company and incur increased legal, accounting, investor relations and other expenses; and
- experience delays or encounter issues with any of the above.

In addition, if we obtain marketing authorization for our platform, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. As a result, we will need substantial additional funding to support our operating activities. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings, debt and grant revenue. Adequate funding may not be available to us on acceptable terms, or at all.

If we are unable to obtain funding, we will be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. Although we continue to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

As of June 30, 2021, we had unrestricted cash and cash equivalents of $313.5 million. We expect that our cash and cash equivalents of $313.5 million as of June 30, 2021 will be sufficient to fund our operations through at least the next 12 months from the date our condensed financial statements are issued. We may need substantial additional funding to support our continuing operations and pursue our long-term business plan. We may seek additional funding through the issuance of our common stock, other equity or debt financings, or collaborations or partnerships with other companies. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our research efforts for our assays and development and manufacturing activities. We may not be able to raise additional capital on terms acceptable to us, or at all. Any failure to raise capital as and when needed would compromise our ability to execute on our business plan and may cause us to significantly delay or scale back our operations.

We outsource essentially all of our manufacturing. Design work, prototyping and pilot manufacturing are performed in-house before outsourcing to third party contract manufacturers. Our outsourced production strategy is intended to drive rapid scalability and avoid the high capital outlays and fixed costs related to constructing and operating a manufacturing facility. Certain of our suppliers of components and materials are single source suppliers. To support our anticipated commercial launch, we have invested in automated cartridge manufacturing production lines for our Talis One cartridges. Those assets deemed to have an alternative future use have been capitalized as property and equipment while those assets determined to not have an alternative future use have been expensed. The automated cartridge manufacturing lines are capable of producing one million Talis One cartridges per month, which we expect will scale to meet demand through 2021.

COVID-19 pandemic

Since it was reported to have surfaced in December 2019, a novel strain of coronavirus (COVID-19) has spread across the world and has been declared a pandemic by the World Health Organization. Efforts to contain the spread of COVID-19 have intensified and governments around the world, including in the United States, Europe and Asia, have implemented travel restrictions, social distancing requirements, stay-at-home orders and have delayed the commencement of non-COVID-19-related clinical trials, among other restrictions. As a result, the current COVID-19 pandemic has presented a substantial public health and economic challenge

around the world and is affecting our employees, patients, communities and business operations, as well as contributing to significant volatility and negative pressure on the U.S. economy and in financial markets.

We expect that COVID-19 precautions will directly or indirectly impact the timeline for some of our planned clinical trials for our non-COVID-19 related products in development and we are continuing to assess the potential impact of the COVID-19 pandemic on our current and future business and operations, including our expenses and clinical trials, as well as on our industry and the healthcare system.

As a result of the outbreak, many companies have experienced disruptions in their operations and in markets served. We are considered an essential business and therefore the impact to our operations has been limited. To date, we have initiated some and may take additional temporary precautionary measures intended to help ensure our employees' well-being and minimize business disruption. For the safety of our employees and their families, we have temporarily reduced the presence of our employees in our facilities. Certain of our third-party service providers have also experienced shutdowns or other business disruptions. We are continuing to assess the impact of the COVID-19 pandemic on our current and future business and operations, including our expenses and planned clinical trial and other development timelines, as well as on our industry and the healthcare system.

As a result of the COVID-19 pandemic, or similar pandemics and outbreaks, we have and may in the future experience severe disruptions, including:

- interruption of or delays in receiving products and supplies from the third parties we rely on to, among other things, manufacture components of our instruments, due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, which may impair our ability to sell our products and consumables;
- limitations on our business operations by the local, state, or federal government that could impact our ability to sell or deliver our instruments and consumables;
- delays in customers' purchasing decisions and negotiations with customers and potential customers;
- business disruptions caused by workplace, laboratory and office closures and an increased reliance on employees working from home, travel limitations, cyber security and data accessibility limits, or communication or mass transit disruptions; and
- limitations on employee resources that would otherwise be focused on the conduct of our activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

Three vaccines for COVID-19 have been authorized for emergency use by the FDA as of June 2021. There has been a recent drop in COVID-19 testing volumes in the U.S. There can be no assurance that demand for our COVID-19 testing will continue to exist in the future due to successful containment efforts, the successful vaccination of a majority of Americans, or due to other events.

Enterprise Resource Planning

During the six month period ending June 30, 2021, we implemented a new enterprise resource planning (ERP) system to provide better information and to support our commercial scale-up.

Components of our results of operations

Grant revenue

To date, all of our revenue has been derived from government grants, which includes an April 2018 subaward grant from Boston University as part of the CARB-X initiative, a May 2018 grant from the NIH to support our advancement of a Diagnostics via Rapid Enrichment, Identification, and Phenotypic Antibiotic Susceptibility Testing of Pathogens from Blood project (NIH grant), a July 2020 subaward grant from the University of Massachusetts Medical School for Phase 1 of the NIH's Rapid Acceleration of Diagnostics - Advanced Technology Platforms (RADx) initiative and a contract from the NIH directly for Phase 2 of the RADx initiative.

In July 2021, the Company and the NIH agreed to an amended contract for the completion of the RADx initiative. The amendment extended the contract to October 31, 2021, and decreased the potential payment for the remaining milestone from $7.9 million to $4.0 million. The remaining $4.0 million available under the amended RADx contract is contingent upon us meeting our agreed-upon contractual milestone.

Under the CARB-X and NIH grants there is the possibility of an additional $2.8 million and $2.1 million, respectively, through April 2023.

These grants are not in scope of the contracts with customers accounting guidance as the government entities and/or government-sponsored entities are not customers under the agreements.

Grant funds received from third parties are recorded as revenue if we are deemed to be the principal participant in the arrangement. If we are not the principal participant, the funds from grants are recorded as a reduction to research and development expense. Reimbursable costs paid prior to being billed are recorded as unbilled grant receivables. Funds received in advance are recorded as deferred grant revenue. Our management has determined that we are the principal participant under our grant agreements, and accordingly, we record amounts earned under these arrangements as grant revenue.

Operating expenses

Research and development expenses

Research and development expenses consist primarily of internal and external costs incurred for our research activities, the development of our platform, investment in manufacturing capabilities as well as costs incurred pursuant to our government grants and include:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- the cost of laboratory supplies and developing and manufacturing of our platform;
- contract services, other outside costs and costs to develop our technology capabilities;
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs;
- cost of outside consultants, including their fees and related travel expenses, engaged in research and development functions;
- expenses related to regulatory affairs; and
- fees related to our scientific advisory board.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid or accrued research and development expenses. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and expensed as the related goods are delivered or the services are performed.

Until future commercialization is considered probable and the future economic benefit is expected to be realized, we do not capitalize pre-launch inventory costs prior to completion of marketing authorization unless the regulatory review process has progressed to a point that objective and persuasive evidence of regulatory approval is sufficiently probable, and future economic benefit can be asserted. We record such costs to research and development costs, or if used in marketing evaluations reported to selling, general and administrative expense. A number of factors are taken into consideration, based on management’s judgment, including the current status in the regulatory approval process, potential impediments to the approval process, anticipated R&D initiatives and risk of technical feasibility, viability of commercialization and marketplace trends.

Prior to receiving an EUA, costs of property and equipment related to scaling up our manufacturing capacity for commercial launch are recorded to research and development expense when the asset does not have an alternative future use.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase for the foreseeable future as we initiate clinical trials for our platform, ramp-up our manufacturing and commercialization efforts and continue to discover and develop platforms and assays for other infectious diseases and disease states. There are numerous factors associated with the successful commercialization of any assay we may develop in the future for other diseases or disease states, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, sales, product management, corporate and business development and administrative functions.

Beginning in the first quarter of 2021, we started to incur selling related expenses as part of planning for a commercial launch of our products. Selling, general and administrative expenses also include professional fees for legal, patent, accounting, information technology, auditing, tax and consulting services, travel expenses and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our selling, general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization and sales of our platform. We also expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax compliance services, director and officer insurance costs, and investor and public relations costs.

Other income (expense)

Other income (expense), net consists primarily of interest income on cash deposits held at financial institutions, gains and losses on holdings invested in money market funds, and unrealized and realized foreign exchange gains and losses.

Results of operations

Comparison for the three months ended June 30, 2021 and 2020

The following table summarizes our results of operations:

	Three Months Ended June 30,		
(in thousands)	**2021**	**2020**	**Change**
Grant revenue	$ 117	$ 820	$ (703)
Operating expenses:	—	—	
Research and development	54,495	8,184	46,311
Selling, general and administrative	9,983	2,660	7,323
Total operating expenses	64,478	10,844	53,634
Loss from operations	(64,361)	(10,024)	(54,337)
Other expense, net	(111)	(22)	(89)
Net loss and comprehensive loss	$ (64,472)	$ (10,046)	$ (54,426)

Grant revenue

Our revenue for the three months ended June 30, 2021 and 2020 relates to the CARB-X and NIH grants and the RADx initiative. During the three months ended June 30, 2021, $0.1 million of revenue was recognized related to our NIH grant. During the three months ended June 30, 2020, $0.3 million, $0.2 million, and $0.3 million of revenue was recognized related the NIH, CARB-X grants, and RADx grants, respectively.

Research and development expenses

Substantially all of our research and development expenses incurred for the three months ended June 30, 2021 were related to the manufacturing scale-up for, and development of our first potential commercial product utilizing the Talis One system, a rapid, point-of-care molecular diagnostic test to detect COVID-19 directly from a patient sample.

Research and development expenses were $54.5 million for the three months ended June 30, 2021, compared to $8.2 million for the three months ended June 30, 2020, an increase of $46.3 million. The increase was primarily due to increases of $23.0 million related to the automation of consumable manufacturing, an increase of $10.6 million in instrument component costs, an increase of $7.1 million relating to Talis One cartridge materials for the COVID-19 assay, including $3.6 million related to the modification of one of the agreements with our suppliers, and an increase of $2.4 million related to professional and personnel related expenses, including increased consulting expenses, stock compensation expenses, and personnel related expenses as we increased full-time and temporary headcount, and an increase of $3.2 million relating to an increase in outside services, allocated facilities and IT costs, supplies, freight and logistics costs.

The ramp up of our manufacturing efforts, which began in the middle of 2020, is expected to be completed by the end of 2021. As of June 30, 2021, we have incurred approximately $100.5 million related to such manufacturing scale-up costs, of which $92.8 million has been incurred related to high capacity production equipment and $7.7 million has been incurred related to our cartridge expenses. During the three months ended June 30, 2021, the Company incurred $23.3 million of these costs. We expect to incur approximately $12.3 million of additional costs in the near term, which we expect to be recognized in research and development expense until we

receive emergency use authorization. We submitted our EUA application for the Talis One system and COVID-19 assay cartridges in July 2021. See "Liquidity and capital resources – Future funding requirements" below for additional information.

Selling, general and administrative expenses

Selling, general and administrative expenses were $10.0 million for the three months ended June 30, 2021, compared to $2.7 million for the three months ended June 30, 2020, an increase of $7.3 million. The increase was primarily due to increased personnel related expenses of $6.2 million, including salaries and wages, stock-based compensation expenses and personnel related expenses as we have increased headcount consulting and recruiting expenses in these departments, and an increase of $1.1 million related to increased expenses for insurance, intellectual property, and professional services.

Comparison for the six months ended June 30, 2021 and 2020

The following table summarizes our results of operations:

	Six Months Ended June 30,		
(in thousands)	**2021**	**2020**	**Change**
Grant revenue	$ 7,117	$ 1,219	$ 5,898
Operating expenses:			
Research and development	114,688	13,898	100,790
Selling, general and administrative	17,310	4,740	12,570
Total operating expenses	131,998	18,638	113,360
Loss from operations	(124,881)	(17,419)	(107,462)
Other expense, net	(83)	(1)	(82)
Net loss and comprehensive loss	$ (124,964)	$ (17,420)	$ (107,544)

Grant revenue

Our revenue for the six months ended June 30, 2021 and 2020 relates to the CARB-X and NIH grants and the RADx initiative. During the six months ended June 30, 2021, $7.0 million of revenue was recognized related to the completion of Stage 2 and Stage 3 milestones as part of the RADx grant and $0.1 million of revenue was recorded related to our NIH grant. During the six months ended June 30, 2020, $0.6 million, $0.3 million, and $0.3 million of revenue was recognized related the NIH, CARB-X grants, and RADx grants, respectively.

Research and development expenses

Substantially all of our research and development expenses incurred for the six months ended June 30, 2021 were related to the manufacturing scale-up for, and development of our first potential commercial product utilizing the Talis One system, a rapid, point-of-care molecular diagnostic test to detect COVID-19 directly from a patient sample.

Research and development expenses were $114.7 million for the six months ended June 30, 2021, compared to $13.9 million for the six months ended June 30, 2020, an increase of $100.8 million. The increase was primarily due to increases of $51.5 million related to the automation of consumable manufacturing, an increase of $24.8 million in instrument component costs, an increase of $13.0 million relating to Talis One cartridge materials for the COVID-19 assay, including $3.6 million related to the modification of one of the agreements with our suppliers, and an increase of $5.8 million related to professional and personnel related expenses, including increased consulting expenses, stock compensation expenses, and personnel related expenses as we increased full-time and temporary headcount, and an increase of $5.7 million relating to an increase in outside services, allocated facilities and IT costs, supplies, equipment, freight and logistics costs.

During the six months ended June 30, 2021 we have incurred $51.6 million in expenses related to our manufacturing scale-up activities.

Selling, general and administrative expenses

Selling, general and administrative expenses were $17.3 million for the six months ended June 30, 2021, compared to $4.7 million for the six months ended June 30, 2020, an increase of $12.6 million. The increase was primarily due to increased personnel related expenses of $10.4 million, including salaries and wages, stock-based compensation expenses and personnel related expenses as we have increased headcount, consulting and recruiting expenses in these departments, and an increase of $2.2 million related to increased expenses for insurance, and professional services, and intellectual property.

Liquidity and capital resources

Sources of liquidity

On February 12, 2021, we completed our IPO, pursuant to which we issued and sold 13,800,000 shares of our common stock and an additional 2,070,000 shares pursuant to the exercise in full by the underwriters of their option to purchase additional shares of our common stock, at a public offering price of $16.00 per share. The net proceeds from the IPO were $232.5 million after deducting underwriting discounts and commissions and other offering expenses.

We believe our cash balance as of June 30, 2021 is sufficient for our operations for at least the next 12 months from the date our condensed financial statements are issued based on our existing business plan and our ability to control the timing of significant expense commitments.

Future funding requirements

We do not have any commercial-scale manufacturing facilities and expect to rely on third parties to manufacture the Talis One system and related cartridges. We have entered into, and expect to enter into additional, agreements with contract manufacturers to support our manufacturing scale-up. We will also need engage third-party logistics providers to manage the movement of materials between suppliers and contract manufacturers and for finished goods warehousing. We also intend to invest in additional manufacturing capacity to meet market demand if the Talis One system is approved for marketing. The ramp up of these manufacturing efforts, which began in the middle of 2020, is expected to result in a significant increase in our research and development expenses until regulatory approval of our products is achieved.

We do not yet have any products approved for sale, and we have never generated any revenue from contracts with customers. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize our Talis One system. Until we can generate a sufficient amount of revenue from the commercialization of Talis One system, if ever, we expect to finance our future cash needs through public or private equity offerings or debt financings.

To date, our primary uses of cash have been to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We currently have no other ongoing material financing commitments, such as other lines of credit or guarantees. We have recently increased our spending on automated cartridge manufacturing scale-up and instrument manufacturing, and expect expenses related to manufacturing to increase significantly as we prepare for a potential near-term commercial launch. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our platform. In addition, if we obtain marketing approval for our platform, we expect to incur significant commercialization expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of any future collaborators. We expect to incur additional costs associated with operating as a public company. Accordingly, we may choose to obtain additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Since our inception, we have incurred significant losses and negative cash flows from operations. We have an accumulated deficit of $297.9 million through June 30, 2021. We expect to incur substantial additional losses in the future as we conduct and expand our research and development, manufacturing and commercialization activities. Based on our planned operations, we expect that our unrestricted cash of $313.5 million as of June 30, 2021, will be sufficient to fund our operations for at least 12 months after these financial statements are issued. However, we may need to raise additional capital through equity or debt financing, or potential additional collaboration proceeds prior to achieving commercialization of our products. Our ability to continue as a going concern is dependent upon our ability to successfully secure sources of financing and ultimately achieve profitable operations.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of the Talis One system, we are unable to estimate the exact amount of our operating capital requirements. Our future capital requirements will depend on many factors, including:

- our ability to receive, and the timing of receipt of, an EUA for our COVID-19 test;
- the effectiveness and availability of the three vaccines in the U.S. that were authorized as of June 2021;
- the amount of capital, and related timing of payments, required to build sufficient inventory of our Talis One system and test cartridges in advance of and during commercial launch;

- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for our platform if we receive marketing approval;
- limitations of, or interruptions in, the quality or quantity of materials from our third party suppliers;
- our ability to implement an effective manufacturing, marketing and commercialization operation;
- the scope, progress, results and costs of our ongoing and planned operations;
- the costs associated with expanding our operations;
- the number and development requirements of assays for other diseases or disease states that we may pursue;
- intervention, interruptions or recalls by government or regulatory agencies;
- enhancements and disruptive advances in the diagnostic testing industry;
- our estimates and forecasts of the market size addressable by our Talis One system;
- security breaches, data losses or other disruptions affecting our information systems;
- the regulatory and political landscape upon the launch of our commercialization of the Talis One system;
- the revenue, if any, received from commercial sales of our products if approved, including additional working capital requirements if we pursue a reagent rental model for our Talis One instrument;
- our ability to establish strategic collaborations; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims.

Cash flows

The following table summarizes our cash flows for each of the periods presented:

	Six Months Ended June 30,	
	2021	2020
	(in thousands)	
Cash used in operating activities	$ (55,895)	$ (17,535)
Cash used in investing activities	(1,120)	(337)
Cash provided by financing activities	232,757	111,540
Net increase in cash, cash equivalents and restricted cash	$ 175,742	$ 93,668

Operating activities

During the six months ended June 30, 2021, cash used in operating activities was $55.9 million, resulting primarily from our net loss of $125.0 million partially offset by an increase in our accrued expenses and accounts payable of $49.4 million and $6.6 million, respectively, a decrease in our prepaid research and development of $9.6 million, and non-cash items of $4.5 million, made up of stock-based compensation of $3.6 million, amortization of our right-of-use assets on operating leases of $0.5 million, and depreciation expense of $0.4 million. The increase in our accrued expenses of $49.4 million was primarily associated with our manufacturing scale-up project. We have increased spending on cartridge manufacturing scale-up and instrument manufacturing as we prepare for a potential commercial launch. These increases were partially offset by an increase in other long-term assets of $1.0 million relating to the long-term deposit held on one of our operating leases.

During the six months ended June 30, 2020, cash used in operating activities was $17.5 million, resulting primarily from our net loss of $17.4 million, increase of prepaid research and development of $3.4 million, a decrease in accrued expenses and other liabilities of $3.1 million, a decrease in unbilled grant receivable of $1.2 million and an increase in long-term assets of $0.3 million. This was offset by an increase in accounts payable of $4.0 million, $1.7 million of non-cash items including stock-based compensation of $1.1 million, depreciation and amortization of $0.4 million and non-cash lease expense of $0.3 million.

Investing activities

During the six months ended June 30, 2021 and 2020, we used $1.1 million and $0.3 million of cash, respectively, for investing activities related to purchases of property and equipment.

Financing activities

During the six months ended June 30, 2021, net cash provided by financing activities was $232.8 million, primarily consisting of $232.6 million of proceeds from the issuance of common stock in our initial public offering and $0.2 million in proceeds from stock option exercises.

During the six months ended June 30, 2020, net cash provided by financing activities was $111.5 million, consisting of proceeds from the issuance of preferred stock.

Contractual obligations and commitments

The following table summarizes our non-cancellable contractual obligations at June 30, 2021, and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments due by period		
(in thousands)	Total	Less than 1 year	1 to 3 years
Operating leases(1)	$ 5,998	$ 1,004	$ 4,994
Purchase commitments(2)	64,127	64,127	—
Manufacturing production lines(3)	8,825	8,825	—
Total	$ 78,950	$ 73,956	$ 4,994

(1) Represents minimum contractual lease payments on our real estate leases in Menlo Park, California and Chicago, Illinois. During the first quarter of 2021, we entered into a lease laboratory and office space in Redwood City, CA. Because the lease has not commenced, we have excluded the commitment from the above analysis as of June 30, 2021. The Redwood City, CA lease will extend for an initial term of 10.5 years with a minimum commitment of approximately $2.6 million annually with fixed escalations of 3.0% per annum.

(2) Represents firm purchase commitments in the normal course of business of $2.2 million and $61.9 million of Talis One instruments and Talis One cartridges, respectively.

(3) Represents firm commitments relating to the scale-up of manufacturing capacity for Talis One cartridges, primarily attributed to investments in production lines.

Apart from the contracts with payment commitments that we have reflected in the table, we have entered into other contracts in the normal course of business with certain contract manufacturing organizations and other third parties for manufacturing services. Payments due upon cancellation consist only of payments for services provided and expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation.

Critical accounting policies and significant judgments and estimates

This discussion and analysis of financial condition and results of operation is based on our unaudited condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities as of the date of the financial statements and the reported amounts of expenses during the reporting period. On an ongoing basis, management evaluates its estimates and assumptions.

Our critical accounting policies and estimates are discussed in our Annual Report. There have been no material changes to our critical accounting policies and estimates during the six months ended June 30, 2021.

Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our unaudited condensed financial statements included within Item I of this Quarterly Report.

Emerging growth company status

In April 2012, JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Therefore, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this extended transition period and, as a

result, we may adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies instead of the dates required for other public companies.

We may take advantage of these exemptions for up to the last day of the fiscal year ending after the fifth anniversary of our initial public offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (1) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (2) the last day of our fiscal year following the fifth anniversary of the date of our initial public offering; (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 as of June 30, 2021.

Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of June 30, 2021 due to the material weakness in our internal control over financial reporting described below. In light of this fact, our management has performed additional analyses, reconciliations, and other post-closing procedures and has concluded that, notwithstanding the material weakness in our internal control over financial reporting, the financial statements for the periods covered by and included in this Quarterly Report fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with GAAP.

Material weaknesses in internal control over financial reporting

In connection with the audit of our financial statements as of and for the year ended December 31, 2020, we and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting related to a lack of effective review of the estimated vendor progress related to the level of completion associated with our manufacturing scale-up project, which resulted in material adjustments to prepaid research and development expenses. 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 our financial statements will not be prevented or detected on a timely basis. During the first quarter of 2021, we began implementing specific remediation actions to address the material weakness, which included the following specific remediation actions:

- Adding new control activities, modifying existing controls, and enhancing the documentation that evidences that controls are performed;
- Supplementing our internal accounting resources with additional external accounting and finance resources; and
- Expanding the hiring of accounting and finance personnel with more experience in developing and implementing internal controls specific to research and development and manufacturing operations.

We are in the process of implementing these additional control activities. Our goal is to remediate this material weakness by the end of 2021, subject to there being sufficient opportunities to conclude, through testing, that the enhanced controls are operating effectively, in order to meet our requirements to certify our controls under Section 404 of the Sarbanes-Oxley Act of 2002. Our independent registered public accounting firm has not assessed the effectiveness of our internal control over financial reporting and, under the JOBS Act, will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an “emerging growth company”.

Changes in Internal Control over Financial Reporting

Other than the changes intended to remediate the material weakness noted above, there was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(e) and 15d15(e) of the Exchange Act that occurred during the three months ended June 30, 2021 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors, and there can be no assurances that favorable outcomes will be obtained. We currently are not a party to any material legal proceedings.

Item 1A. Risk Factors.

Careful consideration should be given to the following risk factors, together with the other information contained in this Quarterly Report, including our financial statements and the related notes. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. This Quarterly Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See "Special note regarding forward-looking statements."

Risks related to our business and strategy

There can be no assurance that the COVID-19 test we are developing for the detection of the SARS-CoV-2 virus will be granted an EUA by the FDA. If no EUA is granted or, once granted, it is revoked or the emergency declaration is terminated, we will be unable to sell this product in the near future and will be required to pursue 510(k) clearance or other marketing authorization, which would likely be a lengthy and expensive process.

Our regulatory strategy is to submit for the equivalent of a Clinical Laboratory Improvement Amendment of 1988 (CLIA)-waived authorization for use of the Talis One system with COVID-19 molecular diagnostic assay in non-laboratory settings. We initially submitted a request for an EUA to the FDA in January 2021 for our Talis One system with COVID-19 molecular diagnostic assay for the automated detection of nucleic acid from the SARS-CoV-2 virus in nasal swab samples from individuals suspected of COVID-19 by their healthcare provider in CLIA-moderate settings. In late February, the FDA informed the company that it cannot ensure the comparator assay used in the primary study has sufficient sensitivity to support Talis's EUA application. On March 8, 2021, we announced that we withdrew our January application in favor of focusing on an application to authorize testing at the point-of-care. In late March 2021, we made certain modifications to our clinical validation strategy for the point-of-care environment, and submitted an EUA application for the Talis One COVID-19 assay kit in CLIA waived settings in the July 2021. The clinical validation utilizes a different comparator assay, which we believe will address the FDA's concerns, but there can be no assurance that the FDA will deem the information provided in the most recent application to be sufficient to support emergency use authorization.

An EUA would allow us to market and sell our system with this assay without the need to pursue the lengthy and expensive 510(k) clearance process or any other marketing authorization process. The FDA may issue an EUA during a public health emergency if it determines that, based on the totality of the scientific evidence, that it is reasonable to believe that the product may be effective, that the known and potential benefits of a product outweigh the known and potential risks, that there is no adequate, approved and available alternative and if certain additional regulatory criteria are met. These standards for marketing authorization are lower than if the FDA were to review our test under its traditional marketing authorization pathways, and we cannot assure you that our COVID-19 assay kit would be cleared or approved under those more onerous clearance and approval standards. As a result, if we do not receive an EUA for our Talis One system with COVID-19 assay kit, the commercial launch of such products could be significantly delayed, which would adversely impact our business, financial condition and results of operations. The effects of any such delay would also be exacerbated if the demand for COVID-19 tests continues to decline prior to our receipt of any marketing authorization.

If an EUA is granted for our Talis One system for its intended use in detecting SARS-CoV-2, we will rely on the FDA policies and guidance in connection with the marketing and sale of such products. If these policies and guidance change unexpectedly and/or materially or if we misinterpret them, potential sales of our products could be adversely impacted. In addition, the FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, or if we fail to comply with the conditions of such EUA.

It is uncertain whether the widespread availability of approved and effective vaccinations could expedite or influence any such decision making with respect to the underlying health emergency.

The FDA may also revoke an EUA when the circumstances justifying its issuance no longer exist, such as when an alternative is authorized for marketing through the standard procedures, such as through a 510(k) clearance. The FDA has stated that, given the magnitude of the COVID-19 health crisis and the testing capacity challenges in the United States, it has no intention of terminating EUAs for COVID-19 diagnostic tests based solely on a test receiving 510(k) clearance. However, the FDA may change this position at any time and without notice. If granted, we cannot predict how long an EUA for the Talis One system and COVID-19 assay kit will remain in place. FDA policies regarding diagnostic tests, therapies and other products used to diagnose, treat or mitigate COVID-19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence. Changes to FDA regulations or requirements could require changes to our authorized test, necessitate additional measures, or make it impractical or impossible for us to market our test. The revocation of an EUA, if granted, could necessitate that we pursue the lengthy and expensive 510(k) clearance process, which is now available since a COVID-19 assay has received *de novo* 510(k) classification. Indeed, FDA has recommended that manufacturers of tests subject to an EUA pursue pre-market submissions such as a 510(k), *de novo* classification, or PMA, as applicable, during the declared public health emergency so that their devices can remain on the market after the emergency terminates. As a result, any such revocation could adversely impact our business, financial condition and results of operations.

We may also seek an additional EUA from the FDA for our respiratory panel test in combination with a test for the detection of the SARS-CoV-2 virus. To date, no such combination test has received an EUA in the absence of a previously 510(k)-cleared flu test and the FDA's guidance on the possibility of such an authorization is unclear. If granted, the additional EUAs would allow us to market and sell such additional tests without the need to pursue the lengthy and expensive clearance or approval process for such additional tests (at least for as long as such EUAs are maintained). There is no guarantee that we will be able to obtain any additional EUAs. Further, we cannot predict when any such EUA would terminate in connection with a determination by the FDA regarding the end of the SARS-CoV-2 public health emergency. After the emergency declaration is terminated or the EUA is earlier revoked, we will be required to have 510(k) clearance in order for us to continue marketing and distributing our products. Failure to obtain additional EUAs or the revocation of any EUAs, if obtained, could adversely impact our business, financial condition and results of operations.

We may not be able to obtain marketing authorization for our Talis One system or *for any assay kit, which would adversely affect our business, financial condition and results of operations.*

We have focused our efforts on the development of the Talis One system for FDA clearance or other marketing authorization as a point-of-care testing platform for infectious diseases. A significant portion of our commercial strategy is dependent upon the initial commercialization of our Talis One system with COVID-19 assay kit pursuant to an EUA, if granted, and on receiving subsequent marketing authorizations with inclusion in clinical guidelines to strengthen our position in establishing coverage and reimbursement of our products with both public and private payors. If we are unable to receive marketing authorization pursuant to an EUA, or if any EUA we receive is later withdrawn or terminates at the conclusion of the public health emergency, we will be required to pursue marketing authorization through the FDA's standard pre-market review pathways, in this case a traditional 510(k) clearance. We cannot guarantee that we would be able to satisfy the requirements for marketing authorization under that pathway. If we do not receive such marketing authorizations in a timely manner, or at all, or we are not successful in receiving such guideline inclusion, we may not be able to commercialize our products successfully or at all. Additionally, third-party payors may be unwilling to provide sufficient coverage and reimbursement for our products necessary for hospitals and other healthcare providers to adopt our solutions as part of their treatment strategy.

Moreover, development of the data necessary to obtain marketing authorization of a diagnostic test is time-consuming and carries with it the risk of not yielding the desired results. The performance achieved in initial studies may not be repeated in later studies that may be required to obtain marketing authorizations. In addition, limited results from earlier-stage verification studies may not predict results from studies conducted to obtain marketing authorization. Unfavorable results from ongoing preclinical and clinical studies could result in delays, modifications or abandonment of ongoing analytical or future clinical studies, or abandonment of a product development program, or may delay, limit or prevent regulatory approvals or clearances or commercialization of our products, any of which may materially adversely affect our business, financial condition and results of operations. Furthermore, results that would be sufficient for regulatory approval may not demonstrate strong performance characteristics, limiting the market demand for the system, which would adversely affect our business. See "—Risks related to regulatory matters."

We contract with a significant number of third parties for the manufacturing and supply of products, which supply may become limited or interrupted or may not be of satisfactory quality and quantity.

We do not have any commercial-scale manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of the Talis One system and our tests, as well as for commercial supply if any of our products are authorized for marketing. This reliance exposes us to significant risk that we will not have sufficient quantities of our products at an acceptable cost or quality, which could delay, prevent or impair our clinical trials and commercialization efforts. The manufacturing of our Talis One

instrument and cartridge involves over 500 raw materials, intermediates and subassemblies. While we do not have any commercial-scale manufacturing facilities, we have invested in the development of multiple automated assembly lines for production of the test cartridges. The automated lines are required to meet the near-term volume commercial needs for the Talis One system, if we receive an EUA for our COVID-19 test. However, the lines are not complete and could incur substantial delays, costs and may not perform as anticipated, and any failure to perform as anticipated could require us to make significant capital expenditures to make adjustments. Any such delays or required expenditures could prevent us from launching our Talis One system with COVID-19 assay kit if we receive marketing authorization, which would adversely impact our business, financial condition and results of operations. The effects of any such delays would also be exacerbated as the demand for COVID-19 tests continues to decline prior to our assembly lines becoming fully operational at scale.

As we have not yet operated our assembly lines at scale, it may be difficult to predict the cost of manufacturing our cartridges. We are undertaking a number of initiatives designed to reduce the cost of manufacturing our instruments and diagnostic tests, including reducing the costs of supplies. There is no guarantee that we will be able to achieve planned cost reductions from such initiatives. There may also be unforeseen occurrences that increase our costs, such as increased prices of the components of our diagnostic tests, changes to labor costs or less favorable terms with third-party suppliers or contract manufacturing partners. As a result, even if our automated lines perform as anticipated, we may be unable to manufacture our products, if authorized for marketing, in a profitable manner.

Almost all the materials, enzymes and reagents used in or with our instrument and cartridges are obtained from single source suppliers, which exposes us to significant supplier risk. In addition, we may purchase supplies through purchase orders and may not have long-term supply agreements with, or guaranteed commitments from, many of our suppliers, including single source suppliers. A loss of sufficient supply of such components could require us to expend significant time and resources to develop or license replacement technology and obtain additional marketing authorizations. While we are evaluating redundancy vendors for reagents and other materials there can be no assurance that we will successfully contract for such materials. To further mitigate risk, we are implementing multi-month, multi-lot safety stock strategy to promote an uninterrupted supply of critical or scarce reagents and other materials and, when we can, we negotiate for termination provisions and purchase rights with our third-party manufacturers to allow enough time for us to find replacement suppliers, if necessary. However, mitigating this risk by keeping a safety stock level of inventory, requires careful management and may result is losses associated with expired inventory or inventory that is otherwise unsuitable for use in our products or for commercial sale.

Our third-party manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, or unstable political environments, or health pandemics or epidemics. For example, due to the health crisis of the COVID-19 pandemic, some of the suppliers of materials and components for our instrument and cartridges are facing extreme demand for their services. In particular, certain manufacturers of multiple components of our instrument are currently unable to provide such components to us, or are unable to provide such components on reasonable timelines, without a requirement from the government to do so pursuant to the Defense Production Act of 1950, as amended (DPA). Our contract with the NIH for Phase 2 of its RADx initiative had been modified to incorporate a Health Resources Priorities and Allocations System (HRPAS) priority rating of DO pursuant to the DPA. This allowed us to place the same priority rating on orders for industrial resources that we need to fulfill our rated order with our suppliers. While our contract with RADx, which was set to expire on July 30, 2021, has been amended to extend the performance period to October 31, 2021, the DPA priority rating was not concurrently extended and therefore expired as of July 30, 2021. Since we no longer have the priority rating, we may be unable to manufacture our products in sufficient quantities and such event would have a material adverse effect on our business, financial condition and results of operations.

We have engaged a third-party logistics company to manage the movement of materials between suppliers and for finished goods warehousing. However, if any of our suppliers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new suppliers and may face delays in processing samples or developing and commercializing our products. For example, a sole supplier supplies us with the enzymes used in our test cartridges. While we acquire these proprietary enzymes from the supplier on customary terms, if we had to replace our enzymes, we may also need to acquire alternate enzymes, and optimize our tests with new enzymes, buffers and amplification conditions. This would most likely result in significant delays in delivering our products to the market and require new applications for marketing authorizations. In addition, the COVID-19 crisis may cause shortages of key supplies, such as pipettes and nasal swabs, that are necessary components of our products. The ability to provision such key supplies may be outside our control and may limit the use of our products and the purchase of our tests.

If our third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our instrument and diagnostic tests, the supply of our instrument and diagnostic tests to customers and the development of any future diagnostic tests will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition and results of operations.

Furthermore, all entities involved in the manufacture of our products, are subject to extensive regulation. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with these regulations. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do so on commercially reasonable terms, if at all. Further, we may be unable to use the product produced by that manufacturer, or if the manufacturer has manufactured product for our commercial sale, if and when we obtain approval, we could be subject to a recall of such product. Any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our products may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturers in order to have another third-party manufacture our products.

The process of changing manufacturers is time consuming, may involve substantial costs and is likely to result in delays or interruptions in the development of products and/or the commercialization of products, if approved. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop products in a timely or affordable manner.

Our, or a third party's, failure to execute on our manufacturing requirements, to do so on commercially reasonable terms and to comply with applicable regulations could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of our products under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for our products;
- requirements to cease development or to recall batches of our products; and
- in the event of approval to market and commercialize our products, an inability to meet commercial demands for our products or any other future products.

In order to commercialize our products, if approved, we will need to manufacture them in large quantities. We, or our manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our products in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we or our manufacturing partners are unable to successfully scale-up the manufacture of our products in sufficient quality and quantity, the development, testing and clinical trials of that product may be delayed or become infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

Additionally, our third-party manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, or unstable political environments, or health pandemics or epidemics such as the ongoing COVID-19 pandemic.

We have no products approved for commercial sale. We have no or limited experience in developing, marketing and commercializing diagnostic platforms and tests, and we are continuing to evaluate the sales model for the Talis One system*, which may make it difficult to evaluate the success of our business and to assess our future viability.*

To date, we have no commercialization experience as a company. As a result, we have limited experience forecasting future financial performance for our products 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 common stock to decline. In addition, we are continuing to evaluate the appropriate sales model for our Talis One system and cannot predict the proportion of customers that would purchase the Talis One instrument or utilize our planned reagent rental model in which the Talis One system is rented. Changes in the proportion of our customers directly purchasing as compared to accessing the reagent rental model will cause our results of operations to fluctuate making predictions with regard to our operating results highly variable particularly during the early stages of our commercial launch.

Assuming we are successful in obtaining an EUA, we expect to initially market and sell the Talis One system with our COVID-19 assay kit in the United States. Substantially all of our revenue will initially be dependent upon such sales, which we expect will continue to be the case until such time as we obtain marketing authorization for subsequent tests. As a result, our future success will depend in large part on our ability to effectively launch the Talis One system with our COVID-19 assay kit and subsequently introduce enhanced or new tests for the Talis One system. The launch of new products is inherently uncertain and requires the completion of commercialization activities that are complex, costly, time-intensive and uncertain, and require us to accurately

anticipate patients', providers' and, if applicable, payors' attitudes and needs and 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 on a timely basis, or at all.

Our commercial success depends, in part, on the acceptance of our diagnostic tests and services as being safe and relatively simple for medical personnel to learn and use, clinically flexible, operationally versatile and, with respect to providers and payers, cost effective. We cannot predict how quickly, if at all, payers, providers, clinics and patients will accept future diagnostic tests and services or, if accepted, how frequently they will be used. These constituents must believe that our diagnostic tests offer benefits over other available alternatives. The degree of market acceptance of our current and future diagnostic tests and services depends on a number of factors, including:

- whether our customers are willing to incur the upfront costs associated with purchasing Talis One instruments;
- whether there is adequate utilization of our tests by clinicians, health systems and other target groups based on the potential and perceived advantages of our diagnostic tests over those of our competitors;
- the convenience and ease of use of our diagnostic tests relative to those currently on the market;
- the effectiveness of our sales and marketing efforts;
- our ability to provide incremental data that show the clinical benefits and cost effectiveness, and operational benefits, of our diagnostic tests;
- the coverage and reimbursement acceptance of our products and services;
- pricing pressure, including from group purchasing organizations (GPOs), seeking to obtain discounts on our diagnostic tests based on the collective bargaining power of the GPO members;
- negative publicity regarding our or our competitors' diagnostic tests resulting from defects or errors;
- the accuracy of our tests relative to those of our competitors;
- product labeling or product insert requirements by the FDA or other regulatory authorities; and
- limitations or warnings contained in the labeling cleared or approved by the FDA or other authorities.

With respect to our COVID-19 test, our commercial success could also depend on the availability and effectiveness of any vaccinations for COVID-19. Three vaccines for COVID-19 were authorized for emergency use in the U.S. as of June 30, 2021. There has been a drop in COVID-19 testing volumes in the U.S. There can be no assurance that demand for our COVID-19 testing will continue to exist in the future due to successful containment efforts, the successful vaccination of a majority of Americans, or due to other events. Commercial success of our respiratory panel, which is designed to detect influenza A, influenza B or SARS-CoV-2, could further depend on receiving FDA authorization via the emergency use authorization pathway. The federal government may terminate the emergency use authorization pathway prior to submission of our application for authorization, thereby requiring us to pursue the more onerous 501(k) pathway for market authorization for the respiratory panel, which could further delay bringing our product to market. A delay in receiving authorization could cede market share to competitors who have already obtained authorization for combined COVID-flu tests. Additionally, even if our diagnostic tests achieve widespread market acceptance, they may not maintain that market acceptance over time if competing diagnostic tests or technologies, which are more cost effective or are received more favorably, are introduced. Failure to achieve or maintain market acceptance and/or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations.

We may experience research and development, regulatory, marketing and other difficulties that could delay or prevent our introduction of enhanced or new products and result in increased costs and the diversion of management's attention and resources from other business matters. For example, any molecular diagnostic tests that we may enhance or develop may not prove to be clinically effective, or may not meet our desired target product profile or 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 molecular diagnostic test performance in commercial settings 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 entering into collaborative arrangements; the collaborative arrangements we enter into may not be successful or we may not be able to maintain those that are successful; healthcare providers may not use any tests that we may enhance or develop; or we may otherwise have to abandon a product or service in which we have invested substantial resources.

An important factor in our ability to commercialize our products is collecting data that supports the value proposition of our products, and in particular that our tests are just as accurate and reliable as central lab testing. The data collected from any studies we complete may not be favorable or consistent with our existing data or may not be statistically significant or compelling to the medical

community or to third-party payors seeking such data for purposes of determining coverage for our products. Any of the foregoing could have a negative impact on our ability to commercialize our future products, which could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to an order from federal or state governments, including pursuant to the DPA, to distribute the Talis One instrument and our COVID-19 assay kit directly to the government or as directed by the government, which could adversely affect our business, financial condition and results of operations.

The DPA is a federal statute that confers upon the President of the United States a broad set of authorities to influence domestic industry in the interest of national defense. "National defense" can include emergency and disaster response and, since the start of the current COVID-19 crisis, the President of the United States has used this authority more than 30 times to address the public health crisis. Through the DPA, the executive branch has struck agreements with multiple companies to accelerate COVID-19 countermeasures, like N95 protective masks, testing swabs, and vaccine development, and, in September 2020, used the DPA to acquire point-of-care diagnostic testing instruments from two of our potential competitors for placement in nursing homes. The government has now also applied the DPA to our RADx contract to acquire our Talis One instrument, requiring us to prioritize their order over others. The government may similarly apply the DPA, or another law or program, to our other existing contracts or a new contract to acquire our testing instruments or to direct us to distribute our products in a particular manner, and we may be likewise required to prioritize distribution to certain government agencies or other recipients, or to allocate inventory, supplies or facilities for government or government-directed use. The DPA provides that orders pursuant to the statute must "meet regularly established terms of sale or payment" and further provides that no person "shall be held liable for damages or penalties for any act or failure to act resulting directly or indirectly from compliance with a rule, regulation, or order" under the DPA. However, compliance with the DPA could potentially cause business disruption, interfere with our commercial sales and marketing efforts, and depending on the demand, could even prevent or delay our ability to sell our products commercially, or may have other implications that significantly affect our commercialization and development efforts and general ability to conduct our business operations as planned. For example, government directed use of our products under such a program may result in our instruments not being placed in settings where they will be used often for additional tests following the COVID-19 crisis which would adversely affect our long-term commercial plan that is based on the addition of multiple tests for use with the Talis One system. In addition, such government requirements may adversely affect our regular operations and financial results, result in differential treatment of customers and/or adversely affect our reputation and customer relationships. It is also possible that any change in the current administration could impact the manner in which the government uses the DPA and its other authorities, and result in additional or different risk to us.

The COVID-19 pandemic could materially adversely affect our business, financial condition and results of operations.

The COVID-19 pandemic is negatively impacting worldwide economic and commercial activity and financial markets, as well as increasing demand for certain components that we use in our Talis One system. Certain manufacturers of multiple components of our Talis One system are unable to provide such components to us, or are unable to provide such components on reasonable timelines, without a requirement from the government to do so pursuant to the DPA. Our RADx contract was previously modified to incorporate a priority rating of DO pursuant to the DPA. This allowed us to place the same priority rating on orders for industrial resources that we need to fulfill our rated order with our suppliers. While our contract with RADx, which was set to expire July 30, 2021, has been amended to extend the performance period to October 31, 2021, the DPA rating was not concurrently extended and therefore expired as of July 30, 2021. . COVID-19 has also resulted in significant business and operational disruptions, including business closures, supply chains disruptions, travel restrictions, stay-at-home orders and limitations on the availability of workforces. We expect that COVID-19 precautions will directly or indirectly impact the timeline for some of our planned clinical trials for our non-COVID-19 related products in development and we are continuing to assess the potential impact of the COVID-19 pandemic on our current and future business and operations, including our expenses and clinical trials, as well as on our industry and the healthcare system. The full impact of COVID-19 is unknown and is rapidly evolving. The extent to which COVID-19 negatively impacts our business and operations will depend on the severity, location and duration of the effects and spread of COVID-19, the actions undertaken by national, regional and local governments and health officials to contain the virus or treat its effects, how quickly and to what extent economic conditions improve and normal business and operating conditions resume, and whether the supply of components will remain sufficient to satisfy market demand and any impact on its pricing. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk factors" section, such as those relating to our reliance on a limited number of suppliers and our need to raise additional capital to fund our existing operations.

If our products do not perform as expected, including due to errors, defects or reliability issues, our reputation and market acceptance of our products could be harmed, and our operating results, reputation and business will suffer.

Our success depends on physician and customer confidence that we can provide reliable and highly accurate diagnostic tests and enable better patient care. We believe that physicians and other healthcare providers are likely to be particularly sensitive to defects,

errors or reliability issues in our products, including if our products fail to accurately diagnose infections with high accuracy from patient samples, and there can be no guarantee that our products will meet their expectations. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue as our product deliveries increase and our product portfolio expands.

Our products use a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors. For example, the Talis One system, comprised of a compact instrument, universal single-use assay cartridges and software, including a central cloud database, may contain undetected errors or defects when first introduced or as new versions are released. Our diagnostic tests may contain errors or defects or be subject to reliability issues, and while we have made efforts to test them extensively, we cannot assure that our current diagnostic tests, or those developed in the future, will not have performance problems. 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 or they may cause our products to malfunction. Due to the complexity of our instrument and cartridge, it may be difficult or impossible to identify the reason for such performance. Performance issues would increase our costs in the near-term and accordingly adversely affect our business, financial condition and results of operations. In addition, failure to maintain high-quality customer support, or a market perception that we do not maintain high-quality customer support, could adversely affect our reputation and our ability to sell our Talis One system. We may also be subject to warranty claims or breach of contract for damages related to errors, defects or reliability issues in our products.

Further, our products are designed to be used at the customer's location by untrained personnel. We cannot provide assurance that our customers will always use our products in the manner in which we intend. Any intentional or unintentional misuse of our products by our customers could lead to substantial civil and criminal monetary and non-monetary penalties, and could cause us to incur significant legal and investigatory fees.

If our products do not perform, or are perceived to not have performed, as expected or favorably in comparison 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.

Additionally, many of the pathogens for which we are developing tests are known to mutate over time. Such mutations may negatively affect the accuracy of our tests or even make our tests obsolete. The failure of our products to perform as expected could significantly impair our operating results and our reputation, including if we become subject to legal claims arising from any defects or errors in our products or test results.

Operational, technical and other difficulties adversely affecting test performance may harm our reputation, impact the commercial attractiveness of our products, increase our costs or divert our resources, including management's time and attention, from other projects and priorities. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

Our products may be subject to recalls in the future. A recall of products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA has the authority to require the recall of commercialized products that are subject to FDA regulation. Manufacturers may, also, under their own initiative, recall a product or service if any deficiency is found. For reportable corrections and removals, companies are required to make additional periodic submissions to the FDA after initiating the recall, and often engage with the FDA on their recall strategy prior to initiating the recall. A government-mandated or voluntary recall by us or a distributor could occur as a result of an unacceptable health risk, component failures, malfunctions, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our commercialized products would divert managerial and financial resources and adversely affect our business, results of operations, financial condition and reputation. A recall of Talis One instruments could be required for any number of problems. Given the number of components, determining the cause of the malfunction may be particularly challenging and costly. In addition, any recall of Talis One instruments would decrease the market for our authorized tests given the decreased availability of such instruments. We may also be subject to liability claims, be required to bear other costs or take other actions that may negatively impact our future sales and our ability to generate profits. Companies are also required to maintain certain records of corrections and removals, even if these do not require reporting to the FDA. We may initiate voluntary recalls involving our commercialized products. The FDA or other agency could take enforcement action for failing to report the recalls when they were conducted. In addition, if we are required to make changes to our products to redress the deficiencies leading to the recall, we may be required to seek marketing authorization for the modified device prior to commercializing it. Any recall announcement by us or a governmental authority, or any changes that we make to our products as a result of such recall, could harm our reputation with customers and negatively affect our business, financial condition, and results of operations.

If we initiate a recall, including a correction or removal, for one of our commercialized products, issue a safety alert, or undertake a field action or recall to reduce a health risk, this could lead to increased scrutiny by the FDA, other governmental and regulatory enforcement bodies, and our customers regarding the quality and safety of our products, and to negative publicity, including FDA

alerts, press releases, or administrative or judicial actions. Furthermore, the submission of these reports could be used against us by competitors and cause customers to delay purchase decisions or cancel orders, which would harm our reputation.

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

We anticipate continued growth in our business operations both inside and outside the United States. Any future growth could create strain on our organizational, administrative, and operational infrastructure, including quality control, customer service, and sales force management. Our ability to manage our growth properly will require us to continue to improve our operational, financial, and managerial controls, as well as our reporting systems and procedures.

The COVID-19 pandemic and current lack of available testing, at the point-of-care, means there is currently significant demand for accurate point-of-care COVID-19 tests. If we receive an EUA, we intend to meet as much of this demand as we can, and are currently undertaking rapid growth in all aspects of our business. We anticipate that such activities will increase as we build out a commercial operation. If we are able to successfully commercialize our products, we will need to incorporate new equipment, implement new technology systems, automate equipment processes, obtain additional facilities, hire new personnel with different qualifications, and procure additional manufacturing capabilities to allow us to further develop and manufacture new and existing tests. In addition, following the initial commercial launch, if our volume grows and our test menu expands, if authorized, we expect that we will need to continue to implement customer service, billing, and general process improvements and expand our internal quality assurance program to support increased demand. Customer service could prove to be particularly important given the lack of experience our potential customers will have with our products. While we are currently undertaking the construction of new facilities and improvements to our facilities as part of our rapid growth, such construction may be delayed for reasons that are outside of our control. As a result of the foregoing, there is no assurance that any necessary increases in scale, expansion of personnel, equipment, facilities software and computing capacities, or process enhancements will be successfully implemented.

Further, the challenges of addressing the demand for COVID-19 tests due to the pandemic is exacerbated by the fact that we are currently a pre-commercial company. If we receive an EUA for our Talis One system, we expect to sell our instrument and test for the first time during the crisis. We do not have processes, procedures, or models in place to forecast, predict or manage demand for our products or for ancillary functions such as customer service, technological support, and billing. This inexperience could expose us to several risks. For example, it could make it more likely that we mismanage inventory or distribution, resulting in expired or otherwise unusual products or components of our products. In addition, we do not currently have any experience in selling our instrument or tests, to date. Furthermore, in the event that demand for our products were to exceed our initial ability to supply our products, we may initially prioritize the wrong customers, the wrong type of customer, or the wrong geographic areas, any of which will have a negative impact on our potential revenue.

In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, which will adversely affect our business, financial condition and results of operations.

Due to our limited financial resources, we may not be able to manage the expansion of our operations or recruit and train additional qualified personnel in an effective manner. Failure to manage this growth could result in higher costs, declining quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products and could damage our reputation, which in turn could have a material adverse effect on our business, financial condition and results of operations.

The diagnostic testing industry is subject to rapid change, which could make our current or future products obsolete.

Our industry is characterized by rapid changes, including technological and scientific breakthroughs, frequent new product introductions and enhancements and evolving industry standards, all of which could make our current products and the other products we are developing obsolete. Concerns about obsolescence could make it particularly difficult to successfully deploy our Talis One system to a sufficiently broad customer base to enable us to profitably sell our authorized tests in the future. Our future success will depend on our ability to keep pace with the evolving needs of customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of scientific and technological advances. We must continuously enhance our Talis One system and develop new tests to keep pace with evolving standards of care. If we do not update our products to reflect new scientific knowledge our products could become obsolete and sales of our current products and any new products we develop could decline or fail to grow as expected.

If we are unable to establish sales and marketing and customer support capabilities or enter into agreements with third parties to sell and market our current or future products, we may not be successful in commercializing our current or future products, if and when they are approved, and we may not be able to generate any revenue.

We do not currently have a sales or marketing infrastructure and have limited experience in the sales, marketing, customer support or distribution of medical devices. To achieve commercial success for any product for which we retain sales and marketing responsibilities, we must build our sales, marketing, customer support, managerial and other capabilities or make arrangements with third parties to perform these services. We recently hired a Chief Commercial Officer, a VP, Enterprise Sales, a National Sales Director, and sales force. We are currently planning to establish internal sales and marketing teams to address the COVID-19 test opportunity if we receive an EUA for our Talis One system and anticipate that this will require significant near-term hiring.

There are risks involved with both establishing our own sales and marketing and customer support capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of the Talis One system with COVID-19 assay kit or for any future authorized test for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our current or future products on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to enterprise accounts, institutions and/or physicians or educate adequate numbers of these customers on the benefits of ordering our products;
- the initial lack of multiple testing menus to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing, customer support and distribution services, our revenues or the profitability of these revenues to us are likely to be lower than if we were to market and sell any current or future products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our current or future products or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our current or future products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our current or future products. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

We may rely on a small number of customers for a significant portion of our revenue, which may materially adversely affect our financial condition and results of operations.

Our initial sales and marketing strategy is focused on enterprise accounts, including, urgent care chains that serve on the front lines of COVID-19 diagnosis, needing millions of rapid tests to triage symptomatic patients, traditional medical establishments, including hospitals, ambulatory surgery centers, cancer treatment and dialysis centers, independent practice associations, accountable care organizations, and public health clinics that need rapid and high-quality testing to best serve their patients and non-traditional establishments, including schools, the travel industry, and workplaces. Given the number of Talis One instruments we initially expect to have available for sale following any authorization, such strategy, may result in a customer base that is, initially, concentrated among one or a few customers. There are risks whenever a large percentage of total revenues are concentrated with a limited number of payers and customers. It is not possible for us to predict the level of demand for our diagnostic tests and services that will be generated by any of these customers in the future. If these largest customers were to significantly reduce their use of our instrument, leading to fewer cartridge sales than we are forecasting, it would have a material adverse effect on our business, financial condition and results of operations and could cause significant fluctuations in our results of operations.

Our sales cycle may be lengthy and variable, which may make it difficult for us to forecast revenue and other operating results.

We expect that our enterprise account sales process will involve numerous interactions with multiple individuals within any given organization, and often includes in-depth analysis by potential customers of our products, performance of proof-of-principle studies, preparation of extensive documentation and a lengthy review process. As a result of these factors and the budget cycles of our customers, the time from initial contact with a potential enterprise customer to our receipt of a purchase order may vary significantly and be many months or longer. Given the length and uncertainty of this expected sales cycle, we may experience, fluctuations in our product revenue on a period-to-period basis.

We may not successfully implement our strategy to provide customers access to our system *through alternative non-direct capital sales channels, including our planned reagent rental program or other sales and marketing practices.*

Our ability to execute our growth strategy depends upon our ability to drive adoption of the Talis One system. In addition to direct capital sales of our instrument, we intend to implement methods for customers to access to our system through alternatives such as the rental of our instrument or a promotional instrument placement instead of purchase. Our ability to execute on these programs is unproven. We cannot assure you that we will be successful in developing a rental or placement program nor that it will gain market acceptance. Our failure to execute on these strategies will cause us to be dependent on capital equipment sales and may hinder or delay adoption of our system.

If our current or future products are not competitive in their intended markets, we may be unable to increase or sustain our revenues or achieve profitability.

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. Due to the significant interest and growth in diagnostics, we expect ongoing intense competition.

We anticipate facing competition primarily from centralized laboratories and diagnostic companies offering both point-of-care and at-home solutions. Competitors include those offering molecular, antibody and antigen tests. Competitors in the reference lab category include Laboratory Corporation of America Holdings (commonly referred to as LabCorp) and Quest Diagnostics Incorporated, along with many hospital laboratories. Competitors with point-of-care molecular diagnostic technology platforms that are either currently available or that are in development include Abbott Laboratories, Binx Health, Inc., Cepheid (a subsidiary of Danaher Corporation), Cue Health Inc., Lucira Health, Inc., Mesa Biotech, Inc. (recently acquired by Thermo Fischer Scientific Inc.), Roche Molecular Systems, Inc., and Visby Medical, Inc. Each of the preceding companies have received an EUA for a point-of-care COVID-19 test. In addition, BioFire Diagnostics, LLC has received FDA marketing authorization under the *do novo* review pathway for its Respiratory Panel 2.1 There are also smaller or earlier-stage companies developing tests that may also prove to be significant competitors, in the COVID-19 market or in the women's health and/or sexual health markets. Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, regulatory clearance approval and compliance, and sales and distribution than we do. Mergers and acquisitions involving diagnostics companies may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies or customer networks. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize diagnostic products or services that are more accurate, more convenient to use or more cost-effective than our products or services. Our competitors also may obtain FDA or other regulatory clearance or approval for their products more rapidly than we may obtain clearance or approval or other marketing authorizations for ours, which could result in our competitors establishing a strong market position before we are able to enter a particular market.

Further, some of our competitors' products are sold at prices that are lower than our anticipated pricing, which could cause sales of our products to decline or force us to reduce our prices, which would harm our revenues, operating income or market share. If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability.

To remain competitive, we must continually research and develop improvements to our products. However, we cannot assure you that we will be able to develop and commercialize the improvements to our products on a timely basis. Our competitors may develop and commercialize competing or alternative products and improvements faster than we are able to do so, which would negatively affect our ability to increase or sustain our revenue or achieve profitability.

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

Our estimates of the annual addressable markets for our COVID-19 test and the additional tests under development are based on a number of internal and third-party estimates as well as the assumed rates at which such products will be reimbursed, or the assumed prices at which we can sell our products 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, including as a result of factors outside our control, thereby reducing the predictive accuracy of these underlying factors. Specifically, with respect to the market for our COVID-19 test, the market and competitive landscape are continuously changing. Any number of factors that are outside of our control could make our estimates invalid including the development and distribution of a safe and effective vaccine and/or effective therapies and interventions for COVID-19. Three vaccines for COVID-19 were authorized for emergency use by the FDA in as of June 30, 2021. There can be no assurance that demand for our COVID-19 testing will continue to exist in the future due to successful containment efforts, the successful vaccination of a majority of Americans, or due to other events. If the actual number of patients who would benefit from our products, the price at which we can sell future products or the annual addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business, financial condition and results of operations.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For instance, legal, political and economic uncertainty surrounding the exit of the United Kingdom from the European Union (EU) may be a source of instability in international markets, adversely affect our operations in the EU and United Kingdom and pose additional risks to our business, financial condition, and results of operations. A severe or prolonged global economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our manufacturers and suppliers, possibly resulting in supply disruption. 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 are highly dependent on our senior management team and key personnel, and if we are unable to recruit, train and retain key personnel, we may not achieve our goals.

Our future success depends on our ability to recruit, develop, retain and motivate key personnel. The loss of members of our senior management, research and development, science and engineering, manufacturing and sales and marketing teams could result in delays in product development and harm our business.

We do not maintain fixed-term employment contracts or key man life insurance with any of our employees. Competition for qualified personnel is intense. The life sciences industry as a whole has been challenged by shortages of qualified technical personnel, especially those with experience in infectious disease and/or *in vitro* diagnostics, resulting in increased competition for new hires and increased employee turnover. Our growth depends, in particular, on attracting, retaining and motivating highly skilled sales personnel with the necessary clinical background and ability to understand our systems at a scientific and technical level. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract, develop, retain and motivate qualified personnel could materially harm our operating results and growth prospects.

If we were sued for product liability or professional liability, we could face substantial liabilities that exceed our resources.

The marketing, sale, and use of our products could lead to the filing of product liability claims were someone to allege that our products identified inaccurate or incomplete information regarding their infections, or otherwise failed to perform as designed. We may also be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon the information we provide in the ordinary course of our business activities. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

We maintain product liability and professional liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could damage our reputation, which could impact our results of operations.

We depend on our information technology and telecommunications systems, and those of our third-party service providers, contractors and consultants, and any failure of these systems could harm our business.

We depend on our information technology and telecommunications systems and those of our third-party service providers, contractors and consultants for significant elements of our operations. We have installed and are expanding a number of enterprise software systems that affect a broad range of business processes and functional areas, including, for example, systems handling human resources, financial controls and reporting, contract management, and other infrastructure operations. These information technology and telecommunications systems support a variety of functions. In addition, our third-party service providers depend upon technology and telecommunications systems provided by outside vendors.

Despite the implementation of preventative and detective security controls, such information technology and telecommunications systems are vulnerable to damage or interruption from a variety of sources, including telecommunications or network failures or interruptions, system malfunction, natural disasters, malicious human acts, terrorism and war. Failures or significant downtime of our information technology or telecommunications systems, or those used by our third-party service providers, contractors or consultants could prevent us from conducting our comprehensive genomic analyses, preparing and providing reports and data to clinicians, handling customer inquiries, conducting research and development activities, and managing the administrative aspects of our business.

If the information technology systems of our third-party service providers and other contractors and consultants become subject to disruptions, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. 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, financial condition and results of operations.

Security breaches, loss of data, and other disruptions of our or our third-party service providers' information technology or telecommunications systems could result in a material disruption of our business and expose us to reputational damage and substantial liability.

In the ordinary course of our business, we and our third-party service providers will collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of and share (Process or Processing)sensitive data, including legally protected health information (PHI), personally identifiable information, intellectual property and proprietary business information owned or controlled by us or our customers. In addition, we offer online customer-facing portals accessible through public web portals. It is critical that we Process sensitive data in a secure manner to maintain the confidentiality and integrity of such confidential information. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems, and cloud-based data center systems. These applications and related data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information.

Cyberattacks, denial-of-service attacks, ransomware attacks, business email compromises, computer malware, viruses, social engineering (including phishing) and other malicious internet-based activity are prevalent in our industry and our customers' industries and continue to increase. In addition, we may experience attacks, unavailable systems, unauthorized access or disclosure due to employee or other theft or misuse, denial-of-service attacks, sophisticated attacks by nation-state and nation-state supported actors, and advanced persistent threat intrusions. Although we take measures to protect such information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party service providers may be vulnerable to attacks by hackers or malicious software, physical break-ins or breaches due to inadvertent or intentional actions by our employees, third-party service providers, and/or other third parties, malfeasance or other disruptions. We cannot guarantee that the recovery systems, security protocols, network protection mechanisms and other security measures that we have integrated into our systems, networks and physical facilities, which are designed to protect against, detect and minimize security breaches, will be adequate to prevent or detect service interruption, system failure data loss or theft, or other material adverse consequences. No security solution, strategy, or measures can address all possible security threats or block all methods of penetrating a network or otherwise perpetrating a security incident. We also face the ongoing challenge of managing access controls to our information technology systems. If we do not successfully manage these access controls, it further exposes us to risk of security breaches or disruptions. Any such security breaches or disruptions could compromise the security or integrity of our networks or result in the loss, misappropriation, and/or unauthorized access, use, modification or disclosure of, or the prevention of access to, sensitive data or confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information). For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. If our or our vendors' information systems are breached, sensitive data are compromised, surreptitiously modified, rendered inaccessible for any period of time or maliciously made public, or if we fail to make adequate or timely disclosures to the public or law enforcement agencies following any such event, whether due to delayed discovery or a failure to follow existing protocols, it could result in significant fines, penalties, orders, sanctions and proceedings or actions against us by governmental bodies or other regulatory authorities, clients or third parties. Any of the foregoing could result in significant legal and financial exposure and reputational damages that could potentially have a material adverse effect on our business, financial condition, results of operations and prospects.

Cyber-attacks are increasing in frequency and evolving in nature. We are at risk of attack by a variety of adversaries, including state-sponsored organizations, organized crime, hackers or “hacktivists” (activist hackers), through the use of increasingly sophisticated methods of attack, including long-term, persistent attacks referred to as advanced persistent threats. The techniques used to obtain unauthorized access or sabotage systems include, among other things, computer viruses, malicious or destructive code, ransomware, social engineering attacks (including phishing and impersonation), hacking and denial-of-service attacks. Furthermore, these techniques change frequently, and we may be unable to implement adequate preventative measures or stop security breaches while they are occurring. The recovery systems, security protocols, network protection mechanisms and other security measures that we have integrated into our applications, systems, networks and physical facilities, which are designed to protect against, detect and minimize security breaches, may not be adequate to prevent or detect service interruption, system failure or data loss. Third parties may also exploit vulnerabilities in, or obtain unauthorized access to, platforms, applications, systems, networks and/or physical facilities utilized by our vendors. We have previously been, and may in the future become, the target of cyber-attacks by third parties seeking unauthorized access to our or our customers’ data or to disrupt our operations or ability to provide our services. For example, we have been subject to phishing incidents and we may experience additional incidents in the future. Our applications, systems, networks and physical facilities are also subject to compromise from internal threats, such as theft, misuse, unauthorized access or other improper actions by employees, vendors and other third parties with otherwise legitimate access to our systems. Given the unpredictability of the timing, nature and scope of information technology disruptions, there can be no assurance that any security procedures and controls that we or our third-party service providers have implemented will be sufficient to prevent cyber-attacks from occurring. The latency of a compromise is often measured in months, but could be years, and we may not be able to detect a compromise in a timely manner. New techniques may not be identified until they are launched against a target, and we may be unable to anticipate these techniques or detect an incident, assess its severity or impact, react or appropriately respond in a timely manner or implement adequate preventative measures, resulting in potential data loss or other damage to our information technology systems.

As the breadth and complexity of the technologies we use and the software and instruments we develop continue to grow, the potential risk of security breaches and cyber-attacks also increases. Our policies, employee training (including phishing prevention training), procedures and technical safeguards may be insufficient to prevent or detect improper access to confidential, proprietary or sensitive data, including personal data. In addition, the competition for talent in the data privacy and cybersecurity space is intense, and we may be unable to hire, develop or retain suitable talent capable of adequately detecting, mitigating or remediating these risks. As cybersecurity threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. The inability to implement, maintain and upgrade adequate safeguards could have a material adverse effect on our business.

We expect that we may have numerous vendors and other third parties who receive personal data from us in connection with the products we offer our customers. In addition, we have migrated certain data, and may increasingly migrate data, to a cloud hosted by third-party vendors. Some of these vendors and third parties also have direct access to our systems. Due to applicable laws and regulations or contractual obligations, we may be held responsible for any information security failure or cyber-attack attributed to our vendors as they relate to the information we share with them. In addition, because we do not control our vendors and our ability to monitor their data security is limited, we cannot ensure the security measures they take will be sufficient to protect confidential, proprietary, or sensitive data, including personal data, or prevent cyber-attackers from gaining access to our infrastructure or data through our vendors or other third parties.

Regardless of whether an actual or perceived cyber-attack is attributable to us or our third-party service providers, such an incident could, among other things, result in improper disclosure of information, harm our reputation and brand, reduce the demand for our products, lead to loss of customer confidence in the effectiveness of our security measures, disrupt normal business operations or result in our systems or products being unavailable. The costs to respond to a security breach and/or to mitigate any security vulnerabilities that may be identified could be significant, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service, negative publicity, and other harm to our business and our competitive position. We could be required to fundamentally change our business activities and practices in response to a security breach or related regulatory actions or litigation, which could have an adverse effect on our business.

We have contractual and legal obligations to notify relevant stakeholders of security breaches. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of security breaches involving certain types of data. In addition, our agreements with certain customers and partners may require us to notify them in the event of a security breach involving customer or partner data on our systems or those of subcontractors Processing customer or partner data on our behalf. Such mandatory disclosures are costly, could lead to negative publicity, may cause our customers to lose confidence in the effectiveness of our security measures, and require us to expend significant capital and other resources to respond to or alleviate problems caused by the actual or perceived security breach may cause us to breach customer contracts. Depending on the facts and circumstances of such an incident, it may require us to spend material resources to investigate or correct the breach and to prevent future security breaches and incidents. The costs related to significant security breaches or disruptions could be material and exceed the limits of any cybersecurity insurance we maintain, increase our risk of regulatory scrutiny, expose us to legal liabilities, including litigation, regulatory enforcement,

indemnity obligations or damages for contract breach, divert the attention of management from the operation of our business and cause us to incur significant costs, any of which could affect our financial condition, operating results and our reputation. Moreover, there could be public announcements regarding any such incidents and any steps we take to respond to or remediate such incidents, and if securities analysts or investors perceive these announcements to be negative, it could, among other things, have a substantial adverse effect on the price of our common stock. Such an event also could harm our reputation and result in litigation against us. In addition, our remediation efforts may not be successful. Any of the foregoing events could have a material adverse effect on our business, financial condition and results of operations.

Our agreements may require us to use industry-standard, reasonable, or other specified measures to safeguard sensitive personal information or confidential information, and any actual or perceived breach of such measures may increase the likelihood and frequency of audits under our agreements, which is likely to increase the costs of doing business. An actual or perceived security breach could lead to claims by relevant stakeholders that we have failed to comply with such legal or contractual obligations. As a result, we could be subject to legal action or our customers or partners could end their relationships with us. There can be no assurance that any limitations of liability in our contracts, which we have in certain agreements, would be enforceable or adequate or would otherwise protect us from liabilities or damages.

Litigation resulting from security breaches may adversely affect our business. Unauthorized access to our applications, systems, networks, or physical facilities could result in litigation with our customers, partners, or other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, or adversely affect our reputation. We could be required to fundamentally change our business activities and practices in response to such litigation, which could have an adverse effect on our business. If a security breach were to occur, and the confidentiality, integrity or availability of our data or the data of our partners or our customers was disrupted, we could incur significant liability, or our applications, systems, or networks may be perceived as less desirable, which could negatively affect our business and damage our reputation. If we fail to detect or remediate a security breach in a timely manner, or a breach otherwise affects a large amount of data of one or more customers, or if we suffer a cyberattack that impacts our ability to operate our business, we may suffer material damage to our reputation, business, financial condition, and results of operations. Further, we may not have adequate insurance coverage for security incidents or breaches, including fines, judgments, settlements, penalties, costs, attorney fees and other impacts that arise out of incidents or breaches. Depending on the facts and circumstances of such an incident, the damages, penalties and costs could be significant and may not be covered by insurance or could exceed our applicable insurance coverage limits. If the impacts of a security incident or breach, or the successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), it could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to all or part of any future claim or loss. Our risks are likely to increase as we continue to expand our business, grow our customer base, and Process, store, and transmit increasingly large amounts of proprietary and sensitive data.

We or the third parties upon whom we depend may be adversely affected by power outages, earthquakes, fires, health pandemics or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our facilities are located in areas, which have experienced severe earthquakes and fires and are at risk for rolling or prolonged power outages. If these earthquakes, fires, other natural disasters, power outages health pandemics or epidemics, terrorism and similar unforeseen events beyond our control, including for example the ongoing COVID-19 pandemic, prevented us from using all or a significant portion of our facilities, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time and/or could result in the loss of commercial inventory or inventory and supplies required for our clinical trials. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

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

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

- failure by us or our distributors to obtain regulatory clearance, authorization or approval for the use of our products in various countries;
- 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, anti-corruption laws, regulatory requirements, reimbursement or payor regimes and other governmental approvals, permits and licenses;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining intellectual property protection and maintaining, defending and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- employment risks related to hiring employees outside the United States;
- 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 sell our products 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 exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- 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 U.S. Foreign Corrupt Practices Act (FCPA), its books and records provisions, or its anti-bribery provisions, or laws similar to the FCPA in other jurisdictions in which we may now or in the future operate, such as the United Kingdom's Bribery Act of 2010 (U.K. Bribery Act); and
- onerous anti-bribery requirements of several member states in the EU, the United Kingdom, and other countries that are constantly changing and require disclosure of information to which U.S. legal privilege may not extend.

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

We may never obtain authorization to market our tests in any other foreign country for any of our products and, even if we do, we may never be able to commercialize them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to eventually market any of our products in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding quality, safety, performance 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. For example, the performance characteristics of our products may need to be validated separately in specific ethnic and genetic populations. Marketing authorization 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 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 have no 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 will be unrealized.

We may not have adequate insurance coverage.

We may not have adequate insurance coverage. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Performance issues, service interruptions or price increases by our shipping carriers and warehousing providers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.

Expedited, reliable shipping and delivery services and secure warehousing are essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our diagnostic tests to our customers and for tracking of these shipments, and from time to time require warehousing for our diagnostic tests, sample collection kits and supplies. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our diagnostic tests and increased cost and expense to our business. In addition, any significant increase in shipping or warehousing rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters, civil unrest and disturbances or other service interruptions affecting delivery or warehousing services we use would adversely affect our ability to process orders for our diagnostic tests on a timely basis.

We have entered into licenses, collaborations and strategic alliances, and may enter into additional arrangements like these in the future, and we may not realize the anticipated benefits of such arrangements.

The development and potential commercialization of products will require substantial additional capital to fund expenses. We may form or seek further strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to any products that we may develop and commercialize, including in territories outside the United States. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or in-license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, or if there are materially adverse impacts on our or the counterparty's operations resulting from COVID-19, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement.

Additionally, we sometimes collaborate with academic institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

Further, rights to certain of the components and technology incorporated into our products are, and in the future, may be held by others, such as one of our suppliers, thinXXS. We may be unable to in-license any rights to components, methods of use, processes or other third party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, or if we lose access to components or technologies controlled by others, we may be required to expend significant time and resources to develop or license replacement technology. Any such redevelopment or any delays in entering into new collaborations or strategic partnership agreements related to our technologies could delay the development and commercialization of our products in certain geographies, which could harm our business prospects, financial condition, and results of operations.

We may acquire other businesses, which could require significant management attention, disrupt our business, dilute stockholder value and adversely affect our results of operations.

We may in the future make additional acquisitions or investments in complementary companies, diagnostic tests or technologies that we believe fit within our business model and can address the needs of our customers and potential customers. In the future, we may not be able to acquire and integrate other companies, diagnostic tests or technologies in a successful manner. We may not be able to find suitable acquisition candidates, and we may not be able to complete such acquisitions on favorable terms, if at all. In addition, the pursuit of potential acquisitions may divert the attention of management and cause us to incur additional expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. If we do complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals, including increases in revenue, and any acquisitions we complete could be viewed negatively by our customers, investors and industry analysts.

Future acquisitions may reduce our cash available for operations and other uses and could result in amortization expense related to identifiable assets acquired. We may have to pay cash, incur debt or issue equity securities to pay for any such acquisition, each of which could adversely affect our financial condition or the value of our common stock. The sale or issuance of equity to finance any such acquisitions would result in dilution to our stockholders. The incurrence of indebtedness to finance any such acquisition would result in fixed obligations and could also include covenants or other restrictions that could impede our ability to manage our operations. In addition, our future results of operations may be adversely affected by the dilutive effect of an acquisition, performance earn-outs or contingent bonuses associated with an acquisition. Furthermore, acquisitions may require large, onetime charges and can result in increased debt or contingent liabilities, adverse tax consequences, additional stock-based compensation expenses and the recording and subsequent amortization of amounts related to certain purchased intangible assets, any of which items could negatively affect our future results of operations. We may also incur goodwill impairment charges in the future if we do not realize the expected value of any such acquisitions.

Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

Risks related to regulatory matters

We intend to seek to market our products for point-of-care clinical diagnostic use and will be required to obtain marketing authorizations before they can be marketed. Any such regulatory process would be expensive, time-consuming and uncertain both in timing and in outcome. If we fail to obtain or maintain necessary marketing authorizations, or if such authorizations for future products are delayed or not issued, it will negatively affect our business, financial condition and results of operations.

While we are focused initially on the development of the Talis One system with COVID-19 assay kit, pursuant to an EUA, our strategy is to expand our product line to encompass products that are intended to be used as point-of-care diagnostics for a variety of infectious diseases. Such products will be subject to regulation by the FDA as medical devices, including requirements for regulatory clearance or approval of such products before they can be marketed. Accordingly, we will be required to obtain marketing authorization in order to sell our future products in a manner consistent with FDA laws and regulations. Such processes are expensive, time-consuming and uncertain; our efforts may never result in any marketing authorization; and failure by us to obtain or comply with such marketing authorizations could have an adverse effect on our business, financial condition or operating results.

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our Talis One system and any tests we propose for use with it, are substantially equivalent to a legally marketed predicate device or safe or effective for their proposed intended uses, or meet other standards required to obtain relevant marketing authorizations;
- the disagreement of the FDA with the design or implementation of any clinical trials or the interpretation of data from preclinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from preclinical studies or clinical trials may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;

- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will be found compliant in connection with any future regulatory inspections. Moreover, the FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by any such agency, which may include any of the following sanctions:

- adverse publicity, warning letters, untitled letters, it has come to our attention letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure;
- operating restrictions, partial suspension or total shutdown of production;
- denial of our requests for regulatory clearance or PMA approval or other marketing authorization of new products, new intended uses or modifications to existing products;
- withdrawal of marketing authorization that have already been granted; or
- criminal prosecution.

If any of these events were to occur, it would negatively affect our business, financial condition and results of operations.

In addition, a CLIA-waived designation by the FDA is required for our products to be used at the point-of-care, and outside of the clinical laboratory setting. Laboratory tests regulated under CLIA are categorized by the FDA as waived, moderate complexity or high complexity based on set criteria. Tests that are waived by regulation, or cleared, approved, or otherwise authorized by the FDA for home use or a point-of-care test, are deemed waived following marketing authorization. Otherwise, a manufacturer of a test categorized as moderate complexity may request categorization of the test as waived through a CLIA Waiver by Application submission to the FDA. The manufacturer must provide evidence to the FDA that a test meets the CLIA statutory criteria for waiver, including, among other things, that the test employs methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible. When a test is categorized as waived, it may be performed by laboratories with a Certificate of Waiver, which is issued by the Centers for Medicare & Medicaid Services (CMS), the federal agency responsible for the oversight of clinical laboratories, which includes issuing waiver certificates. If we fail to obtain, or experience significant delays in obtaining, a waiver approval by the FDA for our tests, our tests will only be able to be performed by CLIA certified and state licensed laboratories, which may limit our commercial success and have an adverse effect on our business, financial condition or operations.

Our commercial success could be compromised if our customers do not receive coverage and adequate reimbursement for our products, if authorized for marketing.

The potential end-users of our Talis One system and diagnostic tests include urgent care chains that serve on the front lines of COVID-19 diagnosis, needing millions of rapid tests to triage symptomatic patients; and traditional medical establishments including hospitals, ambulatory surgery centers, independent practice associations, accountable care organizations, and public health clinics that need rapid and high-quality testing to best serve their patients. If these end-users do not receive adequate reimbursement for the cost of our products from their patients' healthcare insurers or payors, the use of our products could be negatively impacted. Furthermore, the net sales of our products could also be adversely affected by changes in reimbursement policies of government or private healthcare payors.

Due to the overall escalating cost of medical products and services, especially in light of the COVID-19 outbreak and its straining of healthcare systems across the globe, there is increased pressure on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in the United States, available levels of reimbursement may change for our products, if authorized for marketing. Third-party reimbursement and coverage may not be available or adequate in either the United States or international markets, current reimbursement amounts may be decreased in the future and future legislation, and regulation or reimbursement policies of third-party payors, may reduce the demand for our products or our ability to sell our products on a profitable basis.

In the United States, if our products receive clearance or approval from the FDA, we expect that our customers will use standard industry billing codes, known as CPT codes, to bill for our tests. If these codes were to change, there is a risk of an error being made

in the claim adjudication process. Such errors can occur with claims submission, third-party transmission or in the processing of the claim by the payer. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment received, either of which may materially impact the demand for our testing products. If we introduce new testing products, we may need to apply for new codes to describe our tests, which may not be approved or if approved, may not have adequate reimbursement rates, any of which could result in reduced demand for our tests or additional pricing pressures.

Hospitals, physicians and other healthcare providers who purchase diagnostic products in the United States generally rely on third-party payors, such as private health insurance plans, Medicare and Medicaid, to reimburse all or part of the cost of the product. Therefore, our market success is highly dependent upon government and commercial third-party payors providing coverage and adequate reimbursement for our test. While we believe our COVID-19 test will qualify for coverage that is currently available for other COVID-19 tests on the market, coverage criteria and reimbursement rates for diagnostic tests are subject to adjustment by payors, and current reimbursement rates could be reduced, or coverage criteria restricted in the future, which could adversely affect the market for our tests. In particular, the availability of coverage and adequate reimbursement may be impacted at the duration of the public health emergency period. In addition, the availability of other forms of testing in the future, such as at-home COVID-19 tests, could impact the reimbursement rate and market acceptance for our COVID-19 test.

There has been federal and state legislation and other reform initiatives regarding the coverage and reimbursement for COVID-19 diagnostic testing in response to the COVID-19 pandemic. For example, the Family First Coronavirus Response Act (FFCRA) generally requires group health plans and health insurance issuers offering group or individual health insurance to cover FDA approved COVID-19 tests and associated diagnostic costs with no cost-sharing, as long as the test is deemed medically appropriate and furnished on or after March 18, 2020 and during the applicable public health emergency period. The FFCRA also permits states to cover testing for the uninsured through Medicaid with federal financing. Additionally, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) expanded the FFCRA to include a broader range of diagnostic tests and services as well as requiring plans and issuers to cover out-of-network COVID-19 test claims at up to the cash price that the provider has posted on a public website.

CMS announced plans in March 2020 to cover the cost of COVID-19 diagnostic testing under the Medicare program and identified the amount at which it would reimburse for such tests, which has been adjusted numerous times. For example, Medicare adjusted its payment methodology effective January 1, 2021, such that it will pay $100 per test only to those laboratories that complete high throughput COVID-19 diagnostic tests within two calendar days of the specimen being collected and will only pay $75 per test to laboratories that take longer than two days to complete such test. This change is indicative of the evolving nature of the coverage and reimbursement of COVID-19 tests.

We also cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business in the future, or the effect any future legislation or regulation will have on us. Although we cannot predict the full effect of recent legislative changes, such changes individually or in the aggregate may result in decreased profits to us and/or lower reimbursement by payers for our tests, which may adversely affect our business, financial condition and results of operations.

In addition, the coverage and reimbursement market is ever changing and we are not in control of how our competitors' coverage and pricing strategies are established. Some of our competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced, less complex tests that payors and physicians could view as functionally equivalent to our products, which could force us to lower the list price of our tests and impact our operating margins and our ability to achieve and maintain profitability. In addition, technological innovations that result in the creation of enhanced diagnostic tools that are more effective than ours may enable other hospitals, physicians or medical providers to provide specialized diagnostic tests similar to ours in a more patient-friendly, efficient or cost-effective manner than is currently possible. If we cannot compete successfully against current or future competitors, we may be unable to increase or create market acceptance and sales of our products, which could prevent us from increasing or sustaining our revenue or achieving or sustaining profitability.

Modifications to our marketed products may require new EUAs, 510(k) clearances, PMA approvals, or other marketing authorizations, or may require us to cease marketing or recall the modified products until clearances, approvals, or other marketing authorizations are obtained.

Modifications to any products for which we receive clearance, approval, or other marketing authorization may require new regulatory approvals, clearances, or marketing authorizations, including 510(k) clearances or PMA approvals, or in the case of our COVID-19 test, new EUAs, or require us to recall or cease marketing the modified systems until these clearances, approvals, or other marketing authorizations are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. For a product subject to 510(k) clearance, a manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change

in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance, approval, or marketing authorization is required. If the FDA disagrees and requires new clearances, approvals, or other marketing authorizations for the modifications, we may be required to recall and to stop marketing the modified products, which could require us to seek new marketing authorizations and harm our operating results. In these circumstances, we may be subject to significant enforcement actions. Moreover, even if we seek new clearances, approvals, or other marketing authorizations for our modifications, we may not obtain clearance, approval, or other marketing authorizations in a timely manner, if at all. Obtaining clearances and approvals can be a time consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Clinical trials may be necessary to support future product submissions to the FDA. The clinical trials that may be required for our products are expensive and time-consuming, their outcome is uncertain, and if our clinical trials do not meet the stated endpoints in their evaluations, or if we experience significant delays in any of these tests or trials, our ability to commercialize our products and our financial position will be impaired.

Clinical development is a long, expensive and uncertain process with several clinical trials involved, any of which is subject to significant delays. Due to known or unknown circumstances beyond our control, it may take us several years to complete our testing, and failure can occur at any stage of testing. Delays associated with products for which we are directly conducting preclinical or clinical trials may cause us to incur additional operating expenses.

Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials. The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example:

- we may be required to submit an IDE application to the FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators and/or an Institutional Review Board (IRB), or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations (CROs), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;

- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- regulators, IRBs, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- approval policies or regulations of the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. Conducting successful clinical studies will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts.

We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice (GCP) requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

Even if we receive marketing authorization for a planned product, we and our suppliers will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

Any product for which we obtain clearance, approval, or other marketing authorization, and the manufacturing processes, post-market surveillance, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight, requirements, and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, unless exempt, we and our suppliers are required to comply with the FDA's QSR and other regulations enforced outside the United States which cover the manufacture of our products and the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of medical devices. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for an EUA, 510(k) clearance or PMA approval of new products or modified products;
- operating restrictions;
- withdrawal of EUAs, 510(k) clearances on PMA approvals that have already been granted;
- refusal to grant export approval for our products; or criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

In addition, we are required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as the QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory clearance or approval is withdrawn, it would have a material adverse effect on our business, financial condition and results of operations.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting

obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Changes in funding or disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner, or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product applications to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including for 35 days beginning on December 22, 2018, the U.S. government shut down several times and certain regulatory agencies, including the FDA, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, in March 2020 the FDA announced its intention to postpone most inspections of foreign and domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to remote interactive evaluations to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We expect to rely on third parties in conducting future clinical studies of diagnostic products that may be required by the FDA or other regulatory authorities, and those third parties may not perform satisfactorily.

We do not have the ability to independently conduct clinical trials that may be required to obtain FDA and other regulatory clearance or approval for future diagnostic products. Accordingly, we expect that we would rely on third parties, such as, laboratories, clinical investigators, CROs, consultants, and collaborators to conduct such studies if needed. Our reliance on these third parties for clinical and other development activities would reduce our control over these activities but will not relieve us of our responsibilities. We will

remain responsible for ensuring that each of our clinical studies is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us to comply with standards, commonly referred to as GCPs, for conducting, recording and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of patients in clinical studies are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to current GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, including on account of the outbreak of infectious disease, such as the COVID-19 pandemic, or otherwise, we may be affected by increased costs, program delays or both, any resulting data may be unreliable or unusable for regulatory purposes, and we may be subject to enforcement action.

If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies and contractual obligations could adversely affect our business.

We Process proprietary and sensitive data potentially including personal information, confidential information, PHI, and financial data necessary to operate our business, for legal and marketing purposes, and for other business-related purposes.

Data privacy and regulation of privacy, information security and Processing has become a significant issue in the United States, countries in Europe, and in other countries in which we operate. The legal and regulatory framework for privacy and security issues is rapidly evolving, and is expected to increase our compliance costs and exposure to liability. There are numerous state and federal laws and regulations that govern the privacy, information security, Processing and protection of individually identifiable information (Data Protection Laws), the scope of which are changing, subject to differing interpretations and may be inconsistent among countries, or conflict with other rules. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. We are or may also be subject to the terms of our privacy policies external and internal privacy and security policies, codes, representations, certifications, industry standards, publications and frameworks (Privacy Policies) and contractual obligations to third parties related to privacy, data protection, and information security and Processing, including contractual obligations to indemnify and hold harmless third parties from the costs or consequences of non-compliance with Data Protection Laws or other obligations (Data Protection Obligations). We strive to comply with applicable laws, regulations, policies, and other legal obligations relating to privacy, data protection, and information security to the extent possible. However, the regulatory framework for privacy and data protection worldwide is, and is likely to remain, uncertain for the foreseeable future, and it is possible that these or other actual or alleged obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other rules or our practices. We expect that there will continue to be new Data Protection Laws and Data Protection Obligations, and we cannot yet determine the impact such future Data Protection Obligations may have on our business. Any significant change to Data Protection Laws and Data Protection Obligations, including without limitation, regarding the manner in which the express or implied consent of customers for Processing is obtained, could increase our costs and require us to modify our operations, possibly in a material manner, which we may be unable to complete and may limit our ability to store and Process data and operate our business. Failure to comply with any of these Data Protection Laws or Data Protection Obligations could result in enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business.

As we seek to expand our business, we are, and will increasingly become, subject to various laws, regulations and standards, as well as contractual obligations, relating to the collection, use, retention, security, disclosure, transfer and other Processing of sensitive and personal information in the jurisdictions in which we operate. In many cases, these laws, regulations and standards apply not only to third-party transactions, but also to transfers of information between or among us and other parties with which we have commercial relationships. These laws, regulations and standards may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that will materially and adversely affect our business, financial condition and results of operations. The regulatory framework for data privacy, data security and data transfers worldwide is rapidly evolving and, as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. Data Protection Laws and data protection worldwide is, and is likely to remain, uncertain for the foreseeable future, and our actual or perceived failure to address or comply with these laws could: increase our compliance and operational costs; limit our ability to market our products or services and attract new and retain current customers; limit or eliminate our ability to Process data; expose us to regulatory scrutiny, actions, investigations, fines and penalties; result in reputational harm; lead to a loss of business result in litigation and liability, including class action litigation; cause to incur significant costs, expenses and fees (including attorney fees); cause a material adverse impact to business operations or financial results, and; otherwise result in other material harm to our business (Adverse Data Protection Impact).

We strive to comply with applicable Data Protection Laws, Privacy Policies and Data Protection Obligations to the extent possible, but we may at times fail to do so, or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees, partners or vendors do not comply with applicable Data Protection Laws, Privacy Policies and Data Protection Obligations. We may be subject to and suffer an Adverse Data Protection Impact if we fail (or are perceived to have failed) to comply with applicable Data Protection Laws, Privacy Policies and Data Protection Obligations, or if our Privacy Policies are, in whole or part, found to be inaccurate, incomplete, deceptive, unfair, or misrepresentative of our actual practices. In addition, any such failure or perceived failure could result in public statements against us by consumer advocacy groups, the media or others, which may cause us material reputational harm. Our actual or perceived failure to comply with Data Protection Laws, Privacy Policies and Data Protection Obligations could also subject us to litigation, claims, proceedings, actions or investigations by governmental entities, authorities or regulators, which could result in an Adverse Data Protection Impact, including required changes to our business practices, the diversion of resources and the attention of management from our business, regulatory oversights and audits, discontinuance of necessary Processing, or other remedies that adversely affect our business.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. These laws and regulations include the Health Information Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), which establishes a set of national privacy and security standards for the protection of PHI, by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates and their subcontractors with whom such covered entities contract for services that involve the creation, receipt, maintenance or transmission of PHI for or on behalf of a covered entity or another business associate. HIPAA requires covered entities and all business associates to develop and maintain policies and procedures with respect to PHI that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information and ensure the confidentiality, integrity and availability of electronic PHI. For instance, we plan to offer cloud-based portal software to help our customers more efficiently use our products. The software will maintain security safeguards that are designed to be consistent with HIPAA, as amended by HITECH, but we cannot guarantee that these safeguards will not fail or that they will not be deemed inadequate in the future. In addition, we could be subject to periodic audits for compliance with the HIPAA Privacy and Security Standards by the Department of Health and Human Services (HHS) and our customers. The HHS Office for Civil Rights may impose significant penalties on entities subject to HIPAA for a failure to comply with a requirement of HIPAA. Penalties will vary significantly depending on factors such as the date of the violation, whether the entity knew or should have known of the failure to comply, or whether the entity’s failure to comply was due to willful neglect. A single breach incident can result in violations of multiple standards. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face significant criminal penalties and imprisonment. HIPAA also authorizes state attorneys general to file suit on behalf of their residents. Courts may award damages, costs and attorneys’ fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. Additionally, if we are unable to properly protect the privacy and security of the PHI of our customers, we could be found to have breached our contracts. Determining whether PHI has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and we cannot be sure how these regulations will be interpreted, enforced or applied to our operations.

In the United States, Data Protection Laws include rules and regulations promulgated under the authority of the Federal Trade Commission, the Electronic Communications Privacy Act, the Computer Fraud and Abuse Act, the California Consumer Privacy Act of 2018, or CCPA, and other state and federal laws relating to privacy and data security. Many states in which we operate have laws that protect the privacy and security of sensitive and personal information, including health-related information. Certain of these laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, the CCPA, which increases privacy rights for California residents and imposes stringent data privacy and security obligations on companies that process their personal information, came into effect on January 1, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers about their data collection, use and sharing practices and provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CCPA has been amended from time to time, and it is possible that further amendments will be enacted, but even in its current form it remains unclear how various provisions of the CCPA will be interpreted and enforced. The CCPA may increase our compliance costs and potential liability. In addition, California voters recently approved the California Privacy Rights Act of 2020 (CPRA) that goes into effect on January 1, 2023. The CPRA would, among other things, 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. The enactment of the CCPA is prompting a wave of similar legislative developments in other states in the United States, which could create the potential for a patchwork of overlapping but different state laws. For example, Virginia has enacted the Consumer Data Protection Act and Colorado has enacted the Colorado Privacy Act, each of which may impose obligations similar to or more stringent than those we may face under other data protection laws. Compliance with any newly enacted privacy and data security laws or regulations may be challenging and cost and time-intensive, and we may be required to put in place additional mechanisms to comply with applicable legal requirements. Some observers have noted that the United States may be at the beginning of a trend toward more stringent privacy legislation, which could increase our potential liability and adversely affect our business, results of operations, and financial condition. Some countries also are considering or have passed legislation requiring local storage and Processing of data, or similar requirements, which could increase the cost and complexity of operating our business. The enactment of the CCPA is prompting a wave of similar legislative developments in other states in the United States, which could create the potential for a patchwork of overlapping but different state laws. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, and there is continuing discussion in Congress of a new federal data protection and privacy law to which we would become subject if it is enacted. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data Processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products involving data are offered, all of which may have a material and adverse impact on our business, financial condition and results of operations.

Laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other Processing of personal information, which impose significant compliance obligations. For example, in the EEA, and the United Kingdom, the Processing and use of personal data, including clinical trial data, is governed by the provisions of the GDPR, which came into effect in May 2018. The GDPR imposes stringent data privacy and security requirements on companies in relation to the Processing of personal data of data subjects within the EEA and the United Kingdom. The GDPR, together with national legislation, regulations and guidelines of the EEA member states and the United Kingdom governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, use, retain, protect, disclose, transfer and otherwise Process personal data, including health data from clinical trials and adverse event reporting. European data protection laws including the GDPR also generally prohibit the transfer of personal data from Europe, including the EEA, the United Kingdom, and Switzerland, to the United States and most other countries unless the parties to the transfer have established a legal basis for the transfer and implemented specific safeguards to protect the transferred personal data. One of the primary mechanisms allowing U.S. companies to import personal information from Europe in compliance with the GDPR has been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the U.S. Department of Commerce. However, the Court of Justice of the European Union, the “Schrems II” ruling, recently invalidated the EU-U.S. Privacy Shield framework. The Swiss Federal Data Protection and Information Commissioner also recently opined that the Swiss-U.S. Privacy Shield is inadequate for transfers of data from Switzerland to the U.S. Authorities in the United Kingdom, whose data protection laws are similar to those of the European Union, may similarly invalidate use of the EU-U.S. Privacy Shield as mechanisms for lawful personal information transfers from those countries to the United States.

The Schrems II decision also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission’s Standard Contractual Clauses, can lawfully be used for personal information transfers from Europe to the United States or most other countries. At present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses (SCCs). The European Commission recently proposed updates to the SCCs, and additional regulatory guidance has been released that seeks to imposes additional obligations on companies seeking to rely on the SCCs. As such, any transfers by us or our vendors of personal data from Europe may not comply with European data protection law; may increase our exposure to the GDPR’s heightened sanctions for violations of its cross-border data transfer restrictions and may reduce demand from

companies subject to European data protection laws. Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our products and operating our business.

Further, following a referendum in June 2016 in which voters in the United Kingdom approved an exit from the EU, the United Kingdom government has initiated a process to leave the EU, known as Brexit. Following December 31, 2020, the GDPR's data protection obligations continue to apply to the United Kingdom in substantially unvaried form under the so called "UK GDPR" or more explicitly, the GDPR continues to form part of the laws in the United Kingdom by virtue of section 3 of the European Union (Withdrawal) Act 2018, as amended (including by the various Data Protection, Privacy and Electronic Communications (EU Exit) Regulations), which potentially exposes us to two parallel data protection regimes, each of which authorizes fines and the potential for divergent enforcement actions. In addition, it is still unclear whether the transfer of personal data from the EU to the United Kingdom will in the future continue to remain lawful under the GDPR. On June 28, 2021, the European Commission issued an adequacy decision under the GDPR which allows transfers (other than those carried out for the purposes of United Kingdom immigration control) of personal data from the EEA to the United Kingdom to continue without restriction for a period of four years ending June 27, 2025. After that period, the adequacy decision may be renewed, however, only if the United Kingdom continues to ensure an adequate level of data protection. During these four years, the European Commission will continue to monitor the legal situation in the United Kingdom and could intervene at any point if the United Kingdom deviates from the level of data protection in place at the time of issuance of the adequacy decision. If the adequacy decision is withdrawn or not renewed, transfers of personal data from the EEA to the United Kingdom will require a valid 'transfer mechanism' and we may be required to implement new processes and put new agreements in place, such as SCCs, to enable transfers of personal data from the EEA to the United Kingdom to continue.

With substantial uncertainty over the interpretation and application of how United Kingdom will approach and address GDPR following the transition period, we may face challenges in addressing their requirements and making necessary changes to our policies and practices, and may incur significant costs and expenses in an effort to do so. Any failure or perceived failure by us to comply with applicable laws and regulations or any of our other legal obligations relating to privacy, data protection, or information security may result in governmental investigations or enforcement actions, litigation, claims, or public statements against us. Any of the foregoing could result in significant liability or cause our customers to lose trust in us, any of which could have an adverse effect on our reputation, operations, financial performance and business. Furthermore, the costs of compliance with, and other burdens imposed by, the laws, regulations, and policies that are applicable our businesses may require us to modify our data Processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products involving data are offered, all of which may have a material and adverse impact on our business, financial condition and results of operations.

Additionally, countries outside of Europe, including without limitation Brazil that recently enacted the General Data Protection Law, or LGPD, are implementing significant limitations on the processing of personal information similar to those in the GDPR. Other countries also are considering or have passed legislation requiring local storage, processing or security of data, or similar requirements, which could increase the cost and complexity of delivering our products.

We will make public statements about our use and disclosure of personal information through our Privacy Policies. Although we endeavor to comply with our Privacy Policies, we may at times fail to do so or be alleged to have failed to do so. The publication of our Privacy Policies can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any failure, real or perceived, by us to comply with our Privacy Policies or with any Data Protection Obligation could cause our customers to reduce their use of our products and could materially and adversely affect our business, financial condition and results of operations. In many jurisdictions, enforcement actions and consequences for non-compliance can be significant and are rising. In addition, from time to time, concerns may be expressed about whether our products or processes compromise the privacy of customers and others. Concerns about our practices with regard to the collection, use, retention, security, disclosure, transfer and other processing of personal information or other privacy-related matters, even if unfounded, could damage our reputation and materially and adversely affect our business, financial condition and results of operations.

We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation and application of health-related and data protection laws, regulations, standards and other obligations are still uncertain, and often contradictory and in flux, it is possible that the scope and requirements of these laws may be interpreted and applied in a manner that is or is alleged to be inconsistent with our management and Processing practices and our efforts to comply with the evolving Data Protection Laws and data Protection Obligations may be unsuccessful.

Any failure or perceived failure by us to comply with our Privacy Policies and our privacy-, data protection-, or information security-related obligations to customers or other third parties or any of our other legal obligations relating to privacy, data protection, or information security may result in governmental investigations or enforcement actions, litigation, claims, or public statements against

us by consumer advocacy groups or others, and could result in significant liability or cause our customers to lose trust in us, which could have an adverse effect on our reputation and business.

In addition, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Although we endeavor to comply with our Privacy Policies and other privacy-, data protection-, or information security-related obligations, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance with our Privacy Policies and other privacy-, data protection-, or information security-related obligations. Any actual or alleged inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with our Privacy Policies, applicable laws, regulations, standards and other Data Protection Obligations, could result in governmental investigations or enforcement actions, litigation, claims, or public statements against us by consumer advocacy groups or others, and could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with customers and have a material and adverse impact on our business.

Our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants, and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-United States regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, which could have a significant impact on our business. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these actions or investigations.

We may be subject to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

We and our collaborators and strategic partners may be subject to broadly applicable healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we develop, market, sell, and distribute our products. These health care laws and regulations include, for example:

- the federal Anti-Kickback Statute (AKS), which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or services for which payment may be made under a federal health care program such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal AKS or specific intent to violate it in order to have committed a violation;
- the federal civil and criminal false claims laws, such as the civil False Claims Act (FCA), which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment or approval by the federal government, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal AKS constitutes a false or fraudulent claim for purposes of the civil FCA;

- HIPAA, which established additional federal civil and criminal liability for, among other things, knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services. Similar to the federal AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payments Sunshine Act requirements under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), which require certain manufacturers of drugs, devices, biologics and medical supplies to report to the CMS, information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, and certain 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 payments and other transfers of value made to or at the request of physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including our planned reagent rental program or other sales and marketing practices, could be subject to challenge under one or more of such laws. Any action brought against us for violation of these 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, among others, significant administrative, civil and criminal penalties, damages, fines, disgorgement, imprisonment, integrity oversight and reporting obligations, and exclusion from participation in government funded healthcare programs such as Medicare and Medicaid. Additionally, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could significantly harm our business, financial condition, and results of operations. In addition, if any of the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant civil, criminal and administrative sanctions, including exclusion from government funded healthcare programs.

Legislative or regulatory reforms may make it more difficult and costly for us to obtain marketing authorization for any future products and to manufacture, market and distribute our products after marketing authorization is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the marketing authorization, manufacture and marketing of regulated products or the reimbursement thereof. In addition, the FDA may change its policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay marketing authorization of our future products under development or impact our ability to modify any then-marketed products on a timely basis. Any new regulations or revisions or reinterpretations of existing laws and regulations may impose additional costs or lengthen review times of planned or future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

For example, over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the pre-market notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA also announced that it intended to finalize guidance to establish a pre-market review pathway for "manufacturers of certain well-understood device types" as an alternative to the 510(k) clearance pathway and that such pre-market review pathway would allow manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process.

In May 2019, the FDA solicited public feedback on its plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates, including whether the FDA should publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may

work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

More recently, in September 2019, the FDA finalized the aforementioned guidance to describe an optional "safety and performance based" pre-market review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway, by demonstrating that such device meets objective safety and performance criteria established by the FDA, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA intends to maintain a list device types appropriate for the "safety and performance based pathway" and develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidances, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance or approval of our products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad.

Any change in the laws or regulations that govern the clearance and approval, or other marketing authorization, relating to our current, planned and future products could make it more difficult and costly to obtain marketing authorization for new products or to produce, market and distribute existing products. Significant delays in or the failure to receive marketing authorization for any new products would have an adverse effect on our ability to expand our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing authorization that we may have obtained and we may not achieve or sustain profitability.

The misuse or off-label use of our Talis One system *using our COVID-19 assay kit may harm our reputation in the marketplace, result in false test results that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.*

We plan to initially seek an EUA for our Talis One system with COVID-19 assay kit for the automated detection of nucleic acid from the SARS-CoV-2 virus in nasal swab samples from individuals suspected of COVID-19 by their healthcare provider. If such marketing authorization is obtained, we would not be permitted to market our Talis One system and COVID-19 assay kit for use in screening of asymptomatic populations, for use in pooling samples for testing, or for use with different specimen samples (other than nasal swab samples). Such uses would be considered "off-label." We plan to train our marketing and direct sales force to not promote the Talis One system and COVID-19 assay kit for uses outside of the FDA-authorized indications for use. We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of inaccurate results if physicians attempt to use our tests off-label. Furthermore, such off-label uses could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties, or withdrawal of any EUA or other marketing authorization we obtain. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

A significant portion of the funding for the development of our Talis One system *comes from U.S. federal government grants, and if the cognizant federal agencies were to eliminate, reduce or delay funding from our agreements, this could have a significant, negative impact on our revenues and cash flows, and we may be forced to suspend or terminate our development programs or obtain alternative sources of funding.*

We have received grant funding from the U.S. federal government, including through a grant from the NIH, National Institute of Allergy and Infectious Diseases, a sub-award from the Biomedical Advanced Research and Development Authority Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) program, a sub-award from the NIH RADx program, and an NIH RADx grant. We anticipate that a portion of the funding for the development of our technologies will come from these agreements, which provide for grant funds ultimately from the government. Our ability to receive the remaining funding provided for under the agreements is dependent on the government and the higher-tier grantees in connection with our sub-awards exercising additional options under the agreements, which they may do or not do at their sole discretion. In addition, activities covered under the base periods and exercised options may ultimately cost more than is covered by the grants and sub-awards or require a longer performance periods to complete than are remaining on our agreements; if we are unable to secure additional funding or allow for additional time for completion, we would have to incur additional costs to complete the activities or terminate the activities before completion. Moreover, the continuation of our agreements depends in large part on our ability to meet development milestones previously agreed to and on our compliance with certain operating procedures and protocols. For instance, work under the CARB-X program is subject to certain unique commercialization, regulatory approval, and access requirements related to developed products and technology, and public access to research results. These agreements may be suspended or terminated should we fail to achieve key milestones, or fail to comply with the operating procedures and processes approved by the government and its audit agencies. There can be no assurance that we will be able to achieve these milestones or continue to comply with these procedures and protocols. Moreover, changes in government budgets and agendas may result in a decreased and deprioritized emphasis on supporting the development of our programs. While the NIH has provided funding for and has indicated a potential for future funding for many activities associated with combating COVID-19, the availability and focus for any NIH funding will likely be finite and may require us to compete with other technologies, both similar and disparate. If our agreements are terminated or suspended, if there is any reduction or delay in funding under our agreements, or if the government or higher-tier grantees determine not to exercise some or all of the options provided for under the agreements, our revenues and cash flows would be significantly and negatively impacted and we may be forced to seek alternative sources of funding, which may not be available on non-dilutive terms, terms favorable to us or at all. If alternative sources of funding are not available, we may be forced to suspend or terminate certain of our related development activities. Furthermore, should we be unable to deploy personnel or derive a benefit from fixed study costs or generate data from clinical sites and studies reimbursed through the agreements, our cash flows would be negatively impacted or we may have to initiate furloughs and layoffs which would likely prove disruptive to our management and operations. This in turn would impair our ability to recommence and complete studies if and when the COVID-19 crisis subsides and we are able to restart many suspended or delayed activities.

Unfavorable provisions in government contracts, including in our grant and sub-award agreements, may harm our business, financial condition and operating results.

U.S. government contracts and grants typically contain unfavorable provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. For example, under our grant and sub-award agreements, the U.S. government and higher-tier grantees, in certain circumstances, have the power to unilaterally:

- suspend or prevent us for a set period of time from receiving new government contracts or grants or extending our existing agreements based on violations or suspected violations of laws or regulations;
- claim and exercise nonexclusive, nontransferable rights to products manufactured and intellectual property and data developed and generated under the agreements and may, under certain circumstances, license such inventions to third parties without our consent;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such contracts and grants;
- cancel, terminate or suspend our agreements based on violations or suspected violations of laws or regulations;
- terminate our agreements in whole or in part for convenience for any reason or no reason, including if funds become unavailable;
- reduce the scope and value of our agreements;
- decline to exercise an option to continue the agreements;
- direct the course of the development of the programs in a manner not chosen by us;

- require us to perform the option periods provided for under the agreements even if doing so may cause us to forego or delay the pursuit of other program opportunities with greater commercial potential;
- take actions that result in longer development timelines than expected; and
- change certain terms and conditions in our agreements.

Generally, government contracts and grants, including our grant and sub-award agreements, contain provisions permitting unilateral termination or modification, in whole or in part. Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed, plus a portion of the agreed fee (if a fee has been negotiated) and settlement expenses on the work completed prior to termination. Except for the amount of services received by the government, termination-for-default provisions do not permit recovery of fees and may subject us to damages, including reprocurement expenses. In addition, in the event of termination or upon expiration of our agreements, the U.S. government or higher-tier grantees may dispute wind-down and termination costs and may question prior expenses under the agreements and deny payment of those expenses. Should we choose to challenge those denials, such a challenge could subject us to substantial additional expenses that we may or may not recover. Further, if our agreements are terminated for convenience, or if we default by failing to perform in accordance with the schedule and terms, a significant negative impact on our cash flows and operations could result.

In addition, government contracts and grants normally contain additional requirements that may increase our costs of doing business and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- public disclosures of certain contract information, which may enable competitors to gain insights into our research program;
- mandatory internal control systems and policies; and
- mandatory socioeconomic compliance requirements, including labor standards, prioritization of subcontracts to small businesses and others, non-discrimination and affirmative action programs and environmental compliance requirements.

If we fail to maintain compliance with these requirements, we may be subject to potential liability and to the termination of our agreements.

Furthermore, we have entered into and will continue to enter into agreements and subcontracts with third parties, including suppliers, consultants and other third-party contractors, in order to satisfy our contractual obligations under our agreements. Negotiating and entering into such arrangements can be time-consuming and we may not be able to reach agreement with such third parties. Any such agreement must also be compliant with the terms of our grant and sub-award agreements. Any delay or inability to enter into such arrangements or entering into such arrangements in a manner that is non-compliant with the terms, may result in violations of our agreements.

In addition, under the agreements, the government and higher-tier grantees will regularly review our development efforts and clinical activities. Under certain circumstances, they may advise us to delay certain activities and invest additional time and resources before proceeding. If we follow such advice, overall program delays and costs associated with additional resources for which we had not planned may result. Also, the costs associated with following such advice may or may not be reimbursed under our agreement. Finally, we may decide not to follow the advice provided and instead pursue activities that we believe are in the best interests of our programs and our business, even if those would not be reimbursed under our agreement.

As a result of the unfavorable provisions in our agreements, we must undertake significant compliance activities. The diversion of resources from our development and commercial programs to these compliance activities, as well as the exercise by the U.S. government or higher-tier grantees of any rights under these provisions, could materially harm our business.

Laws and regulations affecting government contracts and grants, including our grants and sub-award agreements, make it more costly and difficult for us to successfully conduct our business. Failure to comply with these laws and regulations could result in significant civil and criminal penalties and adversely affect our business.

We must comply with numerous laws, regulations, and agency-specific policies and procedures relating to the administration and performance of our grant and sub-award agreements. Among the most significant are:

- the Federal Acquisition Regulation (FAR) and agency-specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts;

- the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the AKS, the Procurement Integrity Act, the FCA and the FCPA; and
- laws, regulations and executive orders restricting the exportation of certain products and technical data.

In addition, as a U.S. government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices, including unique accounting requirements regarding allowable and unallowable costs, and are subject to periodic audits and reviews. As part of any such audit or review, the U.S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Based on the results of its audits, the U.S. government may adjust our agreement-related costs and fees, including allocated indirect costs. This adjustment could impact the amount of revenues reported on a historic basis and could impact our cash flows under the contract prospectively. In addition, in the event the U.S. government determines that certain costs and fees were unallowable or determines that the allocated indirect cost rate was higher than the actual indirect cost rate, it would be entitled to recoup any overpayment from us as a result. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our agreements, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us, which could cause our stock price to decline. Further, as a U.S. government contractor, we are subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities as compared to private sector commercial companies. In addition, the qui tam provisions of the civil FCA authorize a private person to file civil actions on behalf of the federal and state governments and retain a share of any recovery, which can include treble damages and civil penalties.

If we or our third party manufacturing partners fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and our suppliers and manufacturers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations, and the manufacturer of our products, involve the production and use of hazardous and flammable materials and waste, including chemicals and biological and radioactive materials. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Our manufacturers are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Healthcare policy changes may have a material adverse effect on our business, financial condition and results of operations.

The ACA, enacted in March 2010, made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which the ACA may significantly impact our business, the ACA includes: provisions regarding coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures; initiatives to revise Medicare payment methodologies; and initiatives to promote quality indicators in payment methodologies.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, the legislation enacted on December 22, 2017, informally known as the Tax Cuts and Jobs Act (TCJA) repealed the tax-based shared responsibility payment imposed by the ACA, on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." Additionally, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how the any such challenges and the healthcare reform measure of the Biden administration will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers and suppliers of 2% per fiscal year, starting in 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional congressional action is taken. Furthermore, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In addition, there has been numerous governmental reform activity in response to the COVID-19 pandemic. For example, the FFCRA authorized state Medicaid programs to provide access to coverage for certain medically necessary testing, testing-related services and treatment related to COVID-19 at no cost to the individual during the emergency period. Such programs are evolving and vary among state Medicaid programs. In addition, the California Department of Health Care Services implemented a new COVID-19 Uninsured Group program on August 28, 2020. Under the program, California covers COVID-19 diagnostic testing, testing-related services, and treatment services, including hospitalization and all medically necessary care, at no cost to the individual, for up to 12 months or the end of the public health emergency, whichever comes first. It is possible that additional governmental action is taken to address the COVID-19 pandemic, which may impact our business.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us, particularly in light of the new presidential administration. However, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. The expansion of government's role in the U.S. healthcare industry as a result of the ACA's implementation, and changes to the reimbursement amounts paid by Medicare and other payors for our tests and our planned future tests, may reduce our profits, if any, and have a materially adverse effect on our business, financial condition, results of operations and cash flows.

We cannot predict the impact changes to these laws or the implementation of, or changes to, any other laws applicable to us in the future may have on our business, financial condition and results of operations.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused U.S. federal net operating losses (NOLs) for taxable years beginning before January 1, 2018, may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under the TCJA, as modified by the CARES Act, U.S. federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such U.S. federal NOLs in taxable years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the TCJA or the CARES Act.

As of December 31, 2020, we had $30.9 million of U.S. federal NOLs that were generated in 2017 and prior periods that will expire at various dates through 2033, and $84.3 million of U.S. federal NOLs that can be carried forward indefinitely under current law. As of December 31, 2020, we also had aggregate U.S. federal research and development (R&D) credits of approximately $4.2 million. Our NOL carryforwards and R&D credits are subject to review and possible adjustment by the U.S. and state tax authorities.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (Code), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards, R&D credits and certain other tax attributes to offset its post-change income or taxes may be limited. This could limit the amount of NOLs, R&D credit carryforwards or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the U.S. tax rules in respect of the utilization of NOLs, R&D credits and other applicable tax attributes carried forward may further affect the limitation in future years. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOL carryforwards to offset taxable income in tax years beginning after 2019 and before 2023. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the TCJA enacted many significant changes to the U.S. tax laws, and the CARES Act modified certain provisions of the TCJA. Future guidance from the Internal Revenue Service and other tax authorities with respect to the TCJA may affect us, and certain aspects of the TCJA could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to the TCJA or any other federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Risks related to our intellectual property

We may be, in the future, subject to claims against us alleging that we are infringing, misappropriating or otherwise violating the intellectual property rights of third parties, the outcome of which could have a material adverse effect on our business.

Our commercial success depends in part upon our ability to develop, manufacture, market and sell our products and use our technology without infringing, misappropriating or otherwise violating the patents, trademarks or other intellectual property or proprietary rights of third parties. We cannot assure you that technologies we may develop will not infringe existing or future patents owned by third parties. Litigation relating to infringement, misappropriation or other violations of intellectual property rights in biotechnology industry is common, unpredictable and generally expensive and time consuming, including patent infringement lawsuits, trade secret lawsuits, interferences, oppositions, and *inter-partes* review, post-grant review and reexamination proceedings before the United States Patent and Trademark Office (USPTO), and corresponding international patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biotechnology industry, have employed intellectual property litigation as a means to gain an advantage over their competitors. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In the future, we may also be subject to third-party claims and adversarial proceedings or litigation regarding infringement, misappropriation or other violation by us of patent, trademark or other intellectual property rights of third parties. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties. If any such claim or proceeding is brought against us, our collaborators or our third-party service providers, our development, manufacturing, marketing, sales and other commercialization activities could be similarly adversely affected. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that third party patents asserted against us are valid, enforceable, and infringed, which could materially and adversely affect our ability to develop, manufacture, market, sell and commercialize any of our products. To successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe any third party's patents or other intellectual property rights, and we are unsuccessful in demonstrating that such patents or other intellectual property are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing, marketing, selling and commercializing our products. However, we may not be able to obtain any required license on commercially reasonable terms or at all, and if we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, our ability to commercialize our

products may be impaired or delayed, which could in turn significantly harm our business. Even if we were able to obtain a license, it could be non-exclusive, which would give our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing, royalty and other payments. We also could be forced, including by court order, to cease developing, manufacturing, marketing, selling and commercializing the infringing product or technology. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

There may be third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture, or methods of use or treatment that cover our products. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to the technologies we may develop, could be found to be infringed by our technology. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our products may infringe. In addition, third parties, our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may obtain patents in the future that may prevent, limit or otherwise interfere with our ability to make, use and sell our products, and may claim that use of our technologies or the manufacture, use, or sale of our products infringes upon these patents.

Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. In addition, if the breadth or strength of protection provided by the patents and patent applications we own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technology. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays or prohibit us from manufacturing, marketing, selling or otherwise commercializing our products and technology. We may receive, and expect to receive, communications from various industry participants alleging our infringement of their patents, trade secrets or other intellectual property rights and/or offering licenses to such intellectual property.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or commercialization activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Uncertainties resulting from patent and other intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace, our ability to raise additional funds, and could otherwise have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be, in the future, involved in lawsuits to defend or enforce our patents and proprietary rights. Such disputes could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of our technology, products, prohibit our use of proprietary technology or sale of products, or put our patents and other proprietary rights at risk.

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents and intellectual property rights or the patents and intellectual property rights of our licensors. The enforcement of such claims can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. In an infringement proceeding, a court may decide that a patent owned or in-licensed by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly.

If we were to initiate legal proceedings against any other third party to enforce a patent covering our technology, the defendant could assert that our patent is invalid or unenforceable. If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering our technologies, the defendant could counterclaim we infringe their patents or that the patent covering our technology is invalid or unenforceable, or both. In patent litigation in the United States and Europe, defendants alleging invalidity or unenforceability are common. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness, lack of written description or non-enablement. Third parties might allege

unenforceability of our patents because during prosecution of the patent an individual connected with such prosecution withheld relevant information, or made a misleading statement. There is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. Third parties may also raise challenges to the validity of our patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter-partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or products and that we do not have the right to stop the other party from using the invention at issue. The outcome of proceedings involving assertions of invalidity and unenforceability, including during patent litigation, is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution, but that an adverse third party may identify and submit in support of such assertions of invalidity. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). Such a loss of patent protection could have a material adverse effect on our business. Our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights. Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of our licensors.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities, and the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or commercialization activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Uncertainties resulting from patent and other intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace, our ability to raise additional funds, and could otherwise have a material adverse effect on our business, financial condition, results of operations, and prospects. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

If we are not able to obtain, maintain, defend or enforce patent and other intellectual property protection for products, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our success depends in part on our ability to obtain, maintain, defend and enforce patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our products, as well as our ability to preserve our trade secrets, to prevent third parties from infringing, misappropriating or otherwise violating our intellectual property and proprietary rights. Our ability to protect our products from unauthorized use by third parties depends on the extent to which valid and enforceable patents cover them or they are effectively protected as trade secrets. While we have a number of issued patents in the United States and foreign countries, several aspects of our patent portfolio are in much earlier stages of prosecution in the United States and foreign countries. Moreover, we do not own or license any issued patents related to certain aspects of our products and technology, including certain structures and components used in our instruments and established molecular biology techniques. For information regarding our patent portfolio, please see "Business—Intellectual property" In our Annual Report. The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. There can be no assurance that our patent rights will not be invalidated or held to be unenforceable, will adequately protect our technology, products or provide any competitive advantage, or that any of our pending or future patent applications will issue as valid and enforceable patents. Our ability to obtain and maintain patent protection for our products is uncertain due to a number of factors, including that:

- we or our licensors may not have been the first to invent the technology covered by our pending patent applications or issued patents;
- we or our licensors may not be the first to file all patent applications covering our methods or products, as patent applications in the United States and most other countries are confidential for a period of time after filing;
- our products and related methods may not be patentable;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;
- others may independently develop identical, similar or alternative technologies;
- others may design around our patent claims to produce competitive technologies or methods or products that fall outside of the scope of our patents;
- we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection;
- parties with access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, may disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection;
- we may not seek or obtain patent protection in countries that may eventually provide us a significant business opportunity;
- any patents issued to us may not provide a basis for commercially viable products or methods, may not provide any competitive advantages or may be successfully challenged by third parties;
- the patents of others could harm our business;
- a third party may challenge our patents and, if challenged, a court may hold that our patents are invalid;
- a third party may challenge our patents in various patent offices and, if challenged, we may be compelled to limit the scope of our allowed or granted claims or lose the allowed or granted claims altogether;
- our competitors could conduct research and development activities in countries where we will not have enforceable patent rights and then use the information learned from such activities to develop competitive methods or products for sale in our major commercial markets; and
- the growing scientific and patent literature relating to molecular testing, including our own patents and publications, may make it increasingly difficult or impossible to patent new products and methods in the future.

Even if we have or obtain patents covering our products or methods, we may still be barred from making, using and selling such products or methods because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering compositions, products or methods that are similar or identical to ours, which could materially affect our ability to successfully develop our technology or to successfully commercialize any approved products alone or with collaborators. Patent applications in the U.S. and elsewhere are generally published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our methods and products could have been filed by others without our knowledge. Additionally, pending claims in patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies or related products. These patent applications may have priority over patent applications filed by us.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to third party pre-issuance submissions of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter-partes* review, or interference proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our products and technology and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products and technology, or limit the duration

of the patent protection of our products and technology. Such proceedings also may result in substantial cost and require significant time from our employees and management, even if the eventual outcome is favorable to us.

Furthermore, we cannot guarantee that any patents will be issued from any of our pending or future patent applications. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in diagnostic patents. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. While we will endeavor to protect our technology with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and sometimes unpredictable.

In addition, third parties may be able to develop technology that is similar to, or better than, ours in a way that is not covered by the claims of our patents, or may have blocking patents that could prevent us from marketing our products or practicing our own patented technology. Moreover, patents have a limited lifespan. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after it is filed and the life of a patent, and the protection it affords, is limited. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Without patent protection for current or future methods and related products, we may face competing technology. Given the amount of time required for the development and testing, and regulatory review where necessary, patents protecting such technology might expire before or shortly after such technology is commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology similar or identical to that we or our collaborators may develop.

Moreover, certain of our patents and patent applications are, and others may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third party co-owners' interest in such patents or patent applications, such co-owners may be able to use or license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We depend on intellectual property licensed from third parties and we are currently party to several in-license agreements under which we acquired rights to use, develop, manufacture and/or commercialize certain of our system *components. If we breach our obligations under these agreements or if any of these agreements is terminated, or otherwise experience disruptions to our business relationships with our licensors, we may be required to pay damages, lose our rights to such intellectual property and technology, or both, which would harm our business.*

We are dependent on patents, know-how, and proprietary technology, both our own and licensed from others. We are a party to a number of intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. For example, we have licensed technology related to frangible seals and reagent plugs in our Talis One cartridges, under an agreement with thinXXS. Our existing license agreements impose (under certain circumstances), and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, including due to the impact of the COVID-19 pandemic on our business operations or our use of the intellectual property licensed to us in an unauthorized manner, or we are subject to a bankruptcy, we may be required to pay damages and the licensor may have the right to terminate the license. Any termination of these licenses could result in the loss of significant rights and could harm our ability to develop, manufacture and/or commercialize our platform or product candidates.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

The growth of our business may depend, in part, on our ability to acquire or in-license additional proprietary rights, including to advance the development or commercialization of our products. In that event, we may be required to expend considerable time and resources to license such technology. From time to time, in order to avoid infringing third-party patents, we may be required to license technology from additional third parties to further develop or commercialize our products. We may be unable to acquire or in-license any relevant third-party intellectual property rights, including any such intellectual property rights required to manufacture, use or sell our products, that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, and as a result we may be unable to develop or commercialize the affected product candidates, and we may have to abandon development of the relevant products, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors' access to the same technologies licensed to us.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our products. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional products that we may seek to acquire.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer.

We depend, in part, on our licensors to file, prosecute, maintain, defend, and enforce patents and patent applications that are material to our business.

Patents relating to certain components of our Talis One cartridge are controlled by a third party. Such third party has rights to file, prosecute, maintain, and defend the patents we have licensed from such licensor. If our licensors or any future licensees having rights to file, prosecute, maintain, and defend patent rights that are critical to our products fail to conduct these activities, including due to the impact of the COVID-19 pandemic on our licensors' business operations, our ability to develop and commercialize our products may be adversely affected and we may not be able to prevent competitors from making, using, or selling competing products. We cannot be certain that such activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need in our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after our assuming control. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. For example, we have identified certain third party patents that may be asserted against us with respect to our technology. These patents may expire prior to commercial launch of our products, if authorized for marketing. We believe that the relevant claims of these third party patents are likely invalid or unenforceable, and we may choose to challenge those patents, though the outcome of any challenge that we may initiate in the future is uncertain. We may also decide in the future to seek a license to those third party patents, but we might not be able to do so on reasonable terms. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications in the United States and most other countries are confidential for typically a period of 18 months after filing, or may not be published at all, we cannot be certain that we were the first to file any patent application related to our product candidates. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U.S. applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the Leahy-Smith America Invents Act (AIA), which brought into effect significant changes to the U.S. patent laws, including new procedures for challenging pending patent applications and issued patents.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Obtaining and maintaining a patent portfolio entails significant expense, including periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications. These expenditures can be at numerous stages of prosecuting patent applications and over the lifetime of maintaining and enforcing issued patents. We may or may not choose to pursue or maintain protection for particular intellectual property in our portfolio. If we choose to forgo patent protection or to allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. Furthermore, we employ reputable law firms and other professionals to help us comply with the various procedural, documentary, fee payment and other similar provisions we are subject to and, in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Legal action that may be required to enforce our patent rights can be expensive and may involve the diversion of significant management time. There can be no assurance that we will have sufficient financial or other resources to file and pursue infringement claims, which typically last for years before they are concluded. In addition, these legal actions could be unsuccessful and result in the invalidation of our patents, a finding that they are unenforceable or a requirement that we enter into a licensing agreement with or pay monies to a third party for use of technology covered by our patents. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents, or have used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to successfully protect or enforce our intellectual property rights, our competitive position could suffer, which could harm our results of operations.

Some of our intellectual property has been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies, and compliance with such regulations may limit our exclusive rights and our ability to contract with non-U.S. manufacturers.

Our intellectual property rights may be subject to a reservation of rights by one or more third parties. For example, certain intellectual property rights related to structures, such as the rotor or assay chambers, within Talis One test cartridges, including the Talis One COVID-19 test cartridge were generated, at least in part, through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in the cartridges of our current or future products pursuant to the Bayh-Dole Act of 1980 (Bayh-Dole Act). These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has what are referred to as "march-in" rights to, under certain limited circumstances, require the licensor to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that (1) adequate steps have not been taken to commercialize the invention and achieve practical application of the government-funded technology, (2) government action is necessary to meet public health or safety needs, (3) government action is necessary to meet requirements for public use under federal regulations or (4) we fail to meet requirements of federal regulations. The U.S. government also has the right to take title to these inventions if we or our licensors fail to disclose the invention to the government or fail to file an application to register the intellectual property within specified time limits. These rights may permit the government to disclose our confidential information to third parties. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. To the extent any of our future owned or licensed intellectual property is also generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Any exercise by the government of such rights could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. There are numerous recent changes to the patent laws and proposed changes to the rules of the USPTO which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the AIA, enacted in September 2011, resulted in significant changes to the U.S. patent system. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a "first-to-invent" to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. Circumstances could prevent us from promptly filing patent applications on our inventions.

Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (1) file any patent application related to our product candidates and other proprietary technologies we may develop or (2) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

The AIA provided opportunities for third parties to challenge any issued patent in the USPTO. Those provisions apply to all of our U.S. patents, regardless of when issued. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. These provisions could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents.

Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing U.S. patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the 2013 case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to naturally-occurring substances are not patentable. Although we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by Congress, the federal courts or the USPTO may impact the value of our patents. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but the complexity and uncertainty of European patent laws has also increased in recent years. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

In addition, changes in, or different interpretations of, patent laws in the United States and other countries may permit others to use our discoveries or to develop and commercialize our technology without providing any compensation to us, or may limit the scope of patent protection that we are able to obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights.

If the patent applications we hold or have in-licensed with respect to our current and future technology fail to issue, if the validity, breadth or strength of protection of our patent rights is threatened, or if such patent rights fail to provide meaningful exclusivity for our methods and related products that we or our collaborators may develop, it could dissuade companies from collaborating with us, encourage competitors to develop competing technology and threaten our or our collaborators' ability to commercialize future products or services. Any such outcome could have a material adverse effect on our business.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained in the United States. In-licensing patents covering our technology in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection, or from selling or importing our technology in and into the United States or other jurisdictions.

We generally apply for patents in those countries where we intend to make, have made, use, offer for sale or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we may not seek protection in all countries where we will commercialize our products and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. Competitors may use our technology in jurisdictions where we do not pursue and obtain patent protection to develop their own assays and products and may export otherwise infringing assays and products to territories where we have patent protection, but where our ability to enforce our patent rights is not as strong as in the United States. These assays and products may compete with technologies that we or our collaborators may develop, and our patents or other intellectual property rights may not be effective or sufficient to prevent such competition.

The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals or biotechnologies. As a result, many companies have encountered significant difficulties in protecting and defending intellectual property rights in certain jurisdictions outside the United States. Such issues may make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many other countries, including countries in the EU, have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents and could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business.

Furthermore, proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, subject our patents to the risk of being invalidated or interpreted narrowly, subject our patent applications to the risk of not issuing or provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded to us, if any, may not be commercially meaningful, while the damages and other remedies we may be ordered to pay such third parties may be significant. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for certain aspects of our technology, we also consider trade secrets, including confidential and unpatented know-how, important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes or that the assignment agreements that have been entered into are self-executing. Despite these efforts, any of these parties may breach the agreements, intentionally or inadvertently, and disclose our proprietary information, including our trade secrets, or claim ownership in intellectual property that we believe is owned by us. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the U.S. and certain foreign jurisdictions are less willing or unwilling to protect trade secrets.

Moreover, our competitors or other third parties may independently develop knowledge, methods and know-how equivalent to our trade secrets or seek to reverse engineer our technology for which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third parties, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We are also subject both in the U.S. and outside the U.S. to various regulatory schemes regarding requests for the information we provide to regulatory authorities, which may include, in whole or in part, trade secrets or confidential commercial information. While we are likely to be notified in advance of any disclosure of such information and would likely object to such disclosure, there can be no assurance that our challenge to the request would be successful. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed trade secrets or other confidential information of their current or former employers or claims asserting inventorship or ownership of what we regard as our own intellectual property.

Many of our employees, consultants, and advisors are currently or were previously employed at universities or other healthcare, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual’s current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

We may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Alternatively, or additionally, we may

enter into agreements to clarify the scope of our rights in such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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.

Our trademarks or trade names may be challenged, opposed, infringed, circumvented, invalidated, cancelled, declared generic, determined to be not entitled to registration, or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. For example, our application to register the trademark TALIS in the United States is subject to an ongoing opposition before the USPTO with Talis Clinical, LLC, which alleges that our application for registration of the trademark TALIS should not be registered because it is likely to be confused with the prior unregistered trademark TALIS used in connection with medical software and related goods and services. In the event this opposition is successful, or if we enter into a settlement agreement with Talis Clinical, LLC, we could lose rights to this trademark. Any trademark litigation could be expensive. In addition, we could be found liable for significant monetary damages, including treble damages, disgorgement of profits and attorneys' fees, if we are found to have willfully infringed a trademark. We may not be able to protect our exclusive right to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential collaborators or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Our use of "open source" software could subject our proprietary software to general release, adversely affect our ability to sell our products, and subject us to possible litigation.

A portion of our products incorporate so-called "open source" software and we may incorporate open source software into other products or technologies in the future. Such open source software is generally licensed by its authors or other third parties under open source licenses. Some open source licenses contain requirements that we disclose source code for modifications we make to the open source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of our software in connection with open source software could require that we disclose and license some or all of our proprietary code in that software as well as distribute our products that use particular open source software at no cost to the user. We monitor our use of open source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code, however, there can be no assurance that such efforts will be successful. Open source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of certain of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding our products and technologies. Companies that incorporate open source software into their products have, in the past, faced claims seeking enforcement of open source license provisions and claims asserting ownership of open source software incorporated into their product. 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 an open source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our products. In addition, if we combine our proprietary software with open source software in certain ways, 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 ours and otherwise have a material adverse effect on our business.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products or provide services that are similar to ours but that are not protected by our intellectual property;
- we or our licensors might not have been the first to make the inventions covered by our patents;
- we or our licensors might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- issued patents for which we have rights may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products in our commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may fail to adequately protect and police our trademarks and trade secrets;
- the patents of others may harm our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications; and
- we or our licensors may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks related to our financial condition and capital requirements

We have incurred significant losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future, which could harm our future business prospects.

We have historically incurred substantial net losses, including net losses of $125.0 million and $17.4 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, we had an accumulated deficit of $297.9 million. We expect our losses to continue as we continue to devote a substantial portion of our resources to efforts to the commercial launch of the Talis One system and COVID-19 assay kit, and thereafter to increase the adoption of our products, improve these products, scale our manufacturing capabilities and research, develop and commercialize new products. We are exposed to foreign exchange risk in our operations, specifically around our manufacturing scale up activities. The impact of foreign exchange fluctuations on our contracts with third party vendors, which are denominated in a currency other than the U.S. dollar, could adversely impact our results of operations, financial condition and cash flows.

We have devoted a substantial portion of our resources to the development and commercialization of the Talis One system, a molecular diagnostic platform, including clinical and regulatory initiatives to obtain regulatory clearance. These losses have had, and will continue to have, an adverse effect on our working capital, total assets, and stockholders' equity. Because of the numerous risks and uncertainties associated with our research, development and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase

profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations, and cash flows.

We may need to raise additional capital to fund our existing operations, further develop our diagnostic platform, commercialize new products, and expand our operations.

We may seek to sell common or preferred equity or convertible debt securities, enter into another credit facility or another form of third-party funding, or seek other debt financing. We may also need to raise capital sooner or in larger amounts than currently anticipated for numerous reasons, including because of lower demand for our COVID-19 test or as a result of failure to obtain regulatory approvals for our other test panels, or other risks described in this Quarterly Report. In addition, we intend to pursue a reagent rental model where the customer does not purchase our Talis One instrument, which will require substantial additional working capital.

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 facilitate market adoption of our products and address competitive developments;
- fund development and marketing efforts of any future products;
- further expand our operations outside the United States;
- acquire, license or invest in technologies, including information technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and selling, general and administrative expenses.

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

- our ability to successfully launch our product, initially with our COVID-19 test, under an EUA;
- our ability to secure and maintain domestic and international regulatory approval for our products;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our products;
- our rate of progress in, and cost of research and development activities associated with, products in research and early development;
- the effect of competing technological and market developments; and
- the potential cost of and delays in research and development as a result of any regulatory oversight applicable to our products.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, our stockholders' ownership interests will be diluted. Any equity securities we issue could also provide for rights, preferences, or privileges senior to those of holders of our 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 common stock. If we raise funds through borrowings pursuant to a credit agreement, the incurrence of such indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt and acquire or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. If we raise funds through collaborations and alliances and licensing arrangements, we might be required to relinquish significant rights to our platform or technologies or to grant licenses on terms that are unfavorable to us.

Additional equity or debt financing might not be available on reasonable terms, if at all. If we cannot secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more research and development programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more of our development programs, which could lower the economic value of those programs to us.

Lastly, if we are unable to obtain the requisite amount of financing needed to fund our planned operations, it could have a material adverse effect on our business and ability to continue operating as a going concern.

Risks related to ownership of our common stock

The market price of our common stock has been and may continue to be volatile or may decline regardless of our operating performance and you could lose all or part of your investment.

The market price of our common stock may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control, including, but not limited to:

- actual or anticipated fluctuations in our financial condition or results of operations;
- variance in our financial performance from expectations of securities analysts;
- changes in the pricing of our products;
- changes in our projected operating and financial results;
- changes in laws or regulations applicable to our products;
- changes to the proportion of our customers directly purchasing the Talis One system as compared to utilizing our planned reagent rental model;
- announcements by us or our competitors of significant business developments, acquisitions, or new offerings;
- changes in the structure of healthcare payment systems;
- significant data breaches of our company, providers, vendors or pharmacies;
- our involvement in litigation;
- future sales of our common stock by us or our stockholders, as well as the anticipation of lock-up releases;
- changes in senior management or key personnel;
- negative publicity, such as whistleblower complaints or unsupported allegations made by short sellers, about us or our products;
- the trading volume of our common stock;
- changes in investor perceptions of us or our industry;
- changes in the anticipated future size and growth rate of our market;
- general economic, political, regulatory, industry, and market conditions; and
- natural disasters or major catastrophic events.

These and other factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In recent years, stock markets in general, and the market for life science technology companies in particular (including companies in the genomics, biotechnology, diagnostics and related sectors), have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. From February 12, 2021 through August 6, 2021, the closing price of our common stock has ranged between $9.62 and $27.80 per share. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance.

Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

Future sales of our common stock in the public market could cause the market price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

All of our directors and officers and the holders of substantially all of our capital stock and securities convertible into our capital stock are subject to lock-up agreements that restrict their ability to transfer shares of our capital stock for 180 days from the date of our

prospectus filed with the SEC on February 12, 2021. These lock-up agreements limit the number of shares of capital stock that may be sold immediately following our initial public offering. Subject to certain limitations, substantially all of these shares will become eligible for sale upon expiration of the 180-day lock-up period. J.P. Morgan Securities LLC and BofA Securities, Inc. may, in their sole discretion, permit our stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, there were 7,874,134 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2021. We registered all of the shares of common stock issuable upon exercise of such outstanding options or other equity incentives we may grant in the future, for public resale under the Securities Act of 1933, as amended (Securities Act). The shares of common stock will become eligible for sale in the public market to the extent such options are exercised, subject to the lock-up agreements described above and compliance with applicable securities laws.

Further, based on shares outstanding as of June 30, 2021, holders of approximately 31,189,210 shares, or 56.1% of our capital stock, will have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

The issuance of shares in connection with any subsequent issuance could depress the market price of our common stock. We are unable to predict the effect that such issuances and/or sales may have on the prevailing market price of our common stock.

We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, as amended (JOBS Act). For so long as we remain an emerging growth company, we are permitted by Securities and Exchange Commission (SEC) rules and plan to rely on exemptions from certain disclosure requirements that are applicable to other SEC-registered public companies that are not emerging growth companies.

These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes–Oxley Act of 2002, as amended (Sarbanes-Oxley Act), not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different from the information that is available with respect to other public companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions.

In addition, as an emerging growth company the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies, unless we later irrevocably elect not to avail ourselves of this exemption. We have elected to use this extended transition period under the JOBS Act; however, we may choose to early adopt new or revised accounting pronouncements, if permitted under such pronouncements.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which may allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We do not expect to pay any dividends for the foreseeable future. Investors may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid cash dividends on our capital stock, and we do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain all available funds and future earnings to fund the development and expansion of our business. In addition, any future credit facility or financing we obtain may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our common stock, the price of our common stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or securities analysts. If no or few analysts commence coverage of us, the trading price of our common stock could decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our common stock, the price of our common stock could decline. If one or more of these analysts cease to cover our common stock, we could lose visibility in the market for our common stock, which in turn could cause the price of our common stock to decline.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company, which we expect to further increase after we are no longer an emerging growth company. The Sarbanes–Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Stock Market (Nasdaq), and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the specific timing of such costs.

We have broad discretion in the use of the net proceeds from our initial public offering and may not use them effectively.

We have broad discretion in the application of the net proceeds to us from our initial public offering, including for any of the purposes described in the section titled “Use of proceeds,” in our prospectus filed with the SEC on February 12, 2021 and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from our initial public offering, our ultimate use may vary substantially from our currently intended use. Investors will need to rely upon the judgment of our management with respect to the use of proceeds. Pending use, we may invest the net proceeds from our initial public offering in short-term, investment-grade, interest-bearing securities, such as money market accounts, certificates of deposit, commercial paper, and guaranteed obligations of the United States government that may not generate a high yield for our stockholders. If we do not use the net proceeds that we received from our initial public offering effectively, our business, financial condition, results of operations and prospects could be harmed, and the market price of our common stock could decline.

Our principal stockholder owns a very significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of August 6, 2021, our executive officers, directors and five percent or greater stockholders and their respective affiliates, beneficially own, in the aggregate, approximately 64.9% of our outstanding voting stock. Further, 56.1% of our outstanding voting stock is owned by entities affiliated with Baker Bros. Advisors LP (Baker Bros.). In addition, the holders of our Series 1 convertible preferred stock, which, subject to certain limitations, is a voting common stock equivalent, may elect to convert shares of Series 1 convertible preferred stock into shares of Series 2 convertible preferred stock, which is a non-voting common stock equivalent. These shares of Series 2 convertible preferred stock are then convertible into shares of our common stock, subject to certain beneficial ownership limitations.

We also have a nominating agreement with Baker Bros. that provides that, for so long as it continues to own a certain number of shares of our common stock, we have the obligation to support the nomination of, and to cause our board of directors to include in the slate of nominees recommended to our stockholders for election, one or two individuals designated by Baker Bros. As a result, Baker Bros. is able to exercise considerable influence over matters requiring stockholder approval, including the election of directors, amendments of our organizational documents and approval of any merger, sale of substantially all our assets or other significant corporate transactions for the foreseeable future. This concentration of ownership may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you or other stockholders may feel are in your or their best interest as one of our stockholders.

As a result of being a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting, and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We will be required, pursuant to Section 404 of the Sarbanes–Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the fiscal year ending December 31, 2021, which is the year covered by the second annual report following the completion of our initial public offering. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. 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 our annual and interim financial statements will not be detected or prevented on a timely basis. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company if we are not a non-accelerated filer at such time. We are commencing the costly and challenging process of compiling the information systems, processes and internal controls documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes–Oxley Act, but we may not be able to complete our evaluation, testing and any required remediation in a timely fashion once initiated. Our compliance with Section 404 of the Sarbanes–Oxley Act will require that we incur substantial accounting expenses and expend significant management efforts. We currently do not have an internal audit group, and we will need to continue to hire accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes–Oxley Act.

If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Implementation of our new enterprise resource planning system may adversely impact and could negatively affect our business.

We rely extensively on information systems and technology to manage our business and support timely and accurate financial reporting. We have implemented a new enterprise resource planning (ERP) system to provide better information and to support our commercial scale-up.

The new ERP system was deployed for use throughout our company during the period ended June 30, 2021. Implementing a new ERP system is costly and requires significant focus of our financial resources.

Transferring existing business processes and records to a new ERP system involves risks, including loss of information, disruption to our normal operations, changes in accounting procedures and internal control over financial reporting, as well as problems achieving accuracy in the conversion of electronic data. Failure to properly or adequately address any difficulties with the new system could result in increased costs, the diversion of management and employees' attention and resources and could materially adversely affect our operating results, internal controls over financial reporting and ability to manage our business effectively. While the ERP system is intended to further improve and enhance our management and financial reporting capability, implementation of a new critical information system creates risks including possible disruptions that could lead to a failure to make required filings under the federal securities laws on a timely and accurate basis.

We have identified a material weakness in our internal control over financial reporting, and if we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock may be materially adversely affected.

To date, we have never assessed our internal control for the purpose of providing the reports required by the Sarbanes-Oxley Act. In a future assessment, we may identify deficiencies and be unable to remediate them before we must provide the required reports. In connection with the audit of our financial statements as of and for the year ended December 31, 2020, we and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting, related to a lack of effective review of the estimated vendor progress related to the level of completion associated with our manufacturing scale-up project, which resulted in material adjustments to prepaid research and development expenses. Following identification of the material weakness, we have begun undertaking specific remediation actions to address the material weakness in our financial reporting which are outlined elsewhere in this Quarterly Report.

Furthermore, if in the future, we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Market or other adverse consequences that would materially harm our business. In addition, we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, and other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and our financial condition, or divert financial and management resources from our core business.

Our amended and restated certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, any state court located within the State of Delaware, or if all such state courts lack jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a breach of a fiduciary duty owed by any current or former director, officer or other employee, to us or our stockholders; (3) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provisions of the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; (4) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; (5) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (6) any action asserting a claim against us, or any of our directors, officers or other employees, that is governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. The amended and restated certificate of incorporation states that these choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Securities Act, the Securities Exchange Act of 1934 (Exchange Act) or any other claim for which the federal courts have exclusive jurisdiction. This amended and restated certificate of incorporation will further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees and may discourage these types of lawsuits. Furthermore, if a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66 2/3% of the voting power of all of our then outstanding capital stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;

- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66 2/3% of our then-outstanding voting capital stock.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

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

Use of Proceeds from our Initial Public Offering of Common Stock

In February 2021, our Registration Statement on Form S-1 (No. 333-252360) was declared effective by the SEC.

There has been no material change in the planned use of proceeds from our initial public offering from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on February 12, 2021.

Item 3. Defaults Upon Senior Securities.

Not Applicable.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

Not Applicable.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-40047), filed with the SEC on February 17, 2021).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-40047), filed with the SEC on February 17, 2021).
4.1	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on February 8, 2021).
4.2^	Amended and Restated Investor Rights Agreement, dated October 30, 2020, by and among the Registrant and certain of its stockholders (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021).
4.3	Nominating Agreement, dated November 1, 2019, by and among the Registrant, Baker Brothers Life Sciences, L.P. and 667, L.P. (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021).
4.4	Registration Rights Agreement, dated March 26, 2021, by and among the Registrant, Baker Brothers Life Sciences L.P. and 667, L.P. (incorporated by reference to Exhibit 4.5 to the Registrant's Annual Report on Form 10-K (File No. 001-40047) filed with the SEC on March 30, 2021).
10.1	Lease Agreement, dated April 7, 2021, by and between the Registrant and SFF 3565 HAVEN, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File no. 001-40047) filed with the SEC on May 13, 2021).
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) Under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) Under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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.
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.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

^ Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TALIS BIOMEDICAL CORPORATION

Date: August 10, 2021 By: /s/ Brian Coe

Brian Coe

Chief Executive Officer

Date: August 10, 2021 By: /s/ J. Roger Moody, Jr.

J. Roger Moody, Jr.

Chief Financial Officer

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian Coe, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Talis Biomedical Corporation;

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

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

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

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

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

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

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

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

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

Date: August 10, 2021

By: /s/ Brian Coe

Brian Coe
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, J. Roger Moody, Jr., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Talis Biomedical Corporation;

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

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

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

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

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

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

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

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

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

Date: August 10, 2021

By: /s/ J. Roger Moody, Jr.
J. Roger Moody, Jr.
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Talis Biomedical Corporation (the "Company") on Form 10-Q for the period ending June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify to the best of my knowledge, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Exchange Act; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 10, 2021

By: /s/ Brian Coe

Brian Coe
Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Talis Biomedical Corporation (the "Company") on Form 10-Q for the period ending June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify to the best of my knowledge, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Exchange Act; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 10, 2021

By: /s/ J. Roger Moody, Jr.
J. Roger Moody, Jr.
Chief Financial Officer
(Principal Financial Officer)

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.