**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

**FORM 10-K**

**(**Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

FOR THE TRANSITION PERIOD FROM TO

**Commission File Number: 001-40047**

# Talis Biomedical Corporation

(Exact name of Registrant as specified in its Charter)

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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the Registrant's common stock on The Nasdaq Stock Market on June 30, 2021, was $181,704,426. The calculation of the aggregate market value of voting and non-voting common equity excludes shares held by executive officers, directors and stockholders that the Registrant concluded were affiliates of the Registrant on such date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant or that such person is controlled by or under common control with the Registrant.

As of March 10, 2022, there were 56,637,438 shares of the Registrant's common stock and preferred stock outstanding, consisting of 26,773,764 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.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2022 Annual Meeting of Stockholders (the "2022 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K. The 2022 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report relates.

**Table of Contents**

**Special Note Regarding Forward-Looking Statements**

This Annual Report on Form 10-K (this Annual Report) contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” 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 planned regulatory clearance pathways;
- 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;
- our efforts and ability to scale-up manufacturing capabilities at a low-cost;
- 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 maintain and utilize our 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 and maintain 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 and studies;
- our ability to successfully develop additional revenue opportunities and expand our product and service offerings, including our recently launched offerings and any third party products that we may sell;
- 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 Annual 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 Annual 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 Annual 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 Annual Report and the documents that we reference in this Annual Report and have filed as exhibits to this Annual Report 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 Annual 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 I, Item 1A of this Annual 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 I, Item 1A of this Annual Report as part of your evaluation of an investment in our common stock.*

- We rely on a significant number of third party manufacturers and suppliers for our instrument and cartridges, which reliance has created and may continue to create delays due to the complexity of our manufacturing lines and supply chain, as well as exposure to manufacturing and supply limitations or interruptions and quality and quantity issues.
- If the EUA for the Talis One COVID-19 Test System 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 will likely be a lengthy and expensive process.
- We may be unable to validate our manufacturing for the Talis One instrument and cartridges at scale, which may impact our ability to start and/or complete our post-authorization clinical evaluation study required by the EUA for the Talis One COVID-19 Test System, as well as impact our ability to support our research and development pipeline.
- If we change the design of the Talis One instrument and/or cartridge to improve manufacturability at scale, we may need to obtain new FDA authorization for our Talis One COVID-19 Test System.
- The EUA for our Talis One COVID-19 Test System may be revoked or may terminate at the conclusion of the public health emergency, and we may not be able to obtain marketing authorization for additional assays, which would adversely affect our business, financial condition and results of operations.
- 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.
- We have commenced selling the Antigen Tests and are investigating other third-party product opportunities to generate revenue which could divert focus from commercializing our own product, the Talis One system.
- The COVID-19 pandemic has and could continue to 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.
- Our commercial success could be compromised if our customers do not receive coverage and adequate reimbursement for our products.
- 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. 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

### Item 1. Business.

All references to “Talis Biomedical,” “Talis,” “the Company,” “we,” “our,” and “us” in this Annual Report refer to Talis Biomedical Corporation.

### Overview

Talis aims to transform diagnostic testing by developing and commercializing innovative products that are designed to enable accurate, reliable, low cost and rapid molecular testing for infectious diseases and other conditions at the point of care. While timely diagnosis of infectious diseases is critically important to enable effective treatment, testing is primarily performed in centralized laboratories, which require samples to be shipped for processing, delaying the return of results by days. Point-of-care testing solves this problem by delivering the timely information necessary for clinical care. We are developing the Talis One system, a sample-to-answer, cloud-enabled molecular diagnostic platform that, once manufacturing scale-up has been validated, could be deployed to a variety of diagnostic settings in the United States and around the world to diagnose infectious disease in the moment of need, at the point of care. The Talis One system comprises a compact instrument, single-use test cartridges and software that is planned to support a central cloud database, which work together and are designed to provide central laboratory levels of accuracy and be operated by an untrained user.

### Corporate Information

We were formed as a limited liability company under the Illinois Limited Liability Company Act in March 23, 2010 under the name SlipChip LLC. In June 2013, SlipChip LLC merged with and into SlipChip Corporation, a Delaware corporation, with each member of SlipChip LLC exchanging their respective membership interest for shares of common stock of SlipChip Corporation. In February 2018, we changed our corporate name to Talis Biomedical Corporation. Our principal executive offices are located at 230 Constitution Drive, Menlo Park, California 94025, and our telephone number is (650) 433-3000. Our corporate website address is http://talisbio.com.

This Annual Report contains references to our trademarks, including Talis™ and Talis One™, and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

### General

We are developing Talis One assay kits for respiratory infections, and infections related to women’s health and sexually transmitted infections (STIs). In the third quarter of 2021, we submitted a request for Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) for our Talis One system in non-laboratory settings. On November 5, 2021, we received an EUA from the FDA for the emergency use of the Talis One system for our COVID-19 test, which we refer to as the Talis One COVID-19 Test System. This assay platform provides 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. By submitting for the equivalent of a CLIA-waived authorization, the Talis One COVID-19 Test System may be used in either laboratory or non-laboratory settings. Under the terms of the EUA, we were required to submit data from a post-market study to the FDA by March 5, 2022, although we have been granted an extension to provide this data to the FDA four months after the commercial launch of the Talis One COVID-19 Test System. We currently expect that the future commercial launch will be pursuant to such EUA. At present, we can produce the Talis One instrument and cartridges but not at a scale to support our commercial launch. We are currently validating the performance of our manufacturing equipment and procedures and plan to broadly market our Talis One COVID-19 Test System after the phased launch.

We are also developing influenza A and influenza B tests to be included as part of a respiratory panel with our COVID-19 assay (Respiratory Panel), as well as exploring adding a respiratory syncytial virus (RSV) test. Due to recent changes in FDA EUA guidance, we now plan to pursue clearance for the Respiratory Panel under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FDCA). In addition, we plan to initiate a clinical trial to support clearance of a pre-market notification under Section 510(k) of the FDCA for our Talis One system with a

test cartridge for Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis (CT/NG/TV). If approved, this panel may be marketed as a complete panel or as separate individual analytes depending on market needs, reimbursement or other factors. To support our anticipated commercial launch of our Talis One COVID-19 Test System, we have invested in automated cartridge manufacturing lines, the first of which began to come on-line in the first quarter of 2021 and that we are continuing to validate to ensure that they meet our performance criteria.

In addition to our Respiratory Panel, if the CT/NG/TV assay is cleared or otherwise authorized for marketing, this would be our first commercial offering in the women's health category. We are planning to develop additional tests for infections related to women's health, including a panel for STIs and other infections, such as bacterial vaginosis (BV), urinary tract infections (UTI) and herpes simplex virus (HSV).

The COVID-19 pandemic has accelerated the adoption of point-of-care platforms in both traditional and non-traditional care settings, and we believe the Talis One system is well positioned to meet this growing demand. While a variety of technologies are commercially available, we believe that few, if any, sufficiently meet the needs of healthcare providers in order to drive broad adoption of, and transition to, point-of-care testing for a broad range of infectious diseases. For example, antigen detection technologies, which detect proteins from the pathogen, are rapid and relatively low cost, but they have higher limits of detection. Molecular technologies that detect nucleic acids are generally considered highly accurate for infectious disease testing. However, we believe that some currently available point-of-care molecular technologies have sacrificed accuracy to increase speed. Lower accuracy limits a test's utility, particularly in the case of testing for dangerous infectious diseases, such as COVID-19, for which an incorrect test result can have severe consequences. We believe that the ideal point-of-care technology for diagnosing infectious diseases would not only be highly accurate and rapid, but would also be easy to use, low cost, cloud-compatible and enable multiplexing to detect multiple pathogens at the same time.

We are developing the Talis One system to address limitations of existing point-of-care diagnostic testing technologies for infectious diseases. Our system combines robust sample preparation with highly optimized and rapid isothermal nucleic acid amplification technology to enable rapid detection of infectious pathogens in a variety of unpurified patient sample types. We designed the Talis One system to have the following capabilities which we believe will create a competitive advantage over other commercially available point-of-care technologies:

- *Highly accurate*—The Talis One system incorporates a shelf-stable, single-use test cartridge designed to fully integrate a nucleic acid amplification test (NAAT) with sample preparation, including nucleic acid extraction and purification. Sample preparation is well known to be a critical factor to achieve high sensitivity and specificity, along with low limits of detection for target pathogens, in molecular diagnostics. We believe this sample preparation step, which is performed in an automated fashion on our cartridge, has the potential to result in higher sensitivity and specificity than point-of-care technologies that do not perform the sample preparation step. Our Talis One COVID-19 Test System reaches limits of detection as low as 500 viral particles per milliliter. We can achieve similarly high performance on the Talis One system for bacteria with limits of detection of bacterial pathogens as low as one infectious unit per milliliter (IFU/mL) in a variety of unpurified patient sample types, including nasal swab, vaginal swab, saliva and urine.
- *Rapid turnaround time*—The Talis One system is designed to provide a positive or negative result in less than 30 minutes, depending upon the test and the concentration of the pathogen in the sample. We believe this turnaround time meets target customers' needs for a system fast enough to fit into their clinical practice.
- *Ease of use*—We designed the Talis One system for operation by untrained users and to function in a CLIA-waived environment such as physicians' offices, urgent care clinics, elder care and assisted living facilities, cancer treatment and dialysis centers, and potentially in workplaces, schools and other facilities. The Talis One system is designed to be a fully integrated sample-to-answer system requiring two minutes or less of hands-on time by users running the test. The intuitive workflow of the Talis One system is also designed to facilitate the chain of custody of the sample without extensive tracking or handling by the user.
- *Multiplex capability*—The cartridge is designed with five separate reaction chambers. There is the ability to add up to an additional nine chambers for a total of 14 reaction chambers, which we believe could potentially enable a full menu of detection modes, from single organism to syndromic panel tests.

The test cartridge for the Talis One COVID-19 Test System uses three of the five separate assay chambers.

- *Cloud-enabled*—Unlike other point-of-care instruments, the Talis One system incorporates a cellular modem within the instrument, which is designed to connect to the cloud to help customers manage clinical data and workflow. The cloud capability is designed to (a) be remotely and securely accessed to obtain key data required to collect, screen, collate, report and monitor disease infection and pandemic spread on a micro and macro level, which could enable the creation of a public health interface and automatic transmission of "reportable infections," such as COVID-19, to public health authorities in order to facilitate tracking of infectious diseases and (b) enable us to remotely manage instruments in the field, such as providing automated software updates and enable customers to track and manage instruments they have across their networks. For instances where cellular connectivity is unavailable or undesired, the instrument is designed to permit secure connectivity via ethernet. This capability has been built into the Talis One system but will require that we submit additional data to the FDA for review prior to implementation.
- *Scalable for different throughput requirements*—The Talis One system is designed to provide a scalable platform for different volume and throughput requirements. The instruments are portable and designed for multi-instrument deployments to satisfy different testing volume requirements and can be stacked three instruments by three instruments without disturbing the cellular connection to the cloud.
- *Low cost to manufacture*—We designed the Talis One system to be low-cost and manufactured at scale. We believe this could facilitate (a) scale-up in manufacturing and provide a competitive advantage in cost-sensitive environments and (b) customers acquiring multiple Talis One instruments to meet their volume requirements.

We intend to commercialize the Talis One system in the United States through an enterprise account management team and direct sales force. If we increase adoption in the marketplace, we anticipate that this will establish a sales channel through which we can drive future sales of our test menu. Over time, we intend to explore commercialization strategies outside of the United States.

**Our Business Strategy**

Our strategy is to improve medical care through the transformation of diagnostic testing by enabling customers in distributed diagnostic locations to deploy accurate, reliable, low cost and rapid molecular testing for infectious diseases and other conditions. To achieve this, we intend to:

***Pursue commercialization of our COVID-19 Test System in the United States***

- We intend to commercialize the Talis One system through an enterprise sales team and a direct sales force focused initially on placing systems with potential customers that place high value on accuracy, and our broader test menu in development. Target customer segments include (but are not limited to): (1) traditional medical establishments, including physician offices, urgent care chains, hospitals, and public health clinics that that need rapid and high-quality testing to best serve their patients and (2) additional segments, including schools, workplaces, prisons, and elder care facilities.

***Increase our low-cost manufacturing capacity for our Talis One instrument and COVID-19 test cartridges***

- We have ordered components for up to 5,000 instruments from our instrument contract manufacturing partners.
- We have invested in automated cartridge manufacturing lines that are designed to meet the anticipated volume commercial needs for the Talis One system once validation of performance is complete.
- As we improve and scale manufacturing and automation, we expect to drive cost of goods reductions for our tests.

***Complete development of and, if marketing authorizations are obtained, commercialize other tests for other respiratory infections, infections related to women's health and sexually transmitted infections in the United States***

- We are developing additional tests for respiratory infections, including influenza A and B and RSV. For the combination Respiratory Panel, consisting of COVID-19, Influenza A, Influenza B, and potentially RSV, we intend to pursue marketing authorization through the 510(k) clearance pathway and to commercialize thereafter. The FDA's marketing authorization requirements for the Respiratory Panel will impact the timing to develop and commercialize this combination panel, if authorized.
- We are also developing a full menu of tests for infections related to women's health and sexually transmitted infections. We are focusing initially on our CT/NG/TV test, for which we plan to initiate a clinical study to support a 510(k) pre-market notification after the successful completion of the trial. We are subsequently targeting other STIs, such as a panel for sexually transmitted inflection that would include CT/NG/TV, Mycoplasma genitalium, a panel for BV, a panel for UTI, and single target tests for infectious agents such as Group B streptococcus, or HSV. If we obtain marketing authorization from the FDA, we intend to focus our commercialization efforts both on existing customers who may value our broader test menu, as well as obstetricians and gynecologists, the most common purchasers of these tests. We believe that a rapid, affordable and accurate point-of-care platform would enable these physicians to better diagnose and treat patients, practice value-based care, and create revenue opportunities by testing in-house rather than sending tests out to centralized laboratories.

***Pursue marketing clearance and, if received, commercialize our products and expand our operations in selected geographies globally***

- We intend to pursue clearance to affix a CE Mark to enable commercialization of our Talis One COVID-19 Test System in Europe.
- We will evaluate opportunities to commercialize other products in markets outside of the United States through a direct sales force or distributors, depending on the geography and demand.

***Continue to invest in capabilities to drive sustainable growth***

- We intend to focus on innovation to improve the technical performance of our Talis One system and develop an expanded test menu.
- We intend to continue our research and development activities and to leverage proprietary innovations to develop additional systems in the future designed to solve diagnostic challenges for our customers.
- We intend to strive for operational efficiencies and manufacturing capabilities to further drive economies of scale and lower manufacturing costs.

**Industry background**

Infectious disease remains among the top health problems facing populations around the world. While infectious disease is an enduring concern for public health, beginning in 2020, the world has been challenged, and continued to be challenged, by the COVID-19 global pandemic.

While the current pandemic presents a large and acute need for testing for COVID-19, the mortality rate for all infectious disease in the United States ranged between 42 and 63 deaths per 100,000 population, accounting for 5.4% of overall mortality for the period of 1980-2014.

*The drawbacks of centralized laboratory testing*

The need to send samples to a central location for testing introduces delays in treatment or incentivizes prescribing treatment in the absence of a definitive diagnosis. The turnaround time for centralized lab tests is typically one to five days and can often be longer. Therefore, physicians are faced with one of two choices: either wait days for test results before initiating treatment and risk that an infected patient may continue to spread the infection and suffer increasingly negative health effects from delayed treatment or treat empirically while the patient is in front of them. Smaller hospital and clinic laboratories, many in rural settings, may not have the testing volume to justify investing

in high throughput molecular diagnostic instruments, requiring smaller hospitals to send out molecular testing to reference laboratories and wait for the results.

We believe that immediate access to high-quality diagnostic test results will improve medical treatment of disease and avoid inappropriate prescription of antibiotics, which can amplify the growing problem of antibiotic resistant bacteria. In a 2016 study of 1,103 emergency room patients at St. John Hospital & Medical Center in Detroit, 440 patients who had a suspected chlamydia or gonorrhea infection were treated with antibiotics even though the vast majority, 323 patients (74%), ultimately tested negative for the infection. Similarly, in some cases, test result delays lead to patients who do not return after the initial visit, resulting in the health care provider losing these patients to follow-up and unnecessarily exposing additional individuals to detectable and treatable infections. This is particularly problematic in pediatric care and for urgent care and community care clinics.

**Limitations of current point-of-care diagnostic technologies**

There are a broad range of point-of-care technologies available for use in physician offices for a variety of applications, ranging from glucose strips for diabetes to lateral flow immunoassays for detecting high pathogen load infections, such as Strep A or influenza. Molecular testing is less common in point-of-care settings, despite being highly accurate. We believe that this is due to a lack of available point-of-care molecular technologies that sufficiently balance speed, accuracy and cost to meet customer needs and drive broad adoption.

We believe that most molecular diagnostic solutions currently being marketed for use at the point-of-care each have one or more of the following limitations:

- Low performance as measured by sensitivity, specificity and limit of detection can result in misdiagnosis and poor clinical outcomes. Several point-of-care molecular diagnostic platforms provide results in less than 30 minutes but achieve this speed by performing nucleic acid amplification on samples, foregoing sample preparation, which is known to limit the sensitivity, specificity and limit of detection of these nucleic acid tests.
- Slow turnaround time can extend beyond the time a patient will wait for results and potentially result in loss of patient to follow-up. Other available point-of-care systems may provide reliable, high performance results, but these tests can take 45 to 90 minutes to return a result. While results returned within hours is better than days, we believe that the longer a test takes, the less willing patients will be to wait at the clinical site for results, thereby risking patients failing to return after the initial visit and unnecessarily exposing additional individuals to a detectable infectious agent.
- Platforms requiring significant user interaction or monitoring will not work well with clinical workflow. Some platforms sold as point-of-care solutions require users to transfer solutions midway through a run or handle the instrument, test cartridge and/or sample multiple times, in order to process one test. The typical physician’s office does not have laboratory personnel who can monitor an instrument, nor personnel trained in sample custody tracking.
- Platforms that are difficult to manufacture at low cost or at scale can limit adoption. We believe that the cost of purchasing and using diagnostic testing platforms and consumables is a primary concern for customers.
- Limited test menus fail to meet the needs of clinicians. The adoption of diagnostic technologies is contingent upon the technology having both clinical utility, and economic rationale. Without a broad and relevant testing menu, testing platforms may not sufficiently meet the clinical needs of customers to justify the expense. We believe the ability to develop our planned additional assays will create a competitive barrier to entry for other platforms.

**The Talis One system**

We are developing the Talis One system to address the limitations of existing point-of-care diagnostic testing technologies for infectious diseases. Our system combines robust sample preparation with highly-optimized and rapid isothermal nucleic acid amplification technology to enable rapid detection of infectious pathogens in a variety of unpurified patient sample types. The Talis One system is an integrated system that includes a compact instrument, single-use test cartridges and software, including a central cloud database.

*Talis One cartridge*

At the core of our system is the Talis One cartridge, a versatile shelf-stable and single-use test cartridge designed to fully integrate proprietary highly-optimized nucleic acid isothermal amplification assays with sample preparation. The cartridge is designed to handle a wide range of sample types, including nasal swab, vaginal swab, saliva, urine, whole blood, plasma, serum and sputum, to be compatible with lysis by bead-beating in order to process a wide range of pathogens, including viral, bacterial and hard-to-lyse fungal pathogens. The cartridge design incorporates a patented rotary valve that integrates sample purification and is easily adaptable to alternate fluidic layouts to accommodate alternate testing methods that may require pre-treatment of specimens, pre-amplification and/or multiple purification steps to facilitate expansion of the testing menu. The cartridge also incorporates a reagent plug technology licensed from a contract manufacturing partner, which is designed to enable implementation of new tests on the same cartridge backbone simply by inserting plugs with different target assay reagents. The reagent plugs in our cartridges are optically clear, permitting the instrument to visualize and detect fluorescent signals from the amplification assay. Patented assay wells employ a fluidic design and include a mechanism to heat-seal the cartridge for amplicon containment designed to prevent contamination of the work surfaces.

The cartridge, with modifications, is designed to support up to 14-well multiplexing, which we believe will enable development of expanded panels and syndromic applications. The specific cartridge that we developed for the COVID-19 and CT/NG/TV tests provides 5-fold multiplexing, which we believe is sufficient to meet our anticipated product plans.

*Talis One instrument*

The Talis One instrument is designed to enable sample-to-answer capabilities without user intervention. We designed the instrument to be low cost, portable and easy to use. We believe the modular design, which is divided into major subsystems for performing cartridge handling, sample preparation, amplification and detection, will facilitate automated assembly and low-cost manufacturing. The compact size, approximately 7 x 10 x 14 inches, is designed to enable portability and use in various front-line locations. The instrument incorporates a touchpad interface for easily communicating instructions, information and results to the user. An integrated camera that reads and enables registration of a label on the cartridge, facilitates sample custody by linking an image of the cartridge label with test results. The instruments are designed for multi-instrument deployments to satisfy different testing volume requirements and can be stacked three instruments by three instruments without disturbing the cellular connection to the cloud.

*Talis One software and IT*

The Talis One system incorporates software and information technology (IT) capabilities. The instrument is designed to communicate test results to a central cloud database that can be remotely and securely accessed to obtain key data required to collect, screen, collate, report, and monitor disease infection and pandemic spread on a micro and macro level. The cellular and ethernet connectivity built into each Talis One instrument is also designed to enable Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant transmission, storage, and review. Such centralized storage could permit (i) creation of a public health interface granting access to select information to governmental entities and/or (ii) automatic transmission of “reportable infections” to public health authorities. The cloud-based data could serve to help institutions better manage clinical practice and also to improve infection control. With substantially increased adoption over time, the data may offer a mapping of infection patterns that public health and research institutions can use to address care on a larger scale. Additionally, for organizations that may desire multiple instrument placements, such as in multiple exam rooms, multiple departments or distributed testing sites, authorized administrators may be able to monitor, in real-time, the status of any instrument in the organization, as well as manage users, passwords, and certain security features. The continuous connectivity of the Talis One instruments is also designed to enable us to provide automated updates including security patches, instrument configurations, and firmware and software updates, the latter of which could be deployed to enable the instrument to recognize and run newly released tests.

*Talis One workflow*

The Talis One system is capable of being integrated into the clinical workflow as follows: (1) label cartridge with patient information, (2) dispense sample into loading port and close lid, (3) insert cartridge into instrument, and (4)

follow on-instrument instructions to initiate testing, results will automatically display after less than 30 minutes. The workflow may vary for alternate sample types.

The Talis One workflow follows a few simple steps from sample preparation to results. The system is designed to return results in less than 30 minutes and requires two minutes or less of hands-on time for the operator. After the sample is collected and the cartridge is introduced into the instrument, the instrument confirms the operability of the cartridge, runs the assay and communicates the test result to the instrument display. We believe the ease of use, compact size and speed could enable near-patient diagnosis in a broad range of settings.

*Talis One assay kits*

We are a development stage company and, to date, we have not generated revenue from the sales of our own product. As described below, we are developing Talis One assay kits for respiratory infections, infections related to women's health and STIs. Our first test to be marketed will be the Talis One COVID-19 Test System, which focuses on detection of SARS-CoV-2, the virus that causes COVID-19. We are also developing additional tests for the detection of other respiratory infections, such as the Respiratory Panel. We also intend to submit for a 510(k) clearance to commercialize our Talis One system with a test for CT/NG/TV. For other tests that are not eligible for an EUA, we intend to complete the requirements for and submit a 510(k) pre-market notification to the FDA (if available to us; otherwise we would plan to submit another form of marketing authorization under the FDA's standard medical device authorities). We chose our assay development roadmap to address the most common clinically relevant tests that require high sensitivity and specificity and for which timely results provide significant clinical benefit. In addition to the CT/NG/TV test, our women's and sexual health roadmap includes plans to develop and seek marketing authorization for (1) an STI panel including CT, NG, TV, and Mycoplasma genitalium; (2) an assay for HSV; (3) a multitarget panel assay for UTI; (4) a multitarget panel assay for BV; and (5) a single target assay for Group B streptococcus.

**Respiratory infections**

*The Talis One COVID-19 Test System*

The Talis One COVID-19 Test System is our first product that we developed for respiratory infections. The test cartridge for COVID-19 diagnosis contains a NAAT designed for optimal sensitivity and specificity to provide highly accurate results. The assay on the Talis One cartridge is an isothermal NAAT targeting two physically separated locations in the SARS-CoV-2 genome to increase sensitivity and inclusivity. The inclusion of two distinct targets reduces the likelihood that natural mutations in the virus would cause a false negative result when using the Talis One COVID-19 Test System. In the third quarter of 2021, we submitted a request for EUA to the FDA for our Talis One system in non-laboratory setting, and on November 5, 2021, we received an EUA from the FDA for the emergency use of the Talis One COVID-19 Test System. We are currently pursuing authorization to affix a CE Mark from the European Medicines Agency (EMA) for the Talis One COVID-19 Test System and plan to complete this self-certification process under the European In-Vitro Diagnostic Directive by May 2022.

*Respiratory panels*

If we successfully commercialize the Talis One COVID-19 Test System, we plan to incorporate the Influenza A, Influenza B, and potentially the RSV tests with the COVID-19 test in an upper respiratory panel on a single cartridge. We plan to seek marketing authorizations for such multi-panel tests through a 510(k) clearance process.

*Infections related to women's health and sexually transmitted infections*

We are also developing our Talis One system to be used for infections related to women's health and STIs. We intend to complete clinical development of our Talis One system for CT/NG/TV and submit a 510(k) pre-market notification to the FDA after the successful completion of our clinical trials. We further intend to explore authorization to affix a CE Mark from the EMA approximately six months after 510(k) clearance, if obtained. If cleared or otherwise authorized for marketing, this would be our first commercial offering in our women's health menu. We are planning to develop additional tests for infections related to women's health, including a panel for STIs and other infections, such as BV, UTI and HSV.

The American Congress of Obstetricians and Gynecologists recommends annual CT/NG screening of all sexually active women age 25 and younger and for women over age 25 with risk factors. In addition to promoting our test

menu to our existing customers, we will engage in a focused commercialization effort directed towards obstetricians and gynecologists, where we estimate that a substantial majority of CT/NG testing occurs. Traditionally, testing is carried out by centralized laboratories, and we believe that there is a significant opportunity to move these tests to the point-of-care at the office of the obstetrician and gynecologist or in urgent care clinics or primary care facilities. We believe testing at the point-of-care could (a) improve decision making and enable the provider to use this information to treat the patient in the same visit and (b) improve the patient experience and empower providers and patients to adhere to screening guidelines and improve outcomes. We also believe that care providers may be able to create profit opportunities by bringing testing in-house to the point-of-care. We believe the tests that we are developing for our Talis One system have established reimbursement codes, enabling healthcare providers to submit for reimbursement.

*Future applications*

We are developing new algorithms and a bioinformatics pipeline to design rapid isothermal assays that are based on isothermal amplification chemistries. On the Talis One system, we have observed limits of detection of bacterial pathogens as low as one IFU/mL in a variety of unpurified patient sample types, including nasal swab, vaginal swab, saliva and urine. We have also demonstrated, in a research setting, rapid detection of similarly low concentrations for a variety of bacterial, fungal, parasitic and viral pathogens.

**Commercialization**

As part of our menu expansion outside of COVID-19 testing, we are developing relevant in vitro diagnostic tests for a variety of respiratory infections, and infections related to women’s health and STIs. We estimate that the total potential annualized addressable global market opportunity for molecular testing of infectious diseases is over $5.4 billion for 2022 and is expected to grow to over $7.1 billion by 2026.

We intend to commercialize the Talis One system through an enterprise sales team and a direct sales force focused initially on placing systems with potential customers that place high value on accuracy and our broader test menu in development. Target customer segments include (but are not limited to): (1) traditional medical establishments, including physician offices, urgent care chains, hospitals, and public health clinics and (2) additional segments, including schools, workplaces, prisons, and elder care facilities.

We intend to offer our Talis One system to customers via direct purchase of the instrument or through a reagent rental program. Under these options we expect to generate revenue in the form of instrument sales or rentals, test cartridge sales, instrument warranty payments, and test collection device revenue.

We designed our system for the institutional healthcare provider category, particularly those that serve populations who are especially vulnerable to infectious diseases, such as COVID-19. We believe that this market category could be a significant driver of our growth both near and longer-term due to the many types and significant number of potential institutional healthcare providers. Institutional healthcare providers typically represent sizeable patient populations, allowing a relatively large number of patients to be targeted with a limited number of account managers. Although institutional healthcare providers may require a sales cycle lasting several weeks or months, fixed-price arrangements from certain of these customers may provide us with a steady and predictable revenue stream.

While institutional healthcare providers are an important selling focus initially, we believe establishment of a direct sales force will enhance our growth, increase the number of institutional referrals, and expand the footprint of our brand within the U.S. market.

In 2021, we expanded the size of our sales force based on the anticipated timing for the commercial launch of the Talis One COVID-19 Test System and other product opportunities that we may pursue in the future. In late December 2021, we entered into an agreement to act as an authorized distributor for third party COVID-19 antigen tests (Antigen Tests). In January 2022, we began purchasing and distributing the Antigen Tests to customers, including sub-distributors, hospitals, physician's offices, urgent care clinics, and public health clinics. This opportunity has allowed us to generate revenue while leveraging our sales force, commercial infrastructure, and operations team. We are not subject to any minimum purchasing requirements or long-term commitments. We will continue to pursue other such product opportunities that can generate revenue and provide relevant experience to our different business units, while maintaining focus on delivering on our core business product, the Talis One system.

In March 2022, we optimized the size of our sales force based on our current anticipated timing for the commercial launch of the Talis One COVID-19 Test System.

**Competition**

The in vitro diagnostics industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary intellectual property. Due to the significant interest and growth in diagnostics, we expect ongoing intense competition primarily from centralized laboratories and diagnostic companies offering both point-of-care and at-home solutions. We believe key competitive factors include the accuracy, utility, turnaround time and economics of our products, and commercial execution. We also believe our ability to succeed in the future depends on the timing of obtaining regulatory clearances and approvals, as well as the timing of our ability to deliver instruments and consumables into the marketplace in significant volumes. We have encountered manufacturing challenges that have contributed to significant delays in our ability to produce the Talis One system at scale which has then delayed the commercialization of the Talis One system.

Our 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. Our competitors in the point-of-care and/or at-home category, for molecular and/or antigen tests that have received an EUA for their COVID-19 tests, include Abbott Laboratories, Binx Health, Inc., BioFire Diagnostics, LLC, Cepheid (a subsidiary of Danaher Corporation), Cue Health Inc., Lucira Health, Inc., Thermo Fischer Scientific Inc., Roche Molecular Systems, Inc., Visby Medical, Inc., ON/GO, Quidel, and OraSure.

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. Smaller or early-stage companies developing tests may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies or customer networks. If our competitors (a) develop and commercialize diagnostic products or services that are more accurate, more convenient to use or more cost-effective than our products or services and/or (b) 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, our commercial opportunity could be reduced or eliminated, especially if our competitors establish a strong market position before we are able to enter a particular market.

**Government Contract**

*National Institutes of Health - Rapid Acceleration of Diagnostics (RADx)*

In July 2020, we were awarded a $25.4 million contract from the National Institutes of Health (NIH) for Phase 2 of its RADx initiative (NIH Contract), of which $8.9 million had been received as of December 31, 2021, for the validation, approval, and scale-up of capacity for manufacturing of the Talis One instrument and test cartridges. Due to delays in meeting certain milestones, we received several extensions to the NIH Contract that concomitantly extended the time to perform the remaining milestones and reduced the potential milestone payments. The NIH Contract expired on January 30, 2022, and we did not achieve the final two milestones.

**Operations**

*Manufacturing process*

Our products are manufactured by several third parties, including a single contract manufacturer that provisions the parts and assembles our instrument. The instrument assembly is largely manual with some automation in testing. We have various suppliers that provide molded parts and reagents that are assembled by two contract manufacturers for the cartridge. We have made significant investments to scale up cartridge manufacturing including high cavity count molding capability and automation of significant portions of the cartridge assembly process. Due to the complexity of the manufacturing process, we have experienced significant delays in bringing the automated manufacturing lines online. We are focused on developing more internal expertise in manufacturing our cartridges and are developing internal pilot manufacturing lines. Our operations consist of demand forecast planning, raw material procurement, and quality oversight. The operations team is responsible for ensuring adherence to our Quality Management System to meet or exceed applicable standards to support manufacturing, testing and distribution of our products.

*Supply chain management*

We utilize multiple vendors for our supply chain. Currently, many of the materials, enzymes and reagents used in our systems and cartridges are from single source suppliers. However, we are evaluating redundancy vendors for reagents and other materials, where possible. 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. Initially, we plan to source many of the test cartridge materials and provide them to our contract manufacturers. Over time, we plan to transfer acquisition of these materials to our contract manufacturing partners. We have engaged a third-party logistics company to manage the movement of materials between suppliers and for finished goods warehousing, as well as to manage the receipt and shipment to customers of the Antigen Tests.

*Supply Agreement with thinXXS Microtechnology AG (thinXXS)*

In May 2020, we entered into a supply agreement with thinXXS (thinXXS Agreement), a wholly-owned subsidiary of IDEX Corporation (NYSE:IEX), for the purchase of certain materials, including single-use cartridges for use with the Talis One system and components and subassemblies of such single-use cartridges. Pursuant to the thinXXS Agreement, we are required to submit an annual forecast of expected purchase volumes with portions of such annual forecast constituting a binding commitment based on certain percentages set forth in the thinXXS Agreement. We are also required to submit non-binding rolling forecasts to thinXXS. The prices we pay were initially fixed upon execution of the thinXXS Agreement and may not be increased until a specified date. Following such specified date, the purchase prices will be negotiated by the parties. Additionally, subject to certain criteria, thinXXS has the right to be our exclusive supplier of the cartridges, up to a specified annual volume.

The initial term of the thinXXS Agreement is 10 years, after which the thinXXS Agreement will remain in effect unless we provide two years' prior written notice of non-renewal. The thinXXS Agreement can also be terminated (i) after May 2027, by us for convenience, upon two years' prior written notice, (ii) subject to certain conditions, by either party upon 90 days' prior written notice of an uncured material breach of the thinXXS Agreement, and (iii) by either party upon bankruptcy or insolvency of the other party. The parties agreed to amend the thinXXS Agreement and a 2021 purchase order issued under the thinXXS Agreement, in late December 2021, which, among other things, reduced our outstanding payment obligations.

**Intellectual property**

Our intellectual property strategy is focused on protecting our core technologies, including target-specific amplification reagents, integrated cartridges and components thereof, and related instrumentation and software applications through patents and other intellectual property rights. In addition, we protect our ongoing research and development into the detection of infectious diseases through patents and other intellectual property rights in the United States and foreign jurisdictions, such as Japan, China, the United Kingdom and the European Union (through shared registration or examination agencies such as the European Patent Office or European Intellectual Property Office).

*Patents*

As of February 1, 2022, we solely own 14 issued U.S. patents, 20 pending U.S. patent applications, 14 issued foreign patents, 84 pending foreign patent applications, and two pending PCT international patent applications. We co-own three issued U.S. patents, two pending U.S. patent applications, one issued foreign patent, and 14 pending foreign patent applications with Caltech. We exclusively in-license 10 issued U.S. patents, two pending U.S. patent applications, 20 issued foreign patents and two pending foreign patent applications from the University of Chicago and/or Caltech. We believe that the technology we have in-licensed from the University of Chicago and Caltech, respectively, has no impact on our competitive position in our industry. Our patent portfolio generally includes patents and patent applications relating to microfluidic systems, our rapid isothermal amplification method, integrated cartridges and instrument for the Talis One system, as well as components thereof and methods of operating the same. In addition to patents and applications related generally to the Talis One system, our portfolio includes patents and applications drawn to assay reagents for specific targets, including SARS-CoV-2 (the causative pathogen for COVID-19), CT, and NG. Issued U.S. patents in our portfolio of company-owned and in-licensed patents and patent applications (if issued) are expected to expire between 2030 and 2040.

*Trademarks*

Our trademark portfolio is designed to protect the brands of our current and future products and includes U.S. trademark applications for registration for our company name, Talis, and the product name Talis One.

*Trade secrets*

We also rely on trade secrets, including know-how, unpatented technology and other proprietary information, to strengthen our competitive position. We have determined that certain technologies, such as aspects of our amplification chemistry, some bioinformatics, data processing and analysis techniques, and manufacturing processes are better kept as trade secrets, rather than pursuing patent protection. To prevent disclosure of trade secrets to others, it is our policy to enter into nondisclosure, invention assignment and confidentiality agreements with parties who have access to trade secrets, such as our employees, collaborators, outside scientific collaborators, consultants, advisors and other third parties. These agreements also provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

In addition to Company-owned intellectual property, we may also in-license third party intellectual property for use in our products through both exclusive and non-exclusive licensing agreements. Although we have been able to obtain licenses on commercially reasonable terms, there is no guarantee that we may obtain such licenses in the future on reasonable terms or at all.

**Government regulation and product approval**

Our products under development and our operations are subject to significant government regulation.

*Regulation in the United States*

In the United States, our products are regulated as medical devices by the FDA and other federal, state, and local regulatory authorities. Numerous laws and regulations govern the processes by which medical devices are brought to market and marketed, including the FDCA and the FDA's implementing regulations, among others. The FDA regulates the preclinical and clinical testing, approval, manufacture, labeling, distribution, and promotion of medical devices. The FDA enforces these requirements by inspection and market surveillance. Failure to comply with applicable regulatory requirements may result in enforcement action by the FDA, which may include fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusing our request for 510(k) clearance or pre-market authorization (PMA) of new product versions, revocation of 510(k) clearance or PMAs previously granted, and criminal prosecution and penalties.

The FDA classifies all medical devices into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I and Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of Class II devices, including performance standards, post-market surveillance, clinical investigations, patient registries and additional conditions set forth in FDA guidance documents. While most Class I devices are exempt from the 510(k) pre-market notification requirement, manufacturers of most Class II devices are required to submit to the FDA a pre-market notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) pre-market notification is generally known as a 510(k) clearance. Devices deemed by the FDA to pose the greatest risks are placed in Class III, requiring approval of a PMA application. At this time, we have no Class III devices in the pipeline nor plans to add Class III's.

In addition, EUAs and other forms of approval or clearance may be limited for use with tests by authorized laboratories certified under CLIA to perform moderate and high-complexity tests. In order for a test to be used at the point-of-care, the FDA must grant the test waived status under CLIA, which would permit any laboratory with a Certificate of Waiver to perform the test.

The U.S. Secretary of the Department of Health and Human Services (HHS) may declare public health emergencies that have a significant potential to affect national security or the health and security of U.S. citizens. On February 4, 2020, the novel coronavirus was declared a public health emergency, and it was declared that circumstances existed justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus that causes COVID-19. These EUAs will terminate upon declaration that the public health emergency

circumstances have ceased, or the product provided pursuant to EUA has otherwise achieved commercial authorization for the emergency indication for use, such as through 510(k) clearance, *de novo* process, or PMA approval.

In order to be the subject of an EUA, the FDA Commissioner (under authority delegated by the Secretary of the HHS) must conclude that, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a disease attributable to the agents described above, that its known and potential benefits outweigh its known and potential risks, and that there is no adequate, approved and available alternative. The FDA may revise or revoke an EUA to protect the public health.

*510(k) clearance process*

To obtain 510(k) clearance, we must submit a pre-market notification to the FDA demonstrating that the proposed device is substantially equivalent to a previously-cleared 510(k) device, a pre-amendment device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a 510(k) or PMA applications, or is a device that has been reclassified from Class III to either Class II or I. In rare cases, Class III devices may be cleared through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months from the date the application is submitted and filed with the FDA but may take significantly longer. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. In reviewing a pre-market notification submission, the FDA may request additional information, including clinical data, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is not "substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the *de novo* classification process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. Once a de novo application is reviewed and approved, it results in the device having a Class II status and future devices from the company or a competitor may use the company's de novo-classified device as a 510(k) predicate.

After a device receives 510(k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA may review any such decision and may disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA may require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA is obtained. Under these circumstances, the FDA may also subject a manufacturer to significant regulatory fines or other penalties.

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 intends 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. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to

implement such proposals through legislation. 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.

*Pervasive and continuing FDA regulation*

After a medical device is placed on the market, numerous FDA regulatory requirements apply, including, but not limited to the following:

- the Quality System Regulation (QSR), which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- establishment registration, which requires establishments involved in the production and distribution of medical devices, intended for commercial distribution in the United States, to register with the FDA;
- medical device listing, which requires manufacturers to list the devices they have in commercial distribution with the FDA;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and advisory notification reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- complying with the new federal law and regulations requiring Unique Device Identifiers (UDI) on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- labeling regulations, which prohibit "misbranded" devices from entering the market, as well as prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and
- post-market surveillance including the clinical performance of the product after introduction into the market and Medical Device Reporting, which requires manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury, or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

The FDA enforces these requirements by inspection and market surveillance. Failure to comply with applicable regulatory requirements may result in enforcement action by the FDA, which may include one or more of the following sanctions:

- warning letters;
- customer notifications for repair, replacement or refunds;
- fines, injunctions, consent decrees and civil penalties;
- mandatory recall or seizure of our products;
- administrative detention or banning of our products;

- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for 510(k) clearance or PMA of new product versions;
- revocation of 510(k) clearance or PMAs previously granted; and
- criminal prosecution and penalties.

*International Regulation*

Sales of medical devices outside the United States are subject to foreign government regulations and international standards compliance, which vary substantially from country to country. In order to market our products in other countries, we must obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ significantly.

*Other healthcare laws*

Our current and future business activities are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, physician sunshine transparency, and healthy information privacy and security laws and regulations.

The federal Anti-Kickback Statute (AKS) prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual, for an item or service or the purchasing, leasing, ordering, or arranging for or recommending the purchase, lease or order of any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs. The term remuneration has been interpreted broadly to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the AKS has been violated. In addition, a person or entity does not need to have actual knowledge of this statute 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), prohibit 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. Additionally, the FCA authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government intervenes and is ultimately successful in obtaining redress in the matter, or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of life sciences companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. 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. The government has obtained multi-million and multi-billion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The majority of states also have anti-kickback laws which establish similar prohibitions and, in some cases, may apply to items or services reimbursed by any third-party payor, including commercial insurers. HIPAA created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the AKS, a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Moreover, the federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services (CMS), information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by such physicians and their immediate family members. The Physician Payments Sunshine Act includes in its reporting requirements a broad range of transfers of value including, but not limited to, consulting fees, speaker honoraria, charitable contributions, research payments and grants. Failure to report could subject companies to significant financial penalties. Tracking and reporting the required payments and transfers of value may result in considerable expense and additional resources. Several states currently have similar laws and more states may enact similar legislation, some of which may be broader in scope. For example, certain states require the implementation of compliance programs, compliance with industry ethics codes, implementation of gift bans and spending limits, and/or reporting of gifts, compensation and other remuneration to healthcare professionals.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our future operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, additional reporting and oversight requirements, exclusion from participation in federal and state healthcare programs and imprisonment.

*Coverage and reimbursement*

Sales of our products will depend in large part on the availability of adequate coverage and reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. These third-party payors are increasingly limiting coverage and reducing reimbursement for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls and restrictions on coverage and reimbursement. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results.

Hospitals, clinical laboratories and other healthcare provider customers that may purchase our product candidates, if approved, generally bill various third-party payors to cover all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of our product candidates. If our product candidates are cleared or approved by the FDA as point-of-care tests and deemed CLIA-waived following market authorization, we expect that the majority of our diagnostic tests will be performed in physician offices and other point-of-care settings and billed using existing Current Procedural Terminology (CPT) codes. Our healthcare provider customers may not purchase our tests unless third-party payors cover and provide adequate reimbursement for a substantial portion of the price of the tests. If we are not able to obtain coverage and an acceptable level of reimbursement for our tests from third-party payors, there would typically be a greater co-insurance or co-payment requirement from the patient for whom the test is ordered or the patient may be forced to pay the entire cost of the test out-of-pocket, which could dissuade practitioners from ordering our tests and, if ordered, could result in a delay in or decreased likelihood of

collecting payment, whether from patients or from third-party payors. Our customers' access to adequate coverage and reimbursement for our products and/or product candidates by government and private insurance plans is central to the acceptance of our products. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels.

The potential end-users of our Talis One system and diagnostic tests include large elder care chains where vulnerable residents have unmet needs for millions of high sensitivity assays per year; 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, 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.

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.
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 outbreak. For example, the Families 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 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. In addition, 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 outbreak which continue to evolve. For example, effective January 15, 2022, private health insurance companies and group health plans are required to cover eight free over-the-counter at-home COVID-19 diagnostic tests authorized, cleared, or approved by the FDA per covered individual per month.

**Data Privacy**

In the ordinary course of our business, we may process personal data and, accordingly, we are, or may become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection. Such obligations may include, without limitation, the Federal Trade Commission Act, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the California Consumer Privacy Act of 2018 (CCPA), the European Union's General Data Protection Regulation 2016/679 (EU GDPR), the EU GDPR as it forms part of United Kingdom (UK) law by virtue of section 3 of the European Union (Withdrawal) Act 2018 (UK GDPR), and the ePrivacy Directive. In addition, several states within the United States have enacted or proposed data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act.

The CCPA, EU GDPR, and UK GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing may increase our compliance obligations and exposure for any noncompliance. For example, the CCPA imposes obligations on covered businesses to provide specific disclosures

related to a business's collecting, using, and disclosing personal data and to respond to certain requests from California residents related to their personal data (for example, requests to know of the business's personal data processing activities, to delete the individual's personal data, and to opt out of certain personal data disclosures). Also, the CCPA provides for civil penalties and a private right of action for data breaches which may include an award of statutory damages. In addition, it is anticipated that the California Privacy Rights Act of 2020 (CPRA), effective January 1, 2023, will expand the CCPA. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal data, establish restrictions on personal data retention, expand the types of data breaches that are subject to the CCPA's private right of action, and establish a new California Privacy Protection Agency to implement and enforce the new law. U.S. federal and state consumer protection laws may require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

European data privacy and security laws (including the EU GDPR and UK GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. For example, the EU GDPR applies to any company established in the European Economic Area (EEA) and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances.

See the section titled "Risk Factors – Risks related to regulatory matters" for additional information about the laws and regulations to which we are or may become subject and about the risks to our business associated with such laws and regulations.

**Human capital resources**

As of December 31, 2021, we had a total of 262 employees, 242 of whom were full-time employees. Our employees are located in Menlo Park, California, Chicago, Illinois and other locations inside and outside the United States. None of our employees are represented by any collective bargaining agreements. We believe that we maintain good relations with our employees. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

**Available Information**

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (Exchange Act), are filed with the SEC. Such reports and other information filed by us with the SEC are available free of charge on our website at http://investors.talisbio.com when such reports are available on the SEC's website. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. The information contained on the websites referenced in this Annual Report on Form 10-K is not incorporated by reference into this filing. Further, our references to website URLs are intended to be inactive textual references only.

**Item 1A. Risk Factors.**

*Careful consideration should be given to the following risk factors, together with the other information contained in this Annual 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 Annual 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**

*We rely on a significant number of third party manufacturers and suppliers for our instrument and cartridges, which reliance has created and may continue to create delays due to the complexity of our manufacturing lines and supply chain, as well as exposure to manufacturing and supply limitations or interruptions and quality and quantity issues.*

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. The manufacturing of our Talis One instrument and cartridge is a complex process that involves over 500 raw materials, intermediates and subassemblies. The complexity of the instrument and cartridge designs and number of parts involved has presented manufacturing challenges for us and our third party manufacturers. In addition, our reliance on these third party manufacturers exposes us to significant risk that we will not have sufficient quantities of our products at an acceptable cost or quality, which has and could continue to delay, prevent or impair our clinical trials and commercialization efforts. 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. These automated lines are required to meet the projected volume commercial needs for the Talis One COVID-19 Test System once validation of performance is complete. However, the lines are not complete and have and could continue to incur substantial delays, costs and have not performed as anticipated, and any additional failure of the lines to perform as anticipated could require us to make significant capital expenditures to make adjustments. In addition, delays that may occur with one supplier have had and could continue to have a ripple affect with other suppliers. Such ripple effects have and could continue to increase costs or obligate Talis to purchase materials before they are required for commercial purposes which have and could continue to increase costs, increase risk of scrap or damage relationships with our suppliers. For example, we have encountered manufacturing challenges that have contributed to significant delays in our ability to produce the Talis One system at scale which has delayed the commercialization of the Talis One system. Such delays and any future delays or required expenditures have and could continue to prevent us from launching our Talis One COVID-19 Test System, which will adversely impact our business, financial condition and results of operations. The effects of any such delays would also be exacerbated if the demand for COVID-19 tests declines prior to our assembly lines becoming fully operational at scale.

As we have not yet completed the validation of our high-volume assembly lines, it may be difficult to predict the cost of manufacturing our cartridges at scale. 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. However, there is no guarantee that we will be able to achieve planned cost reductions from such initiatives. For example, yield from the automated lines may be low resulting in many components to be scrapped or quality of final products may not meet our requirements, which may increase scrap and therefore, our costs. There have been unforeseen occurrences that have increased our costs for supplies used in manufacturing our cartridges and instruments, and there could be other unforeseen occurrences, 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, including as a result of increased shipping costs caused by the substantial increase in fuel prices. As a result, even if our automated lines perform as anticipated, we may be unable to manufacture our products 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 in 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, unstable political environments, health pandemics or epidemics or rising costs of labor, materials and transportation. For example, due to the health crisis of the COVID-19 pandemic and labor shortages, some of the suppliers of materials and components for our instrument and cartridges are facing extreme demand for their services. If we are unable to procure sufficient supplies for our instruments and cartridges, at the level of quality we need, and at a commercially reasonable cost, 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 at a commercially reasonable cost, 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 pandemic 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 a 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, 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 we desire to or 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 or deliver 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;
- delay in optimizing the use of our automated manufacturing lines;
- requirements to cease development or to recall batches of our products; and
- even 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.

*If the EUA for the Talis One COVID-19 Test System 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 will likely be a lengthy and expensive process.*

On November 5, 2021 we received an EUA from the FDA for our Talis One COVID-19 Test System. In support of the EUA, we were required to submit data from a post-market study to the FDA by March 5, 2022, although we have been granted an extension to provide the data four months after the commercial launch of the Talis One COVID-19 Test System, among other requirements. We currently expect that the future commercial launch will be pursuant to such EUA. At present, we can produce the Talis One instrument and cartridges but not at a scale to support our commercial launch. We are currently validating the performance of our manufacturing equipment and procedures and plan to broadly market our Talis One COVID-19 Test System after the phased launch.

We will rely on the FDA policies and guidance in connection with the marketing and sale of our Talis One system for its intended use in detecting SARS-CoV-2. 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, including our failure to successfully complete, and submit data from our post-market study by the extension date granted by the FDA or any other post-authorization requirements.

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 current 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. We cannot predict how long an EUA for the Talis One COVID-19 Test System will remain in place. FDA policies regarding diagnostic tests, therapies and other products used to diagnose, treat or mitigate COVID-19 remain in flux, and on December 22, 2021, the FDA issued two draft guidance documents for the transition plans for medical devices commercialized pursuant to EUA during the current public health emergency for the review and comment process. 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 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, the 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 initially considered seeking an additional EUA from the FDA for our respiratory panel targeting the detection of the SARS-CoV-2 virus, and Influenza A and B. However, the FDA released additional guidance on November 22, 2021 setting forth additional requirements for EUA applicants, namely that the applicant must either qualify as an experienced developer, or if not a qualified developer, the applicant must have a sponsor. We do not qualify as an experienced developer, nor do we currently have any sponsors for the combination test, therefore, it is unlikely 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 an 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 be unable to validate our manufacturing for the Talis One instrument and cartridges at scale, which may impact our ability to start and/or complete our post-authorization clinical evaluation study required by the EUA for the Talis One COVID-19 Test System, as well as impact our ability to support our research and development pipeline.*

In order to commercialize our products, we will need to manufacture the Talis One instrument and cartridges in large quantities. We have experienced delays in manufacturing our products, and 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. If we are unable to manufacture our products at scale, this will impact our ability to start, as well as complete, the post-authorization clinical evaluation study required by the EUA for the Talis One COVID-19 Test System. Failure to timely complete this clinical study would likely result in the withdrawal of the EUA which event would have a material adverse effect on our business, financial condition and results of operations. 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 our other products 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. We have experienced delays related to the manufacture of the instrument and cartridges due to the complexity of the process. This has subsequently delayed our progress in developing future products by reducing access to material and requiring us to divert significant internal resources to focus on stabilizing the manufacturing process with our manufacturing partners. Also, due to the insufficient supply of instruments and cartridges, we have not been able to commence formal reliability studies to determine product reliability when produced at scale.

*If we change the design of the Talis One instrument and/or cartridge to improve manufacturability at scale, we may need to obtain new FDA authorization for our Talis One COVID-19 Test System.*

As a result of the manufacturing issues that we have encountered with the Talis One instrument and cartridge, we may consider making design changes that could improve the manufacturability at scale, and overall reliability and consistency of the instrument and cartridge. However, if we were to update the design of the instrument and cartridges, we may be required to obtain new FDA approval for the Talis One COVID-19 Test System, and could no longer rely on the EUA and would need to obtain 510(k) clearance for the updated products. While there would likely be long term benefits in enhancing and improving the Talis One instrument and cartridge design, there could be a material negative impact to our business if we are no longer able to market the Talis One COVID-19 Test System until we have obtained 510(k) clearance for the updated products. We would also incur additional design and engineering expense for the updated design work, as well as for the clinical trials required for the 501(k) submission.

*The EUA for our Talis One COVID-19 Test System may be revoked or may terminate at the conclusion of the public health emergency, and we may not be able to obtain marketing authorization for additional assays, 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 depends upon the initial commercialization of our Talis One COVID-19 Test System pursuant to an EUA, 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 the EUA we have received is 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. In addition, any future marketing authorization of the Talis One system for our CT/NG/TV and other women's health assays will require pursuing a 510(k) clearance, or another available approval path.

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 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 experience with the entire commercialization process for the Talis One system. We have gained experience with the initial stages of the process, including demand generation, evaluations, and quoting, and we have recent commercialization experience selling and distributing the Antigen Tests. As a result, we have limited experience forecasting future financial performance for our products, including any third-party products that we may offer, such as the Antigen Tests, 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 acquisition model for our Talis One system and cannot predict the proportion of customers that would procure the Talis One instrument through capital purchase versus our planned equipment leasing model. Our results of operations could fluctuate with high variability depending on the changes in the proportion of our customers who directly purchase as compared to renting the equipment which will make it challenging to predict our operating results, particularly during the early stages of our commercial launch.

We expect to initially market and sell the Talis One COVID-19 Test System in the United States pursuant to our EUA. A substantial portion of our revenue will depend upon such sales, which we expect will continue to be the case until such time as we obtain marketing authorization for subsequent tests, or if we are able to successfully pursue other product opportunities, such as selling third party products like the Antigen Tests. As a result, our future success will depend in large part on our ability to effectively launch the Talis One COVID-19 Test System, subsequently introduce enhanced or new tests for the Talis One system and find other opportunities that could augment our business without materially diverting resources from our focus on the Talis One system. Any future commercialization of the Talis One system for other assays will require pursuing additional EUAs, 510(k) clearance or another available approval path. 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, the future competitive landscape, 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 or when our tests are launched;
- 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 performance 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 the Talis One COVID-19 Test System, our commercial success could also depend on the vaccination rates in the US and effectiveness of the available COVID-19 vaccines against all variants of interest, as this could decrease the demand for COVID-19 tests. 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, the development of safe and effective therapeutics, the impact of new variants, or due to other events. Commercial success of our Respiratory Panel will depend on receiving FDA authorization pursuant to the more onerous 510(k) pathway for market authorization, which could further delay bringing our respiratory product to market. A delay in receiving authorization could allow competitors who have already obtained authorization for combined COVID-flu tests to gain significant market share prior to our entry into the market. 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 develop or further enhance 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 have commenced selling the Antigen Tests and are investigating other third party product opportunities to generate revenue which could divert focus from commercializing our own product, the Talis One system.*

In January 2022, we began purchasing the Antigen Tests from a third party and distributing them to customers, as an authorized distributor. We purchase the Antigen Tests in advance and resell them to customers, including sub-distributors, hospitals, physician's offices, urgent care clinics, and public health clinics. While we have been able to sell the Antigen Tests at a profitable rate, there were initially significant resource demands on different business teams, including finance, legal, operations, commercial infrastructure, and sales, that allowed us to move forward with this opportunity. We are exploring additional partnerships that could allow us to distribute over-the-counter rapid antigen tests for COVID-19, as well as for antigen tests for infections other than COVID-19. If we continue to pursue other third-party product opportunities to generate revenue, there could be required financial outlays, as well as demands on our personnel, that could potentially divert resources away from the Talis One system. There could

be future opportunities that lead to unexpected or unplanned demands on our financial and human capital resources that on their own could have a material adverse effect on our business, financial condition and results of operations, while also materially impacting our commercialization efforts for the Talis One system.

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

The Defense Production Act of 1950, as amended (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 COVID-19 crisis, the sitting President of the United States has used this authority numerous 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 applied the DPA to our RADx contract but allowed that rating to expire upon the original expiration date of the RADx contract on July 30, 2021, before we received the EUA. 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 has and could continue to materially adversely affect our business, financial condition and results of operations.*

The COVID-19 pandemic continues to negatively impact 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 may be 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 originally set to expire July 30, 2021, was amended to extend the performance period to January 30, 2022, the DPA rating was not extended and expired. COVID-19 has also resulted in significant business and operational disruptions, including business closures, supply chain disruptions, travel restrictions, stay-at-home orders and limitations on the availability of workforces. COVID-19 precautions may 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. Although local jurisdictions have subsequently lifted stay-at-home orders and moved to the opening of businesses, worker shortages, vaccine and testing requirements, new variants of COVID-19 and other health and safety recommendations have impacted the ability of businesses to return to pre-pandemic levels of activity and employment. While the overall economy has improved, disruptions to supply chains continue and significant inflation has been seen in the market. The extent to which COVID-19 negatively impacts our business and operations will depend on 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. If the adverse effects of the COVID-19 pandemic continue for a prolonged period or result in sustained economic stress, higher inflation levels or recession, many of the other risks described in this "Risk Factors" section could be exacerbated, such as those relating to our reliance on a limited number of suppliers, our need to raise additional capital to fund our existing operations and our ability to procure sufficient supplies for our instruments and cartridges, at the level of quality we need, and at a commercially reasonable cost.

*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, including SARS-CoV-2, are known to mutate over time. Such mutations may negatively affect the accuracy of our tests or even make our tests obsolete if our tests are unable to detect future variants. 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 shortage of available testing, at the point-of-care, means there is currently significant demand for accurate point-of-care COVID-19 tests. We anticipate that our need to grow our business will increase if we are able to successfully commercialize our products, which will require that we incorporate new equipment, implement new technology systems, automate equipment processes, 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 and once completed, we may experience operational delays transitioning to the new facilities. 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 a pre-commercial company with respect to our own products. 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 unused products or components of our products. In addition, we do not currently have any experience in selling our instrument or test cartridges, 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.

*Although we have now established sales and marketing and customer support capabilities, 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 have implemented a sales and marketing infrastructure for the first time, but 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 effectively execute in the areas of sales, marketing, customer support, technical support, and fulfillment.

We have made significant investments in establishing our sales, service and support personnel and infrastructure, however, we have not utilized such personnel or infrastructure to commercialize the Talis One COVID-19 Test System, as planned, but to support the Antigen Test initiative. In addition, in March 2022, we implemented a reduction in force of approximately 25% (as further described below) which has impacted our sales, service and support personnel. There is a risk that our inability to manufacture or sell our own products soon enough and at sufficient volume, together with the uncertainty of when we will be able to do so, could limit our ability to maintain our commercial organization and personnel at adequate levels. In addition, we may find it challenging to effectively scale up our commercial organization and personnel when needed to facilitate our commercialization efforts.

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

- our inability to retain or hire adequate numbers of effective sales and marketing personnel, particularly following a reduction in force;
- 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  test menu available on the Talis One system, 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 or scaling up our commercial organization.

*We may not successfully implement our strategy to provide customers access to our system through alternative non-direct capital sales channels, including our planned equipment leasing 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 that our rental program will gain market acceptance which 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. Our competitors in the point-of-care and/or at-home category, for molecular and/or antigen tests that have received an EUA for their COVID-19 tests, include Abbott Laboratories, Binx Health, Inc., BioFire Diagnostics, LLC, Cepheid (a subsidiary of Danaher Corporation), Cue Health Inc., Lucira Health, Inc., Thermo Fischer Scientific Inc., Roche Molecular Systems, Inc., Visby Medical, Inc., ON/GO, Quidel, and OraSure. In addition, BioFire Diagnostics, LLC has received FDA marketing authorization under the *de 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 may not be able to develop and commercialize improvements to our products in a timely manner. 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.

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, the development of safe and effective therapeutics, SARS-CoV-2 becomes endemic, 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 local and 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 both the local and global economy and financial markets, particularly as the United States and other countries balance concerns around debt, inflation, growth and budget allocations in their policy initiatives. There can be no assurance that global economic conditions and financial markets will not worsen and that we will not experience any adverse effects that may be material to our cash flows, results of operations, financial position or our ability to access capital, such as the adverse effects resulting from a prolonged shutdown in government operations both in the United States and internationally. Our business is also affected by local economic environments, including inflation, recession, financial liquidity and currency volatility or devaluation. Political changes, including war or other conflicts, some of which may be disruptive, could interfere with our supply chain, our customers and all of our activities in a particular location. 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. In addition, geopolitical, economic and military conditions around the world may directly affect our business. Any hostilities involving any of the countries in which we or our third-party suppliers operate, including terrorist activities, political instability or violence in the region or the interruption or curtailment of trade or transport between such country and its trading partners could adversely affect our business and results of operations. 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. We have had changes in our management and executive leadership team, including appointing a new chief executive officer, which could lead to disruption of our business or distraction of our employees as we adapt to such management changes. 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 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 fail to achieve the expected financial and operational benefits of our recent reduction in force, our business and financial results may be harmed.*

In March 2022, we implemented a reduction in force, of approximately 25%, designed to reduce our operating expenses, preserve cash and align our remaining resources to focus on, among other things, developing internal manufacturing expertise to support the commercial launch of the Talis One system. We anticipate that we will incur approximately $1.0 million of expenses related to the reduction in force, substantially all of which will consist of

one-time charges related to the staff reduction, including cash expenditures and other costs. Substantially all of the committed actions under the reduction in force will take place by the end of March 2022. The estimates of the expenses we expect to incur, including any estimates of annualized savings going forward, are subject to a number of assumptions, risks and uncertainties, and actual results may differ from our estimates. We may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the reduction in force.

*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 help 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.

*If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.*

In the ordinary course of our business, we and our third-party service providers will collect, store, use, transmit, disclose, or otherwise process proprietary, confidential, and sensitive data, including personal data (which includes health-related data and legally protected health information (PHI)), intellectual property, and trade secrets). In addition, we will 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. We rely upon third parties service providers and technologies to operate critical business systems to process confidential information and personal data in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email and other functions. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive data with or from third parties.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources. In addition to traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors now engage in attacks.

We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services. The COVID-19 pandemic and our remote workforce poses increased risks to our information technology systems and data, as more of our personnel work from home, utilizing network connections outside our premises. Future business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to data or could disrupt our ability (and that of third parties upon whom we rely) to provide our services. If such an event were to occur, it could result in a material disruption of our product development programs and our business operations. These threats pose a risk to the security of our systems, the confidentiality and the availability and integrity of our data, and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business.

We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and data. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. 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.

We may be unable to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary expenditures; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause delays in the development of our product candidates, cause customers to stop using our products or services, deter new customers from using our products or services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient of protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. 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 will be 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;

- economic weakness, including inflation, or political and economic instability in particular foreign economies and markets, including wars, terrorism and political unrest, outbreak of disease, natural disasters, boycotts, curtailment of trade and other business restrictions;
- 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;
- 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 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, we are currently experiencing higher costs for transportation and warehousing and significant inflation that could adversely affect our operating margins and results of operations, if these costs continue to rise. 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 COVID-19 Test System, 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:

- o adverse publicity, warning letters, untitled letters, it has come to our attention letters, fines, injunctions, consent decrees and civil penalties;
- o repair, replacement, refunds, recall or seizure;
- o operating restrictions, partial suspension or total shutdown of production;
- o 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;
- o withdrawal of marketing authorization that have already been granted; or
- o 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.*

The potential end-users of our Talis COVID-19 Test 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. 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, 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. Further, effective January 15, 2022, private health insurance companies and group health plans are required to cover eight free over-the-counter at-home COVID-19 diagnostic tests authorized, cleared, or approved by the FDA per covered individual per month. These changes are 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 are required to support our Talis One COVID-19 Test System and 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 terms of the EUA for the Talis One COVID-19 Test System require that we conduct a post-authorization clinical evaluation study to demonstrate that our product meets its intended use and performance claims, which we must submit to the FDA four months after commercial launch of the Talis One COVID-19 Test System.

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.

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 and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.*

We process personal data and other sensitive data (including health data we collect about trial participants in connection with clinical trials); proprietary and confidential business data; trade secrets; intellectual property; and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

Data privacy and information security have become significant issues 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. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. These privacy laws include, without limitation, the following laws and regulations: Section 5 of the Federal Trade Commission Act, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the California Consumer Privacy Act of 2018 (CCPA). HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. The CCPA imposes obligations on businesses to which it applies that include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). In addition, it is anticipated that the California Privacy Rights Act of 2020 (CPRA), effective January 1, 2023, will expand the CCPA. For example, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of an enforcement action. Other states, like Colorado and Virginia, have enacted data privacy laws which differ from the CPRA and become effective in 2023. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts. If we are or become subject to these laws and/or new or amended data privacy laws, the risk of enforcement actions against us could increase because we may be subject to obligations under applicable regulatory frameworks and the number of individuals or entities that could initiate actions against us may increase (including individuals via a private right of action), in addition to further complicating our compliance efforts. In addition, privacy advocates and industry groups have proposed, and may propose in the future, standards with which we are legally or contractually bound to comply.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR) and the equivalent law in the United Kingdom (UK GDPR) impose strict requirements for processing the personal data of individuals, including sensitive data that we may process such as health data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Similar processing penalties and fines exist under the UK GDPR and the uncertainty of data protection laws in the UK following Brexit has increased the complexity of our compliance efforts. Further, individuals may initiate litigation related to our processing of their personal data.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data

to countries such as the United States that do not provide an adequate level of personal data protection. The European Commission released a set of "Standard Contractual Clauses" that are designed to be a valid mechanism by which entities can transfer personal data out of the European Economic Area (EEA) to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, these Standard Contractual Clauses are a valid mechanism to transfer personal data outside of the EEA. The Standard Contractual Clauses, however, require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. Moreover, due to potential legal challenges, there exists some uncertainty regarding whether the Standard Contractual Clauses will remain a valid mechanism for transfers of personal data out of the EEA. In addition, laws in Switzerland and the UK similarly restrict transfers of personal data outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal data protection. Any of these or other similar restrictions and obligations could increase the cost and complexity of doing business in foreign jurisdictions. If we cannot implement valid compliance mechanisms for cross-border personal data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or elsewhere. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe, the United Kingdom and elsewhere; limiting our ability to collaborate with third parties, such as contract research organizations as well as other service providers, that are subject to European and other data privacy and security laws; or requiring us to increase our personal data processing capabilities and infrastructure in Europe and/or elsewhere at significant expense.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model.

Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to operate our business and proceedings against us by governmental entities or others. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the third-party providers (such as contract research organizations) who share this information with us, may contractually limit our ability to use and disclose the information.

If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including our clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our product candidates; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

*All of 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), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and certain ownership and investment interests held by physicians and their immediate family members; 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 guidance, 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 COVID-19 Test System 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.*

The EUA for our Talis One COVID-19 Test System is for the *in vitro* qualitative detection of RNA from the SARS-CoV-2 virus in nasal swab specimens from individuals suspected of COVID-19 by a healthcare provider. We are not permitted to market our Talis One COVID-19 Test System 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 specimens). Such uses would be considered "off-label." We have trained and will train our marketing and direct sales force to not promote the Talis One COVID-19 Test System 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 came 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. In addition, activities covered under the awards 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. 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. For example, although we extended the time to perform certain milestones under the NIH Contract, we also had to reduce the potential milestone payments, and we were unable to satisfy all of the remaining milestones before the NIH Contract expired. In addition, 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 remained 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 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. 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. 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. 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, 2021, 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 $181.2 million of U.S. federal NOLs that can be carried forward indefinitely under current law. As of December 31, 2021, we also had aggregate U.S. federal research and development (R&D) credits of approximately $74.7 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 the section titled “Business—Intellectual Property." 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. 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 System 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 was the subject of an opposition before the USPTO through which Talis Clinical, LLC alleged 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. On September 8, 2021, Talis Clinical, LLC's opposition was sustained by the USPTO. On November 10, 2021, we filed a civil action in the United States District Court for the Northern District of Ohio seeking review of the USPTO's decision in the opposition proceeding. In the event the USPTO's decision in the opposition is upheld by the district court, 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 $192.0 million and $91.1 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of

$364.9 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 COVID-19 Test System, 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 supplier purchase commitments in foreign currencies. 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 Annual 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;
- 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 March 10, 2022, the closing price of our common stock has ranged between $1.74 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.

There were 8,590,411 shares of common stock issuable upon the exercise of options outstanding and 407,720 shares of common stock issuable upon vesting of restricted stock units as of December 31, 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 compliance with applicable securities laws.

Further, based on shares outstanding as of December 31, 2021, holders of approximately 37,489,210 shares, or 66.6% 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 March 10, 2022, our executive officers, directors and five percent or greater stockholders and their respective affiliates, beneficially own, in the aggregate, approximately 76% of our outstanding voting stock. Further, 66.2% 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 are 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 this Annual Report, and any future annual reports. These assessments must 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 continue the costly and challenging process, starting last year, 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 requires 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 September 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 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.*

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. During fiscal year 2021, we began implementing the internal control procedures which addressed a previously identified material weakness relating 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. During the fourth quarter of fiscal year 2021, we successfully completed the testing necessary to conclude that the material weakness has been remediated. Although we were able to remediate our material weakness before the report required in this Annual Report 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.

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 acquirers 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 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

Our corporate headquarters are currently located in Menlo Park, California, where we occupy approximately 24,000 square feet of office and laboratory space under a lease that ends in June 2022, with an option to renew for an additional month through July 2022. In January 2021, we entered into a lease agreement that expires in May 2032 for approximately 41,000 square feet of office and laboratory space in Redwood City, California, with expected occupancy to commence in the third quarter of 2022. In January 2021, we also entered into a lease that expires in February 2033 for approximately 26,400 square feet of laboratory space in Chicago, Illinois, which commenced in the second quarter of 2021. We believe our existing facilities meet our current needs. We will need additional space in the future as we continue to build our development, commercial and support teams. We believe we can find suitable additional space in the future on commercially reasonable terms.

**Item 3. 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.

Our application to register the trademark TALIS in the United States was the subject of an opposition before the USPTO through which Talis Clinical, LLC alleged 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. On September 8, 2021, Talis Clinical, LLC's opposition was sustained by the USPTO. On November 10, 2021, we filed a civil action in the United States District Court for the Northern District of Ohio seeking review of the USPTO's decision in the opposition proceeding.

On or about January 7, 2022, John Modrak filed a class action in the United States District Court for the Northern District of California against us, certain of our officers and directors, and J.P. Morgan Securities LLC, BofA Securities, Inc., Piper Sandler & Co., and BTIG, LLC, underwriters of our February 2021 initial public offering ("IPO"), captioned as *Modrak v. Talis Biomedical Corp., et al.*, No. 3:22-cv-00105, purportedly on behalf of shareholders who purchased shares of our stock that were registered in our IPO. On February 18, 2022, Karen Mitcham filed a substantively identical lawsuit in the same court captioned as *Mitcham v. Talis Biomedical Corp., et al.*, No. 3:22-cv-01039-JD, against us, and the same officers and directors as the *Modrak* lawsuit. The complaints allege that our registration statement and prospectus issued in connection with our IPO was false and misleading and

omitted to state material adverse facts related to the comparator assay used in our primary study, our EUA application for our Talis One COVID-19 Test System, and associated regulatory approval and commercialization. The complaints seek unspecified damages under Section 11 and Section 15 of the Securities Act of 1933, and reasonable attorneys' and expert witnesses' fees and other costs. We dispute these claims and intend to defend these matters vigorously. These claims remain at an early stage, and the extent and outcome of these claims cannot be predicted at this time.

**Item 4. Mine Safety Disclosures.**

Not applicable.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

*Market information*

Our common stock has been publicly traded on the Nasdaq Global Market under the symbol "TLIS" since our initial public offering on February 12, 2021. Prior to that time, there was no public market for our common stock.

*Holders*

As of March 10, 2022, we had approximately 63 holders of record of our common stock and one holder of record of our Series 1 convertible preferred stock.

*Dividend policy*

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

*Recent sales of unregistered securities*

None.

*Use of Proceeds from our Initial Public Offering of Common Stock*

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

We received approximately $233 million in net proceeds from our initial public offering. Through December 31, 2021, we used approximately $156 million of the net proceeds from the offering primarily to fund our ongoing research and development activities, manufacturing scale-up project and pre-launch inventory.

There has been no material change in the planned use of proceeds from our initial public offering from that described in the related prospectus filed February 12, 2021 with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended. Pending such uses, we plan to continue investing the unused proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

### Item 6. [Reserved]

**Item 7. 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 audited financial statements and related notes included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual 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 Annual 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 Annual 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 employs 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 systems to generate revenue from the purchase of such products. Our first commercial test will be the Talis One COVID-19 Test System, which is a rapid point-of-care molecular diagnostic to detect SARS-CoV-2 directly from a patient sample in less than 30 minutes. We are developing assays for the detection of other respiratory infections that could be included as a panel test with the Talis One COVID-19 Test System as well as tests for infections related to women's health and STIs. In December 2021, we entered into an agreement to act as an authorized distributor for third party COVID-19 antigen tests (Antigen Tests). In January 2022, in order to generate revenue to support our operations and sales forces, we began purchasing and distributing these Antigen Tests as an authorized distributor. We plan to continue to utilize this strategy to both generate revenue for as long as we can provision the tests and sell them for a profit and to help develop our customer base for Talis One.

Our products will require marketing authorization from the FDA prior to commercialization. On November 5, 2021, we received an EUA from the FDA for the emergency use of the Talis One system for our COVID-19 test, which we refer to as the Talis One COVID-19 Test System. Due to the COVID-19 global pandemic, we obtained marketing authorization for our Talis One COVID-19 Test System under an 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, the first of which began to come on-line in the first quarter of 2021. We are currently validating the performance of those automated cartridge manufacturing lines. These manufacturing lines are located at our contract manufacturers' sites and are operating by our contract manufacturing partners. We have also received components to build 5,000 Talis One instruments from our instrument contract manufacturer.

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. 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 determine to not have an alternative future use have been expensed.

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 selling, 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, the Company raised $232.5 million (after deducting underwriting discounts, commissions and offering expenses) through an initial public offering to finance operations going forward.

We have incurred recurring losses since our inception, including net losses of $192.0 million and $91.1 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $364.9 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 Talis One system;
- further develop and refine the manufacturing processes for our Talis One system and potentially the design of our Talis One system;
- change or add manufacturers or suppliers of materials used for our Talis One system;
- 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 sales force;
- 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, 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 December 31, 2021, we had unrestricted cash and cash equivalents of $232.5 million. We expect that our cash and cash equivalents of $232.5 million as of December 31, 2021 will be sufficient to fund our operations through at least the next 12 months. Our objective is to preserve our current cash reserves to fund operations through the end of 2024. This target could change as we gain more clarity on the timing and trajectory of the Talis One system launch. 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.

On March 15, 2022, we implemented a reduction in force, of approximately 25%, designed to reduce our operating expenses, preserve cash and align our remaining resources to focus on, among other things, developing internal manufacturing expertise to support the commercial launch of the Talis One system. We anticipate that we will incur approximately $1.0 million of expenses related to the reduction in force, substantially all of which will consist of one-time charges related to the staff reduction, including cash expenditures and other costs. Substantially all of the committed actions under the reduction in force will take place by the end of March 2022. Going forward, we estimate annualized savings of $10.0 million in compensation expenses and $26.0 million in other expenses related to these reductions.

***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 was declared a pandemic by the World Health Organization. Efforts to contain the spread of COVID-19 intensified in 2020 and 2021 and governments around the world, including in the United States, Europe and Asia, implemented travel restrictions, social distancing requirements, stay-at-home orders and 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 has been 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 labs. 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 March 2022. While we do not foresee the authorizations having an immediate and near-term impact on the demand for COVID-19 tests, the vaccines could reduce the future demand for such tests depending on the effectiveness of the vaccines.

**Components of our results of operations**

***Revenue***

To date, we have not generated any revenue from sales of our Talis One system. We expect to generate revenue in the future from product sales of our Talis One instruments and single use cartridges. Our business model is focused on driving the adoption of the Talis One system. Customers would gain access to our instrument via a direct sales model or a reagent rental model. Under direct platform sales, our customers would directly purchase our Talis One instrument and make subsequent independent purchases of our cartridges. This would include, during our early customer engagements, a fully paid workflow license to practice the desired workflow(s) in a specific field of use. In addition, we would also offer platform support to the extent customers require further system and workflow optimization following platform implementation. When we place a system under a reagent rental agreement, we plan to install equipment in the customer's facility without a fee and the customer agrees to purchase our cartridges at a stated price over the term of the reagent rental agreement. Some of these agreements could include minimum purchase commitments. Under a reagent rental model, we plan to retain title to the equipment and such title is transferred to the customer at the conclusion of the initial arrangement. The cost of the instrument under the agreement is expected to be recovered in the fees charged for consumables, to the extent sold, over the term of the agreement.

We cannot predict when, or to what extent we will generate revenue from the commercialization and sale of our system. While we have obtained EUA for our Talis One COVID-19 Test System, we have not generated any revenue from the sales of such system. 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. Our contract manufacturers may not have the ability to produce quality product at scale to meet commercial demand which could delay commercialization efforts. Further, we may not succeed in maintaining regulatory approval for the Talis One COVID-19 Test System or obtaining regulatory approval for other products. Growth and predictability of recurring revenue is impacted by the timing of commercialization and expansion of our products. It is our goal and expectation that recurring revenue will grow over time, both in absolute dollars and as a percentage of our revenue.

*Grant revenue*

Through December 31, 2021, 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 program, 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 the NIH Contract, a contract from the NIH directly for Phase 2 of the RADx initiative.

In October 2021, we and the NIH agreed to amend the NIH Contract to extend the time to perform the remaining milestones to January 30, 2022 and reduce the potential milestone payments from $4.0 million to $2.0 million. The NIH Contract expired on January 30, 2022.

Under the NIH grant, there is the possibility of an additional $1.8 million in payments through April 2023.

In October 2021, we chose not to pursue additional option periods under the CARB-X grant. Therefore, there is no additional funding available under this grant.

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

***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.

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, record such cost 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 research and development initiatives and risk of technical feasibility, viability of commercialization and marketplace trends.

Prior to receiving an EUA and until future commercialization is considered probable, 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 focus our research and development efforts on the Talis One COVID-19 Test System and the development of respiratory panels and tests for infections related to women's and sexual health. We expect to continue to incur significant research and development expenses in the future as we continue the research and development of our platform and assays for other infectious diseases and disease states, initiate clinical trials for future tests, further develop and refine the manufacturing processes for our platform, and continue commercialization efforts. 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. 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.

*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 twelve months ended December 31, 2021 and 2020*

The following table summarizes our results of operations (in thousands):

| (in thousands) | Twelve Months Ended December 31, 2021 | 2020 | Change |
|---|---|---|---|
| Grant revenue | $ 8,193 | $ 10,938 | $ (2,745) |
| Operating expenses: | | | |
| Research and development | 157,591 | 89,019 | 68,572 |
| Selling, general and administrative | 42,418 | 13,103 | 29,315 |
| Total operating expenses | 200,009 | 102,122 | 97,887 |
| Loss from operations | (191,816) | (91,184) | (100,632) |
| Other (expense) income, net | (220) | 54 | (274) |
| Net loss and comprehensive loss | $ (192,036) | $ (91,130) | $ (100,906) |

*Grant revenue*

Our revenue for the twelve months ended December 31, 2021 and 2020 relates to the CARB-X and NIH grants and the RADx initiative. During the twelve months ended December 31, 2021, $7.7 million and $0.5 million of revenue was recognized related the RADx initiative and NIH grant, respectively. During the twelve months ended December 31, 2020, $9.3 million, $1.1 million and $0.6 million of revenue was recognized related the RADx initiative and NIH and CARB-X grants, respectively.

*Research and development expenses*

Substantially all of our research and development expenses incurred for the twelve months ended December 31, 2021 and 2020 were related to the manufacturing scale-up and development of our first potential commercial product utilizing the Talis One COVID-19 Test System.

Research and development expenses were $157.6 million for the twelve months ended December 31, 2021, compared to $89.0 million for the twelve months ended December 31, 2020. The increase of $68.6 million was primarily driven by investments in manufacturing scale up associated with developing aspects of the production line, consisting of $22.9 million for the automation of consumable manufacturing, $16.3 million of Talis One cartridge materials for the COVID-19 assay, and $15.4 million in instrument component costs. Additionally, we incurred incremental manufacturing scale up expenses of $5.4 million related to personnel and payroll related expenses, $4.8 million of depreciation, facilities and IT costs, $2.3 million in freight costs and $1.5 million in outside services and consulting expenses.

Research and development expenses of $157.6 million for the twelve months ended December 31, 2021 included $69.6 million related to manufacturing scale-up, $21.7 million in pre-launch instrument inventory, and $11.8 million in pre-launch cartridge inventory. Research and development expenses of $89.0 million for the twelve months ended December 31, 2020 included $40.9 million related to manufacturing scale-up. The instrument and cartridge inventory amounts are recorded as research and development expenses until future commercialization is considered probable.

The build-out of our automated consumable manufacturing lines, which began in the middle of 2020, has substantially concluded as of December 31, 2021. Costs associated with the remainder of the scale-up project will be substantially reduced as we shift from building our manufacturing infrastructure to validation and optimization.

*Selling, general and administrative expenses*

Selling, general and administrative expenses were $42.4 million for the twelve months ended December 31, 2021, compared to $13.1 million for the twelve months ended December 31, 2020. The increase of $29.3 million was primarily due to an incremental $20.1 million in personnel and payroll related expenses including salaries and wages, sales commission and stock compensation expenses to support our commercial launch, an increase of $4.5 million in facilities, insurance and IT costs and an increase of $3.8 million in outside services and consulting related to being a public company.

**Liquidity and capital resources**

*Sources of liquidity*

Through December 31, 2021, we funded our operations primarily through public equity offerings, private placements of equity securities and through government grants.

On February 17, 2021, we completed our initial public offering (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.

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 letter of credit (LOC), that was entered into in 2020 and required to be held as collateral by the contract manufacturing organization, was concurrently terminated.

As of December 31, 2021, we had unrestricted cash and cash equivalents of $232.5 million. We believe our cash and cash equivalents balance as of December 31, 2021 is sufficient for our operations for at least the next 12 months based on our existing business plan and our ability to control the timing of significant expense commitments. Our objective is to preserve our current cash reserves to fund operations through the end of 2024. This target could change as we gain more clarity on the timing and trajectory of the Talis One system launch.

On March 15, 2022, we implemented a reduction in force, of approximately 25%, designed to reduce our operating expenses, preserve cash and align our remaining resources to focus on, among other things, developing internal manufacturing expertise to support the commercial launch of the Talis One system. We anticipate that we will incur approximately $1.0 million of expenses during the three months ended March 31, 2022 related to the reduction in force. Going forward, we estimate annualized savings of $10.0 million in compensation expenses and $26.0 million in other expenses related to these reductions.

*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 have engaged a third-party logistics provider to manage the movement of materials between suppliers and contract manufacturers and for finished goods warehousing.

Until we can generate a sufficient amount of revenue from the commercialization of Talis One system and third party products that we sell, including the Antigen Tests, 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 have made a prepayment to the landlord of one of our leased properties in advance of commencement. We currently have no other ongoing material financing commitments, such as other lines of credit or guarantees. We expect to incur significant research and development and 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 $364.9 million through December 31, 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 and cash equivalents of $232.5 million as of December 31, 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 maintain an EUA for our Talis One COVID-19 Test System;
- our ability to receive, and the timing of receipt of future regulatory approval for other products;
- our ability to manufacture the Talis One COVID-19 Test System at scale to meet market demand;
- the effectiveness and availability of the three vaccines that were authorized as of March 2022;
- 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 the Talis One system;
- 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, or from commercial sales of third party products, including the Antigen Tests;
- the costs to defend any shareholder suits or other third party litigation;
- 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 (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| | (in thousands) | |
| Net cash used in operating activities | $ (171,384) | $ (87,024) |
| Net cash used in investing activities | (2,866) | (8,201) |
| Net cash provided by financing activities | 234,429 | 246,754 |
| Net increase in cash, cash equivalents and restricted cash | $ 60,179 | $ 151,529 |

*Operating activities*

During the year ended December 31, 2021, net cash used in operating activities was $171.4 million, resulting from our net loss of $192.0 million partially offset by non-cash items of $11.8 million including stock-based compensation of $9.2 million as we increased headcount to support our commercialization. Our net loss was further offset by a decrease of $12.0 million in prepaid research and development driven by the substantial completion of our manufacturing scale up project as of December 31, 2021 and an increase of $2.2 million in accrued expenses and other liabilities. These cash inflows were offset by an increase in other long term assets of $5.5 million.

During the year ended December 31, 2020, net cash used in operating activities was $87.0 million, resulting from our net loss of $91.1 partially offset by non-cash items of $5.1 million. Non-cash items primarily include stock-based compensation of $3.7 million and depreciation expense of $0.8 million. The increase in prepaid research and development of $11.7 million was offset by increases in accounts payable of $3.2 million and accrued expenses and other current liabilities of $7.3 million.

*Investing activities*

During the years ended December 31, 2021 and 2020 we used $2.9 and $8.2 million of cash for investing activities related to purchases of property and equipment.

*Financing activities*

During the year ended December 31, 2021, net cash provided by financing activities was $234.4 million, primarily consisting of $232.5 million of proceeds from the issuance of common stock in our initial public offering, $1.4 million in proceeds from stock option exercises, and $0.4 million in proceeds from common stock issued pursuant to the Company’s employee stock purchase plan.

During the year ended December 31, 2020, net cash provided by financing activities was $246.8 million primarily consisting of $248.2 million of proceeds from the issuance of preferred stock offset by $1.5 million of deferred initial public offering costs.

**Contractual obligations**

*Leases*

See Note 6. Commitments and contingencies, to our audited financial statements included in Item 8 of this Annual Report for a summary of our operating lease commitments as of December 31, 2021.

In January 2021, we entered into a lease agreement with an initial term of 10.5 years for office space in Redwood City, California, with expected occupancy to commence in the third quarter of 2022.

*Manufacturing production lines*

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 demand. These commitments represent firm commitments relating to the scale-up of manufacturing capacity for Talis One cartridges, primarily attributed to investments in production lines. We expect to incur commitments, in the normal

course of business, related to the scale up of production lines of $6.6 million which is expected to be incurred in the twelve month period subsequent to December 31, 2021.

*Purchase commitments*

Purchase obligations include agreements to purchase goods or services that are enforceable and legally binding to us and that specify all significant terms. Purchase obligations exclude agreements that are cancelable without penalty. Recognition of purchase obligations occurs when products or services are delivered. We have purchase commitments of $15.8 million. Our purchase commitments are incurred in the normal course of business and made up of $12.8 million related to Talis One cartridges, $2.0 million for Talis One instruments, and $1.0 million relating to the purchase of the Antigen Tests for distribution, all of which will be incurred in the twelve month period subsequent to December 31, 2021.

Apart from the contracts with payment commitments that we have reflected above, 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 MD&A is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in greater detail in Note 2 to our financial statements appearing within Item 8 of this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

*Research and development expenses*

Capitalizing pre-launch inventory costs will not occur prior to obtaining an EUA or other FDA marketing authorization unless the regulatory review process has progressed to a point that objective and persuasive evidence of regulatory approval is sufficiently probable, commercialization is considered probable and future economic benefit can be asserted. We have incurred significant costs related to the scale-up of manufacturing activities for commercialization. We record such costs as research and development expenses, or if used in marketing evaluations costs are recorded as selling, general and administrative expenses. A number of factors are taken into consideration, based on our management’s judgment, including the current status in the regulatory approval process, potential impediments to the approval process, anticipated research and development initiatives and risk of technical feasibility, viability of commercialization and marketplace trends.

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 or clearance is obtained, and commercialization is probable. 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 our statements of cash flows.

For certain research and development services where we have not yet been invoiced or otherwise notified of actual cost from the third-party contracted service providers, we are required to estimate the extent of the services that have been performed on our behalf and the associated costs incurred at each reporting period. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

Although we do not expect our estimates to be materially different from amounts actually incurred, our 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 our prior estimates of accrued research and development expenses.

*Stock-based compensation*

We measure stock-based compensation expense for stock options and restricted stock units (RSUs) granted to our employees and directors on the date of grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award, on a straight-line basis. We also recognize stock-based compensation expense associated with our employee stock purchase plan (ESPP) based on the grant date fair value required under authoritative guidance. Forfeitures are recorded as they occur.

From time to time, we may grant stock options to employees, including executive officers, that vest upon the satisfaction of both service-based and performance-based vesting conditions. We recognize stock-based compensation over the requisite service period using the accelerated attribution method for awards with a performance condition if the performance condition is deemed probable of being met.

We estimate the fair value of stock options granted to our employees and directors on the grant date, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of subjective assumptions which determine the fair value of stock option awards. These assumptions include:

- *Expected term*. The expected term of options represents the period of time that options are expected to be outstanding. Our historical stock option exercise experience does not provide a reasonable basis upon which to estimate an expected term due to lack of sufficient data. We estimate the expected term by using the simplified method, which calculates the expected term as the average of the time-to-vesting and the contractual life of the options.
- *Expected volatility*. Prior to our IPO, there has been no public market for our common stock, and as a result we do not have any trading history of our common stock, expected volatility is estimated based on the average volatility for comparable publicly traded diagnostic companies over a period equal to the expected term of the stock option grants. The comparable companies are chosen based on their similar size, stage in the life cycle or area of specialty.
- *Risk-free interest rate*. The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the stock option grants.
- *Expected dividend yield*. We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we use an expected dividend yield of zero.

Following the closing of our IPO, we determine the fair market value of our common stock based on its closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

Prior to our IPO, there has been no public market for our common stock. As such, the estimated fair value of the common stock underlying our stock options was determined by our board of directors, with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant, and factors that may have changed from the date of the most recent valuation through the date of the grant, which intended all options granted to be exercisable at a price per share not less than the per share fair value of our common stock underlying those options on the date of grant. We believe that our board of directors has the relevant experience and expertise to determine the fair value of our common stock. Prior to our IPO, given the absence of a public trading market for our common stock, the valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date.

The assumptions we used in the pre-IPO valuation model were based on future expectations combined with management judgment. In the absence of a public trading market, our board of directors with input from management exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of our common stock as of the date of each option grant, including the following factors:

- contemporaneous independent valuations performed at periodic intervals by an independent third-party valuation firm;
- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status and results of preclinical studies for our platform;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the diagnostics industry and trends within the diagnostics industry;
- the lack of an active public market for our common stock; and
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company in light of prevailing market conditions.

In March 2020, we offered to reprice the unexercised stock options of each employee or non-employee director with an exercise price equal to $6.38 or higher per share to the estimated fair market value of our Class A Common Stock on March 13, 2020 of $1.51 per share. The repriced options were subject to the same terms as the original granted options, except for the new exercise price. As a result of the offering, we modified the exercise price of stock options for the purchase of 407,415 shares of common stock with a weighted average exercise price of $15.55 per share, by cancelling these options and reissuing stock options with an exercise price of $1.51 per share to purchase 407,415 shares of common stock. The calculation of the incremental compensation expense is based on the excess of the fair value of the award measured immediately before and after the modification. As a result of the modification, we recognized incremental compensation expense of $0.3 million for the year ended December 31, 2020.

*Leases*

Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the remaining lease term. The present value of future lease payments are discounted using the interest rate implicit in lease contracts if that rate is readily determinable; otherwise we utilize our incremental borrowing rate (IBR), which reflects the fixed rate at which we could borrow on a collateralized basis over a similar term, the amount of the lease payments in a similar economic environment. After lease commencement and the establishment of a right-to-use asset and operating lease liability, lease expense is recorded on a straight-line basis over the lease term.

*Recoverability of long-lived assets*

We review the carrying amount of our long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of an asset or an asset group may not be fully recoverable. If indicators of impairment exist, an impairment loss would be recognized when the estimated undiscounted future cash flows expected to result from the use of the asset or asset group and its eventual disposition are less than its carrying amount. The impairment charge is determined based upon the excess of the carrying value of the asset over its estimated fair value, with estimated fair value determined based upon an estimate of discounted future cash flows or other appropriate measures of estimated fair value. For purposes of recognition of impairment for long-lived assets, we group assets and liabilities at the lowest level for which cash flows are separately identifiable.

**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 audited financial statements included within Item 8 of this Annual Report.

**Emerging growth company status**

In April 2012, the 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. However, we may early adopt these standards, for example we elected to early adopt ASC 842, *Leases*.

In addition, as an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- reduced disclosure about the compensation paid to our executive officers;
- not being required to submit to our stockholders' advisory votes on executive compensation or golden parachute arrangements;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act; and
- an exemption from new or revised financial accounting standards until they would apply to private companies and from compliance with any new requirements adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation.

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. We may choose to take advantage of some but not all of these exemptions.

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

Not applicable.

**Item 8. Financial Statements and Supplementary Data**

**Index to Financial Statements and Notes**

## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Talis Biomedical Corporation

**Opinion on the Financial Statements**

We have audited the accompanying balance sheets of Talis Biomedical Corporation (the Company) as of December 31, 2021 and 2020, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.

Chicago, Illinois
March 15, 2022

**Talis Biomedical Corporation**
**Balance sheets**
***(in thousands, except for share and par value)***

| | December 31, | |
|---|---|---|
| | **2021** | **2020** |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 232,545 | $ 138,483 |
| Restricted cash | — | 34,650 |
| Grants receivable | 183 | 471 |
| Prepaid research and development expenses | — | 12,014 |
| Prepaid expenses and other current assets | 3,387 | 3,106 |
| Total current assets | 236,115 | 188,724 |
| Property and equipment, net | 10,528 | 9,114 |
| Operating lease right-of-use-assets | 12,907 | 567 |
| Other long-term assets | 6,278 | — |
| Total assets | $ 265,828 | $ 198,405 |
| **Liabilities and Stockholders' Equity (Deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 5,122 | $ 4,906 |
| Accrued compensation | 6,369 | 2,739 |
| Accrued liabilities | 6,383 | 7,693 |
| Operating lease liabilities, current portion | 1,232 | 693 |
| Total current liabilities | 19,106 | 16,031 |
| Operating lease liabilities, long-term portion | 12,745 | — |
| Total liabilities | 31,851 | 16,031 |
| Commitments and contingencies (Note 6) | | |
| Convertible preferred stock, $0.0001 par value—no shares authorized as of December 31, 2021 and 229,296,908 shares authorized as of December 31, 2020; no shares issued and outstanding as of December 31, 2021 and 53,509,351 shares issued and outstanding as of December 31, 2020; no aggregate liquidation preference as of December 31, 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 December 31, 2021 and December 31, 2020, respectively; 29,863,674 and no shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively; aggregate liquidation preference of $3 as of December 31, 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 December 31, 2021 and December 31, 2020, respectively; 26,408,031 and 2,126,254 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively | 3 | — |
| Additional paid-in capital | 598,913 | 64,335 |
| Accumulated deficit | (364,942) | (172,906) |
| Total stockholders' equity (deficit) | 233,977 | (108,571) |
| Total liabilities, convertible preferred stock and stockholders' equity (deficit) | $ 265,828 | $ 198,405 |

*See accompanying notes to the financial statements*

**Talis Biomedical Corporation**
**Statements of operations and comprehensive loss**
***(in thousands, except for share and per share amounts)***

| | Year ended December 31, | |
|---|---|---|
| | **2021** | **2020** |
| Grant revenue | $ 8,193 | $ 10,938 |
| Operating expenses: | | |
| Research and development | 157,591 | 89,019 |
| Selling, general and administrative | 42,418 | 13,103 |
| Total operating expenses | 200,009 | 102,122 |
| Loss from operations | (191,816) | (91,184) |
| Other income (expense), net | (220) | 54 |
| Net loss and comprehensive loss | $ (192,036) | $ (91,130) |
| Net loss per share, basic and diluted | $ (8.48) | $ (42.98) |
| Weighted average shares used in the calculation of net loss per share, basic and diluted: | 22,655,339 | 2,120,322 |

*See accompanying notes to the financial statements*

**Talis Biomedical Corporation**
**Statements of convertible preferred stock and stockholders' equity (deficit)**
***(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, 2019 | 37,871,430 | $ 42,755 | — | — | 2,115,583 | $ — | $ 60,636 | $ (81,776) | $ (21,140) |
| Issuance of Common Stock upon exercise of stock options | — | — | — | — | 10,671 | — | 16 | — | 16 |
| 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 tranches of Series C-1 convertible preferred stock | (9,314,766) | — | — | — | — | — | — | — | — |
| Cancellation of third tranches of Series D-1 convertible preferred stock | (955,666) | — | — | — | — | — | — | — | — |
| Cancellation of third tranches of Series D-2 convertible preferred stock | (2,387,171) | — | — | — | — | — | — | — | — |
| Issuance of Series E-1 convertible preferred stock, net of issuance costs of $48 | 2,289,899 | 16,943 | — | — | — | — | — | — | — |
| Issuance of Series E-2 convertible preferred stock, net of issuance costs of $233 | 11,187,189 | 82,776 | — | — | — | — | — | — | — |
| Issuance of Series F-1 convertible preferred stock, net of issuance costs of $3,056 | 4,859,897 | 38,496 | — | — | — | — | — | — | — |
| Issuance of Series F-2 convertible preferred stock, net of issuance costs of $88 | 9,958,539 | 85,048 | — | — | — | — | — | — | — |
| Stock-based compensation expense | — | — | — | — | — | — | 3,683 | — | 3,683 |
| Net loss | — | — | — | — | — | — | — | (91,130) | (91,130) |
| 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 | — | — | — | — | 789,225 | — | 1,444 | — | 1,444 |
| Issuance of Common Stock pursuant to employee stock purchase plan | — | — | — | — | 67,120 | — | 439 | — | 439 |
| 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 | 1 | 290,942 | — | 290,946 |
| Stock-based compensation expense | — | — | — | — | — | — | 9,207 | — | 9,207 |
| Net loss | — | — | — | — | — | — | — | (192,036) | (192,036) |
| Balance at December 31, 2021 | — | $ — | 29,863,674 | 3 | 26,408,031 | 3 | $ 598,913 | $ (364,942) | $ 233,977 |

*See accompanying notes to the financial statements*

**Talis Biomedical Corporation**
**Statements of cash flows**
***(in thousands)***

| | Year ended December 31, | |
|---|---|---|
| | **2021** | **2020** |
| **Operating activities** | | |
| Net loss | $ (192,036) | $ (91,130) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 9,207 | 3,683 |
| Depreciation and amortization | 1,578 | 763 |
| Non-cash lease expense | 1,043 | 611 |
| Changes in operating assets and liabilities: | | |
| Grants receivable | 288 | 1,334 |
| Prepaid expenses and other current assets | (281) | (295) |
| Prepaid research and development | 12,014 | (11,747) |
| Accounts payable | 216 | 3,200 |
| Accrued expenses and other liabilities | 2,202 | 7,262 |
| Lease liabilities | (104) | (796) |
| Other long term assets | (5,511) | 91 |
| Net cash used in operating activities | $ (171,384) | $ (87,024) |
| **Investing activities** | | |
| Purchase of property and equipment | (2,866) | (8,201) |
| Net cash used in investing activities | $ (2,866) | $ (8,201) |
| **Financing activities** | | |
| Proceeds from stock option exercises | 1,444 | 16 |
| Proceeds from stock issuances pursuant to employee stock purchase plan | 439 | — |
| Proceeds from initial public offering, net of issuance costs | 232,546 | — |
| Proceeds from the issuance of convertible preferred stock, net of issuance costs | — | 248,189 |
| Payment of deferred initial public offering costs | — | (1,451) |
| Net cash provided by financing activities | $ 234,429 | $ 246,754 |
| Net increase in cash, cash equivalents and restricted cash | 60,179 | 151,529 |
| Cash, cash equivalents and restricted cash at beginning of year | 173,133 | 21,604 |
| Cash, cash equivalents and restricted cash at end of year | $ 233,312 | $ 173,133 |
| | | |
| **Supplemental disclosure of noncash activities** | | |
| Property and equipment purchases included in accounts payable and accrued expenses | $ 127 | $ 140 |
| 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 | $ 342 | $ 417 |
| Deferred initial public offering costs included in accounts payable and accrued expenses | $ — | $ 928 |

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

| | December 31, | |
|---|---|---|
| | **2021** | **2020** |
| Cash and cash equivalents | $ 232,545 | $ 138,483 |
| Restricted cash - other long term assets | 767 | — |
| Restricted cash | — | 34,650 |
| Total cash, cash equivalents and restricted cash | $ 233,312 | $ 173,133 |

*See accompanying notes to the financial statements*

## 1. Organization and nature of business

Talis Biomedical Corporation (the Company) is a molecular diagnostic company focused on advancing health equity and outcomes through the delivery of accurate infectious disease testing in the moment of need, at the point of care. The Company plans to develop and commercialize innovate products on its sample-to-answer Talis One system to enable accurate, low cost, and rapid molecular testing. In November 2021, the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for use of the Talis One COVID-19 Test System in a variety of healthcare settings. 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*

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 underwriter's 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, affiliated preferred shares with a carrying value of $225.3 million were converted into 29,863,674 Series 1 convertible preferred stock. The remaining outstanding convertible preferred shares were converted into 7,555,432 shares of common stock. Preferred stock outstanding prior to the IPO is referred to as historical convertible preferred stock within.

### *Liquidity*

The Company has incurred significant losses and negative cash flows since inception, including net loss of $192.0 million for the year ended December 31, 2021. As of December 31, 2021, the Company had unrestricted cash and cash equivalents of $232.5 million and $0.8 million of restricted cash.

Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities, including the scale up and commercialization of the Talis One system. 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 December 31, 2021 will be sufficient to fund its operations through at least one year from the date these financial statements are issued. The Company expects to finance its future operations with its existing unrestricted and restricted cash and cash equivalents 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 financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) and the rules and regulations of Securities and Exchange Commission (SEC) for reporting.

### *Segment information*

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to

allocate resources and in assessing performance. The Company's chief operating decision maker is the Chief Executive Officer. The Company views its operations and manages its business in one operating segment.

***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. The Company bases its estimates and judgments on historical experience and on various other assumptions, including knowledge about current events and expectations about actions the Company may take in the future, that the Company believes are reasonable under the circumstances. Significant estimates include, but are not limited to, recoverability of long-lived assets, accrued research and development costs, stock-based compensation expense, the measurement of right-of-use assets and lease liabilities, uncertain tax positions, and the fair value of common stock and convertible preferred stock prior to the Company's IPO. Actual results could vary from the amounts derived from management's estimates and assumptions.

***Reclassifications***

The accompanying balance sheets as of December 31, 2020 reflects the Company's reclassification of unbilled grants receivables to grants receivables, to conform to the presentation of the current period.

***Fair value measurements***

The Company's financial assets carried at fair value consist of cash equivalents held in money market accounts that are valued using quoted prices in active markets for identical instruments. Due to their short-term nature, the carrying values for cash, grants receivable and accounts payable approximate fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- *Level 1*—Quoted prices in active markets for identical assets or liabilities.
- *Level 2*—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- *Level 3*—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value of the instrument.

***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 United States (U.S) Treasury obligations which are stated at fair value. Prior to April 1, 2021, the Company did not have any cash equivalents.

***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 and 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 U.S. 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 and cash equivalents are 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.

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, 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. 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.

The Company is dependent on key suppliers for certain manufacturing and research and development activities. An interruption in the supply of these materials could temporarily impact the Company's ability to commercialize, manufacture inventory and perform research and development, testing and clinical trials related to its products. The Company is also dependent on its manufacturing partners and third party logistic partner that are critical to its ability to supply product to its end customers.

***Property and equipment***

Property and equipment are recorded at cost less accumulated depreciation. Depreciation is recorded using the straight-line method based on the estimated useful lives of the depreciable property or, for leasehold improvements, the remaining term of the lease, whichever is shorter. The useful lives of the assets are as follows:

| | Estimated Useful Life (in years) |
|---|---|
| Lab equipment | 5 years |
| Furnitures and fixtures | 5 years |
| Office and computer equipment | 3 years |
| Leasehold improvements | Shorter of life of the asset or remaining lease term |

Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is recognized in the statement of operations and comprehensive loss. Expenditures for maintenance and repairs are expensed as incurred.

***Impairment of long-lived assets***

A long-lived asset may be impaired when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset's carrying amount. Any required impairment loss would be measured as the amount by which the asset or asset group's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense. The Company reviews the carrying amount of its long-lived assets, including property and equipment, for impairment whenever events indicate that the carrying amount of the assets may not be fully recoverable. There was no impairment recorded for the years ended December 31, 2021 and 2020.

***Leases***

Effective January 1, 2020, the Company adopted Accounting Standards Update (ASU) 2016-02, Leases (Topic 842) (ASC 842), using the modified retrospective transition method. At the inception of an arrangement, the Company

determines whether the arrangement is or contains a lease. The Topic requires a lessee to determine if an arrangement is a lease or contains a lease at contract inception, to recognize right-of-use ("ROU") assets and lease liabilities arising from operating and financing leases with terms longer than 12 months on the balance sheets and to disclose key information about leasing arrangements. Lease expense is recognized on a straight-line basis over the lease term.

For the Company's operating leases, the Company accounts for the lease and non-lease components as a single lease component, the lease liability is initially measured at the present value of the unpaid lease payments at lease commencement date. As most of the leases do not provide an implicit rate, the Company generally uses its incremental borrowing rate as the discount rate for the lease. The Company's incremental borrowing rate is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. The operating lease right-of-use asset includes any lease payments to be made and excludes lease incentives. The Company’s lease terms may include options to extend or terminate the lease when it is reasonably certain that it will exercise that option.

The Company enters into certain manufacturing and supply arrangements with third-party suppliers that may contain embedded leases for the manufacturing of Talis One cartridges, which require highly specialized production lines. If it is determined that the Company controls the underlying assets during construction, the Company may be deemed to be the “owner” for accounting purposes during the construction period and may be required to capitalize the project costs on its balance sheet. As the Company has funded all of the construction costs, the recognition of a financing liability for amounts funded by the third-party supplier is not necessary.

***Research and development costs***

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 EUA or other FDA marketing authorization, commercialization is considered 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. 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 or clearance is obtained and commercialization is probable. 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.

In 2021, the Company substantially completed work on production lines to automate the production of its Talis One cartridges for the COVID-19 assay. The Company has incurred approximately $110.5 million to date as part of the Company’s effort to scale-up its manufacturing capacity including costs incurred for high capacity production equipment, of which $69.6 million has been incurred in the twelve months ended December 31, 2021. Approximately $96.5 million of production equipment acquired is highly specialized for the manufacturing of the Company’s Talis One cartridges and was determined not to have an alternative future use. During the years ended December 31, 2021 and 2020, the Company charged $11.8 million and $0 of pre-launch inventory relating to cartridges and $21.7 million and $7.7 million of pre-launch inventory relating to instrument components to research and development expense, respectively.

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 through discussions internally and with service providers to confirm the accuracy of progress and stage of completion. The Company’s understanding of the status and timing of services performed relative to the actual status and timing of services performed requires significant judgment and actual results may vary.

***Grant revenue and receivables***

Grants awarded to the Company for research and development by government entities are outside the scope of the contracts with customers and contributions guidance. This is because the granting entities are not considered to be customers and are not receiving reciprocal value for their grant support provided to the Company. These grants provide the Company with payments for certain types of expenditures in return for research and development activities or for meeting certain development milestones over a contractually defined period. For efforts performed under these grant agreements, the Company's policy is to recognize revenue when it is reasonably assured that the grant funding will be received as evidenced through the existence of a grant arrangement, amounts eligible for reimbursement are determinable and have been incurred and paid, the applicable conditions under the grant arrangements have been met, and collectability of amounts due is reasonably assured. Costs of grant revenue are recorded as a component of research and development expenses in the Company's statements of operations and comprehensive loss.

Grant funds received from third parties are recorded as revenue if the Company is deemed to be the principal participant in the arrangement. If the Company is 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. Management has determined that the Company is the principal participant under the Company's grant agreements, and accordingly, the Company records amounts earned under these arrangements as grant revenue.

***Preferred stock***

The Company records historical convertible preferred stock at fair value on the dates of issuance, net of issuance costs. The Company has classified historical convertible preferred stock, which is redeemable, as temporary equity in the accompanying balance sheet at December 31, 2020 due to terms that allow for redemption of the shares in cash upon certain change in control events that are outside of the Company's control, including the sale or transfer of the Company by holders of the historical convertible preferred stock which could trigger redemption of the shares.

The carrying values of the historical convertible preferred stock are adjusted to their liquidation preferences if and when it becomes probable that such a liquidation event will occur. The Company did not accrete the value of the historical convertible preferred stock to the redemption values since a future change in control event was not considered probable as of December 31, 2020.

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

In determining if an extinguishment or modification of changes to mezzanine equity-classified preferred shares has occurred, the Company has elected a policy to evaluate if changes add, delete or significantly change a substantive contractual term (e.g., one that is at least reasonably possible of being exercised), or fundamentally change the nature of the convertible preferred shares. This evaluation includes the consideration of both the expected economics as well as the business purpose for the amendment.

As part of the Company's IPO, certain shares of the Company's historical convertible preferred stock converted into shares of the Company's Series 1 convertible preferred stock. The Company records the Series 1 convertible preferred stock at par value on the date of conversion. The Company has classified its Series 1 convertible preferred stock as permanent equity within the accompanying balance sheet at December 31, 2021 due to the immaterial liquidation value of the shares.

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

***Income taxes***

The Company accounts for income taxes under the liability method. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been included in the Company's financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the

differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards, using enacted tax rates expected to be in effect in the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible.

The Company recognizes and measures uncertain tax positions using a two-step approach set forth in authoritative guidance. The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. Judgment is required to evaluate uncertain tax positions. The Company evaluates uncertain tax positions on a regular basis. The evaluations are based on a number of factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of the audit, and effective settlement of audit issues.

The Company's policy is to include penalties and interest expense related to income taxes as a component of income taxes expense, as necessary. The Company has not reported any interest or penalties associated with income tax since inception.

On March 18, 2020, the Families First Coronavirus Response Act (FFCR Act), and in March 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) were each enacted in response to the COVID-19 pandemic. The FFCR Act and the CARES Act contain numerous income tax provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property.

On June 29, 2020, Assembly Bill 85 (A.B. 85) was signed into California law. A.B. 85 provides for a three-year suspension of the use of net operating losses for medium and large businesses and a three-year cap on the use of business incentive tax credits to offset no more than $5.0 million of tax per year. A.B. 85 suspends the use of net operating losses for taxable years 2020, 2021 and 2022 for certain taxpayers with taxable income of $1.0 million or more. The carryover period for any net operating losses that are suspended under this provision will be extended. A.B. 85 also requires that business incentive tax credits including carryovers may not reduce the applicable tax by more than $5.0 million for taxable years 2020, 2021 and 2022.

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 financial statements.

The FFCR Act, CARES Act and A.B. 85 did not have a material impact on the Company's financial statements as of December 31, 2021; however, the Company continues to examine the impacts the FFCR Act, CARES Act and A.B. 85 may have on its business, results of operations, financial condition, liquidity and related disclosures.

***Stock-based compensation***

The Company maintains an equity incentive plan as a long-term incentive for employees, consultants, and directors. The Company accounts for all stock-based awards granted to employees and directors based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The measurement date for stock awards, including stock options and restricted stock units (RSUs) is the date of grant. From time to time, the Company may grant stock options to employees, including executive officers, and consultants that vest upon the satisfaction of both service-based and performance-based vesting conditions. The Company recognizes stock-based compensation over the requisite service period using the accelerated attribution method for awards with a performance condition if the performance condition is deemed probable of being met. Stock-based compensation is classified in the accompanying statements of operations and comprehensive loss based on the function to which the related services are provided. The Company recognizes stock-based compensation expense for the portion of awards that have vested. Forfeitures are accounted for as they occur.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes options-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and the Company's expected dividend yield. The fair value of each restricted stock unit is determined based on the number of shares granted and the value of the Company's common stock on the date of grant.

The fair value of the Company's common stock prior to the Company's IPO was determined by the Board with the assistance of management. The fair value of common stock was determined using valuation methodologies which utilize certain assumptions including probability weighting of events, volatility, time to an exit event, a risk-free interest rate and an assumption for a discount for lack of marketability. In determining the fair value of common stock, the methodologies used to estimate the enterprise value of the Company were performed using methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

***Net loss per share attributable to common stockholders***

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 Series 1 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, unvested RSUs, 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 years ended December 31, 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.

***Deferred initial public offering costs***

Deferred offering costs, which consist of direct incremental legal, consulting, banking and accounting fees relating to the Company's IPO, are capitalized and were offset against proceeds within stockholders' equity (deficit) in February 2021. As of December 31, 2020, there were $2.4 million of deferred IPO offering costs within prepaid and other current assets on the balance sheet.

***Emerging growth company status***

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act, until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

***New Accounting Pronouncements***

*Recently Adopted Accounting Standards*

In August 2020, the Financial Accounting Standards Board (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 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.

**3. Fair value measurements**

The follow table summarizes the Company's financial assets carried at fair value and measured on a recurring basis as of December 31, 2021:

| | December 31, 2021 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Cash equivalents (money market funds) | $ 205,071 | $ — | $ — | $ 205,071 |
| Total assets measured at fair value | $ 205,071 | $ — | $ — | $ 205,071 |

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

**4. Balance sheet components**

***Property and equipment, net***

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

| | December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Lab equipment | $ 8,077 | $ 3,874 |
| Office and computer equipment | 507 | 456 |
| Furniture and fixtures | 407 | 392 |
| Leasehold improvements | 814 | 814 |
| Total | 9,805 | 5,536 |
| Less accumulated depreciation | (3,992) | (2,998) |
| Total | 5,813 | 2,538 |
| Construction in progress | 4,715 | 6,576 |
| Property and equipment, net | $ 10,528 | $ 9,114 |

Depreciation expense for the years ended December 31, 2021 and 2020 was $1.6 million and $0.8 million, respectively. All of the Company's property and equipment is located in the U.S. and Germany, with $2.2 million of lab equipment being located in Germany.

Construction in progress includes high capacity production equipment funded as part of the Company's effort to scale up its manufacturing capacity for commercial launch. The equipment capitalized in construction in progress is production equipment that has been determined to have an alternative future use. Under the build to suit leasing guidance, the Company is considered the accounting owner of this equipment during its construction. Construction in progress is stated at cost and does not depreciate. Once the equipment is completed and ready for its intended use, the Company will assess whether a sale and leaseback have occurred.

***Accrued liabilities***

Accrued liabilities consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Accrued research and development costs | $ 5,303 | $ 6,360 |
| Other liabilities | 1,080 | 1,333 |
| | $ 6,383 | $ 7,693 |

**5. Grants revenue and receivable**

***CARB-X grant***

In April 2018, the Company entered into a subaward agreement with the Trustees of Boston University as part of the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) grant to support the development of a rapid Clinical Laboratory Improvement Amendments-waived molecular diagnostic test to detect chlamydia and gonorrhea directly from a patient sample in 20 minutes or less and develop a similarly rapid phenotypic antibiotic susceptibility test for gonorrhea. The subaward agreement consisted of $4.4 million of initial funding through September 30, 2019. During 2020, the subaward agreement was extended through September 2020 and the initial funding was increased by $1.2 million in order to expand development efforts. In October 2021, the Company chose not to pursue additional option periods under the Biomedical Advanced Research and Development Authority's CARB-X program. Therefore, there is no additional funding available under this grant.

During the year ended December 31, 2021 the Company did not recognize revenue related to the CARB-X grant. During the year ended December 31, 2020, the Company recognized $0.6 million of revenue related to the CARB-X grant.

***NIH grant***

In May 2018, the Company was awarded a grant from the NIH for the Diagnostics via Rapid Enrichment, Identification, and Phenotypic Antibiotic Susceptibility Testing of Pathogens from Blood project. The structure of

the agreement consisted of a $1.3 million initial funding term through April 2019 with the possibility of an additional $4.4 million of funding through April 2023, subject to the availability of funds and satisfactory progress of the project. In April 2020, the Company exercised its second one-year option under the grant, extending the term through April 2021. In April 2021, the Company exercised its third one-year option under the grant, extending the term through April 2022. As of December 31, 2021, there is $1.8 million in additional funding available under the grant through April 2023.

During the years ended December, 31 2021 and 2020, the Company recognized $0.5 million and $1.1 million of revenue related to this grant, respectively.

***NIH Rapid Acceleration of Diagnostics - RADx Initiative contracts***

In July 2020, the Company was awarded a $0.4 million subaward grant from the University of Massachusetts Medical School for Phase 1 of the NIH's RADx initiative and a $25.4 million contract from the NIH directly for Phase 2 of the RADx initiative. The RADx initiative aims to speed the development, validation, and commercialization of innovative, rapid tests that can directly detect COVID-19.

The terms and milestone conditions of the first two stages, for consideration of up to $10.1 million, was agreed to in July 2020 while the milestone conditions and terms of the final three stages, for consideration of up to $15.3 million, was agreed to in December 2020. During the year ended December 31, 2020, the Company recognized $8.9 million related to the first stage of 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 term of the contract to October 31, 2021 and decreased the potential milestone payment from $8.0 million to $4.0 million. In October 2021, the Company and the NIH agreed to a further amended contract for the completion of the RADx initiative, extending the term of the contract to January 30, 2022 and further decreased the potential milestone payment from $4.0 million to $2.0 million. The contract expired on January 30, 2022.

During the year ended December 31, 2021 the Company recognized $7.7 million related to the second stage of Phase 2 of the RADx initiative.

**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. 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 December 31, 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 balance sheet. In the fourth quarter of 2021, the Company made a $4.5 million payment to the landlord for lease payments which is classified within other long-term assets on the balance sheet.

In December 2015, the Company entered a lease agreement in Menlo Park, California for laboratory and office space. The lease agreement commenced on May 1, 2016 and had an expiration date of April 30, 2021. In June 2020, the Company extended the term of this operating lease for six months, extending the lease end date to October 31, 2021. In April 2021, the Company further extended the term of this operating lease for an additional two months, extending the lease end date to December 31, 2021, with an option to extend the term for one additional month to January 2022. In September 2021, the Company further extended the term of this operating lease for an additional two months, extending the lease end date to March 31, 2022.

The Company has an operating lease agreement for equipment for which the related expense is immaterial.

The components of the lease costs and supplemental cash flow information relating to the Company's leases for the years ended December 31, 2021 and 2020 were as follows (in thousands):

| | December 31, | |
|---|---|---|
| **Lease Costs** | **2021** | **2020** |
| Operating lease costs | $ 1,984 | $ 626 |
| Variable lease costs | 110 | 22 |
| Total operating lease costs | $ 2,094 | $ 648 |
| **Cash flows** | | |
| Cash paid for amounts included in the measurement of lease liabilities: | | |
| Operating cash flows used for operating leases | $ 1,050 | $ 811 |

Weighted-average remaining lease terms and discount rates as of December 31, 2021 and 2020 were as follows:

| | December 31, | |
|---|---|---|
| | **2021** | **2020** |
| Weighted-average remaining lease term | 10.2 years | 0.9 years |
| Weighted-average discount rate | 5.2% | 1.2% |

The undiscounted future lease payments for operating leases as of December 31, 2021 were as follows (in thousands):

| **Year ending December 31,** | **Operating Leases** |
|---|---|
| 2022 | $ 1,265 |
| 2023 | 1,644 |
| 2024 | 1,684 |
| 2025 | 1,725 |
| 2026 | 1,766 |
| 2027 and thereafter | 10,335 |
| Total future minimum lease payments | $ 18,419 |
| Less: imputed interest | (4,442) |
| Present value of operating lease liabilities | 13,977 |
| Less: current portion of lease liabilities | (1,232) |
| Noncurrent portion of lease liabilities | $ 12,745 |

***Standby letter of credit***

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 letter of credit (LOC), that was required to be held as collateral by the contract manufacturing organization and was issued in August 2020, was concurrently terminated.

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 balance sheet as of December 31, 2021, because it is unavailable for a period longer than one year from the balance sheet date. The LOC had not been drawn upon through December 31, 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.

***Contingencies***

The Company is party to certain legal matters arising in the ordinary course of its business. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications. The Company records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company currently does not believe that the ultimate outcome of any of the matters is probable or reasonably estimable, or that these matters will have a material adverse effect on its business; however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on the Company because of litigation and settlement costs, diversion of management resources and other factors. Legal costs are expensed as incurred.

***Unconditional purchase obligations***

In the normal course of business, the Company enters into various firm purchase commitments. As of December 31, 2021, these commitments are approximately $15.8 million, all of which is expected to be incurred in 2022.

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

***Convertible preferred stock***

*The Equity Transactions*

Between November 2019 and December 2019, the Company entered into a series of transactions with its existing preferred stockholders and new investors, to (i) raise new capital in a sale of three new series of convertible preferred stock including Series C-1 Preferred, Series D-1 Preferred and Series D-2 Preferred, and (ii) condense its capital structure (Equity Transactions). All existing convertible preferred stockholders were given the opportunity to participate in the new capital raise but were subject to dilution for a lack of participation.

The cash proceeds associated with the sale of the Series C-1 Preferred, Series D-1 Preferred and Series D-2 Preferred was to be received by the Company over three tranches of payments. During the second quarter of 2020, the Company received the Second Tranche Payment at a cash payment per share due and payable upon the Second Tranche Payment of $0.81 per share, resulting in net proceeds of $24.9 million, net of issuance costs of less than $0.1 million.

In June 2020, the Company amended the Series C-1 and Series D-1 Stock Purchase Agreement (SPA) to revise the date by which the third tranche milestone must be met from October 1, 2020 to June 30, 2020, and as a result, the third tranche milestone was not met. Pursuant to the amendment, due to the third tranche milestone not being met, purchasers were not required to fund the Third Tranche Payment and as a result, 9,314,766 shares, 955,666 shares, and 2,387,171 shares of Series C-1 Preferred, Series D-1 Preferred and Series D-2 Preferred, respectively, were cancelled and transferred back to the Company for no consideration, as no consideration had previously been received for such shares.

The Company determined that the amendment to the Series C-1 and Series D-1 SPA represented a modification but that no incremental expense would be recorded as the difference between the fair values of the Series C-1 Preferred, Series D-1 Preferred, and Series D-2 Preferred immediately before and after the amendment was insignificant.

***Series E preferred stock financing and Sixth Restated Certificate of Incorporation***

The Company's June 2020 Sixth Amended Restated Certificate of Incorporation authorized the issuance of up to 77,427,646 shares of convertible preferred stock, of which 13,404,197 shares were designated as Series C-1 Preferred, 13,404,197 shares were designated as Series C-2 Preferred, 11,809,626 shares were designated as Series D-1 Preferred, 11,809,626 shares were designated as Series D-2 Preferred, 13,500,000 shares were designated as Series E-1 Preferred, and 13,500,000 shares were designated as Series E-2 Preferred.

Between June and July 2020, the Company entered into a Series E Preferred Stock Purchase Agreement (Series E SPA) which resulted in the issuance of 2,289,899 shares of its Series E-1 Preferred and also conducted a rights offering with existing common, Series C-1 and Series D-1 preferred stockholders which resulted in the issuance of 11,187,189 shares of its Series E-2 Preferred, both at a purchase price of $7.42 per share, for total net proceeds of $99.7 million, net of issuances cost of $0.3 million. Existing stockholders who were party to the Series E SPA and participated in the rights offering purchased 1,035,932 shares of the Series E-1 Preferred issued and 11,187,189 shares of Series E-2 Preferred issued, amounting to gross proceeds of $90.7 million. Included in the terms of the Series E SPA and rights offering were written options to purchase additional shares of Series E-1 Preferred and E-2 Preferred under the same terms as those provided at the initial closing in June 2020. The Company concluded that the fair value of these financial instruments requiring recognition as liabilities at fair value was insignificant.

***Series F preferred stock financing and Seventh Restated Certificate of Incorporation***

The Company's October 2020 Seventh Amended Restated Certificate of Incorporation authorized the issuance of up to 229,296,908 shares of convertible preferred stock, of which 13,404,197 shares were designated as Series C-1 Preferred, 13,404,197 shares were designated as Series C-2 Preferred, 11,809,630 shares were designated as Series D-1 Preferred, 11,809,630 shares were designated as Series D-2 Preferred, 13,477,088 shares were designated as Series E-1 Preferred, 13,477,088 shares were designated as Series E-2 Preferred, 18,633,312 shares were designated as Series F-1 Preferred, 18,633,312 shares were designated as Series F-2 Preferred, 57,324,227 shares were designated as Series 1 convertible preferred stock and 57,324,227 Series 2 convertible non-voting preferred stock.

In October 2020, the Company entered into the Series F Preferred Stock Purchase Agreement (Series F SPA) and authorized the sale and issuance of up to an aggregate of 18,633,312 shares of both its Series F-1 Preferred and its Series F-2 Preferred, for an aggregate investment amount of up to approximately $153.8 million. In conjunction with entering the Series F SPA in October 2020, the Company issued 1,730,995 shares of its Series F-1 Preferred at a purchase price of $8.55 per share, resulting in total net proceeds of $14.4 million, net of issuance costs of $0.4 million (Series F Initial Closing).

The Company held additional closings to sell up to the aggregate number of Series F-1 Preferred or Series F-2 Preferred shares remaining following the Series F Initial Closing. In November 2020, the Company issued and sold an additional 3,128,902 shares of its Series F-1 Preferred and 9,958,539 shares of its Series F-2 Preferred each at a purchase price of $8.55 per share, resulting in total net proceeds of $109.1 million, net of issuance costs of $2.8 million. Among the proceeds received from this financing, $92.0 million was from existing investors.

***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 (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 historical 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 historical convertible preferred stock were converted into 7,555,432 shares of common stock. As of December 31, 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):

| 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 | 121,757 | 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 authorized and outstanding as of December 31, 2021 and the convertible preferred stock authorized and outstanding as of December 31, 2020 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 convertible preferred stock and Series 2 non-voting convertible preferred stock as of December 31, 2021 and the Company's convertible preferred stock as of December 31, 2020 are as follows:

*Voting*

As of December 31, 2021, 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 non-voting convertible preferred stock have no voting rights except as required by law or as set forth in our amended and restated certificate of incorporation.

As of December 31, 2020, the holders of Series C-1 Preferred, Series D-1 Preferred, Series E-1 Preferred and Series F-1 Preferred (Voting Preferred Stock), voting as a separate class, shall be entitled to elect four members of the Board at each meeting or pursuant to each consent of the Company’s stockholders for the election of directors. The Series C-2 Preferred, Series D-2 Preferred, Series E-2 Preferred and Series F-2 Preferred (Non-Voting Preferred Stock) is non-voting. Any additional members of the Board shall be elected by the holders of common stock and Voting Preferred Stock, voting together as a single class. Each holder of the Voting Preferred Stock shall be entitled to the number of votes equal to the applicable number of shares of common stock into which the shares convert.

*Conversion*

As of December 31, 2021, the Series 1 convertible preferred stock is convertible, at the election of the holder, into Series 2 non-voting 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 non-voting convertible preferred stock is prohibited if the holder exceeds a specified threshold of voting security ownership. The Series 2 non-voting 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 non-voting 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 non-voting 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 non-voting convertible preferred stock.

As of December 31, 2020, each share of the Company's historical convertible preferred stock shall be convertible, at the option of the holder, into the number of common shares determined by dividing their original issuance by the conversion price then in effect for each series (Conversion Rate). Upon any increase or decrease in the conversion price for any series of convertible preferred stock, the Conversion Rates are appropriately increased or decreased. As of December 31, 2020, the conversion price was $7.84 per share for Series C-1 Preferred and Series C-2 Preferred, $3.92 per share for Series D-1 Preferred and Series D-2 Preferred, $10.62 per share for Series E-1 Preferred and Series E-2 Preferred and $12.23 per shares for Series F-1 Preferred and Series F-2 Preferred.

Each share of the Company's historical convertible preferred stock shall be automatically converted into fully-paid, non-assessable shares of common stock, in the sole and absolute discretion of such holder, as of December 31, 2020 at the then effective Conversion Rate of each such share (i) immediately prior to the closing of a firm commitment underwritten initial public offering pursuant to an effective registration statement filed under the Securities Act of 1933, as amended (Securities Act), covering the offer and sale of the common stock, provided that the offering price per share is not less than $7.82, as adjusted for recapitalizations as defined in the Series C-1 and D-1 SPA, the aggregate gross proceeds to the Company are not less than $50.0 million, and the shares of common stock are listed for trading on the New York Stock Exchange or Nasdaq, or (ii) upon the receipt by the Company of a written request for such conversion from the holders of a majority of the Company's historical convertible preferred stock then outstanding (voting as a single class and on an as-converted basis), or, if later, the effective date for conversion specified in such requests.

In the event of automatic conversion of the Company's historical convertible preferred stock, each holder of convertible preferred who, together with its affiliates, hold in excess of 9.99% of the number of shares of common stock outstanding immediately following such automatic conversion, shall have the option to convert any shares of the convertible preferred into either common stock or Series 1 convertible preferred stock, in the discretion of the holder.

Subject to minimum outstanding share requirements and in addition to any other vote or consent required herein or by law, the vote or written consent of the holders of a majority of the outstanding convertible preferred shares and historical convertible preferred stock shall be necessary for approving certain actions, primarily those that may adversely impact the voting or other powers, preferences, or other special rights, privileges or restrictions of the Company's convertible preferred stock.

*Dividends*

As of December 31, 2021, 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. As of December 31, 2021 no such dividends had been declared or accrued.

As of December 31, 2020, the Series C-1 Preferred, Series D-1 Preferred, Series D-2 Preferred, Series E-1 Preferred, Series E-2 Preferred, Series F-1 Preferred, and Series F-2 Preferred outstanding as of December 31, 2020 do not have rights to receive dividends nor participate in the Company's earnings distribution. However, any such dividend or distribution is subject to the prior approval of these preferred stockholders. As of December 31, and 2020 no such dividends had been declared or accrued.

*Liquidation preference*

As of December 31, 2021, 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.

As of December 31, 2020, in the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary, the holders of Series C-1 Preferred, Series C-2 Preferred, Series D-1 Preferred, Series D-2 Preferred, Series E-1 Preferred, Series E-2 Preferred, Series F-1 Preferred and Series F-2 Preferred at December 31, 2020 shall be entitled to receive, prior and in preference to any distribution of any of the assets of the Company to

the holders of the common stock by reason of their ownership of such stock, the greater of (i) an amount per share of $5.48 per share of Series C-1 Preferred and Series C-2 Preferred, $2.74 per share of Series D-1 Preferred and Series D-2 Preferred, $7.42 per share of Series E-1 Preferred and Series E-2 Preferred and $8.55 per share of Series F-1 Preferred and Series F-2 Preferred plus any declared but unpaid dividends as of December 31, 2020 or (ii) such amount per share as would have been payable had all shares of such series of Series C-1 Preferred, Series C-2 Preferred, Series D-1 Preferred, Series D-2 Preferred, Series E-1 Preferred, Series E-2 Preferred, Series F-1 Preferred and Series F-2 Preferred had been converted into common stock immediately prior to such liquidation, dissolution or winding up of the Company. If upon the liquidation, dissolution or winding up of the Company, the assets of the Company legally available for distribution to the holders of the Series C-1 Preferred, Series C-2 Preferred, Series D-1 Preferred, Series D-2 Preferred, Series E-1 Preferred , Series E-2 Preferred, Series F-1 Preferred and Series F-2 Preferred are insufficient to permit the payment to such holders of the full amounts, then the entire assets of the Company legally available for distribution shall be distributed with equal priority and pro rata among the holders of the Series C-1 Preferred, Series C-2 Preferred, Series D-1 Preferred, Series D-2 Preferred, Series E-1 Preferred, Series E-2 Preferred, Series F-1 Preferred and Series F-2 Preferred in proportion to the full amounts they would otherwise be entitled to receive.

Unless stockholders representing a majority of the then-outstanding Voting Preferred Stock, voting together as a single class, elect otherwise, a liquidation event is defined in the Company's amended and restated certificate of incorporation to include (i) any liquidation, dissolution, or winding up of the Company, (ii) the merger or consolidation of the Company in which the holders of capital stock of the Company outstanding immediately prior to such merger or consolidation do not continue to represent immediately following such merger or consolidation at least 50%, by voting power, of the outstanding capital stock of the resulting or surviving entity or (iii) a sale, lease, transfer or other disposition of all or substantially all of the Company's assets. The Company classifies its historical convertible preferred stock outside of stockholders' deficit because the shares contain liquidation features that are not solely within the Company's control.

*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.

*Redemption rights*

As of December 31, 2021 no shares of Series 1 convertible preferred stock and Series 2 non-voting convertible preferred stock are unilaterally redeemable by either the stockholders or the Company; however, the Company's amended and restated certificate of incorporation provides that upon any liquidation event such shares shall be entitled to receive the applicable liquidation preference.

*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. No dividends have been declared or paid during the years ended December 31, 2021 or 2020.

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

| | December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Shares reserved for conversion of outstanding Series C-1 Preferred Stock | — | 9,373,556 |
| Shares reserved for conversion of outstanding Series D-1 Preferred Stock | — | 1,005,013 |
| Shares reserved for conversion of outstanding Series D-2 Preferred Stock | — | 7,253,461 |
| Shares reserved for conversion of outstanding Series E-1 Preferred Stock | — | 1,601,316 |
| Shares reserved for conversion of outstanding Series E-2 Preferred Stock | — | 7,823,208 |
| Shares reserved for conversion of outstanding Series F-1 Preferred Stock | — | 3,398,514 |
| Shares reserved for conversion of outstanding Series F-2 Preferred Stock | — | 6,964,012 |
| 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 | 5,939,604 | 7,737,095 |
| Shares reserved for options to purchase common stock under the 2021 Equity Incentive Plan | 2,650,807 | — |
| Shares reserved for issuance under the 2021 Equity Incentive Plan | 3,842,773 | — |
| Shares reserved for settlement of restricted stock units under the 2021 Equity Incentive Plan | 407,720 | — |
| Shares reserved for issuance under the 2021 Employee Stock Purchase Plan | 482,880 | 1,928,256 |
| Total | 43,187,458 | 47,084,431 |

**8. Stock-based compensation**

***2013 Equity Incentive Plan***

The 2013 Equity Incentive Plan (2013 Plan) provides the Board of Directors the discretion to grant stock options and other equity-based awards to employees, directors, and consultants of the Company. The Board of Directors 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 have been 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.

***2021 Equity Incentive Plan***

In February 2021, the Board of Directors adopted the 2021 Equity Incentive Plan (2021 Plan), and our stockholders approved the 2021 Plan. The 2021 Plan is a successor to and continuation of the 2013 Plan. To date, the Company has only granted ISOs, NSOs and Restricted Stock Units (RSUs) to employees and directors. Therefore, the below discussion is limited to the terms applicable to ISOs and NSOs (collectively, stock options or options), and RSUs.

***2021 Employee Stock Purchase Plan (ESPP)***

In February 2021, the Company's Board of Directors adopted the ESPP, and our stockholders approved the 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 December 31, 2021, there were 67,120 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 $0.4 million related to the ESPP has been recorded for the year ended December 31, 2021.

***Stock option activity***

A summary of option activity during the year ended December 31, 2021 is as follows:

| | Number of Units Outstanding | Weighted Average Exercise 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 | 3,953,160 | $ 7.31 | | |
| Exercised | (789,225) | $ 1.83 | | |
| Forfeited | (2,243,260) | $ 5.70 | | |
| Expired | (67,359) | $ 5.18 | | |
| Outstanding at December 31, 2021 | 8,590,411 | $ 5.48 | 8.8 | $ 6,196 |
| Exercisable at December 31, 2021 | 2,538,244 | $ 4.78 | 8.6 | $ 2,634 |
| Nonvested at December 31, 2021 | 6,052,167 | $ 5.77 | 9.0 | $ 3,590 |

As of December 31, 2021, the total unrecognized stock-based compensation related to stock options, excluding the stock option granted to the Company's former Chief Executive Officer (CEO) with the performance condition (discussed further below), was $20.8 million, which is expected be recognized over a weighted-average period of approximately 3 years.

On August 30, 2021, the Company entered into a separation and consulting agreement with the Company's former CEO. As a result of the agreement, the Company determined that 271,347 options belonging to the former CEO were modified. During the twelve months ended December 31, 2021, the incremental expense recorded for this modification was $0.5 million.

During 2020, the former CEO 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 December 31, 2021, there was $1.8 million of unrecognized compensation expense related to these stock options as the achievement of the performance condition was not deemed probable.

In March 2020, the Company offered to reprice the unexercised stock options of each employee or non-employee director with an exercise price of $6.38 or higher per share to the estimated fair market value of the Company's common stock of $1.51. The repriced options were subject to the same terms as the original granted options, except for the new exercise price. The Company modified the exercise price of stock options for the purchase of 407,415 shares of common stock with a weighted average exercise price of $15.55 per share, by cancelling these options and reissuing stock options with exercise price of $1.51 per share to purchase 407,415 shares of common stock. The calculation of the incremental compensation expense is based on the excess of the fair value of the award measured immediately before and after the modification. As a result of the modification, the Company recognized an incremental compensation expense of $0.3 million for the twelve months ended December 31, 2020.

The weighted-average assumptions that the Company used in Black-Scholes option pricing model to determine the grant date fair value of stock options granted to employees and non-employees were as follows:

| | Year ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Expected term (in years) | 5.8 | 6.3 |
| Expected Volatility | 73.1% | 80.0% |
| Risk-free interest rate | 1.1% | 1.7% |
| Expected Dividend yield | —% | —% |

The weighted-average grant date fair value per share was $4.51 and $2.80 for options granted during the years ended December 31, 2021 and 2020, respectively.

The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of guideline companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the stock-based awards. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

***Restricted stock units***

A summary of RSU activity during the year ended December 31, 2021 is as follows:

| | Number of Units Outstanding | Weighted Average Grant Date Fair Value |
|---|---|---|
| Outstanding at December 31, 2020 | — | $ — |
| Granted | 1,043,720 | $ 4.97 |
| Vested | — | $ — |
| Forfeited | (636,000) | $ 4.49 |
| Outstanding at December 31, 2021 | 407,720 | $ 5.72 |

As of December 31, 2021, the total unrecognized stock-based compensation related to RSUs was $2.2 million, which is expected to be recognized over a weighted average period of approximately 4.0 years.

***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):

| | Year ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Research and development | $ 2,388 | $ 1,480 |
| Selling, general and administrative | 6,819 | 2,203 |
| Total stock-based compensation | $ 9,207 | $ 3,683 |

**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 $0.1 million and $0.1 million for services rendered for the years ended December 31, 2021 and 2020, respectively. During the year ended December 31, 2020, the Company granted stock options with a grant date fair value of $0.3 million pursuant to the consulting

agreement. The Company had immaterial unpaid balances related to the service agreement at December 31, 2021 and 2020.

***Financing Activity***

During the year ended December 31, 2020, the Company received proceeds of $180.3 million from the issuance of Series C-1 Preferred, Series D-2 Preferred, Series E-1 Preferred, Series E-2 Preferred, Series F-1 Preferred and Series F-2 Preferred to stockholders who are considered to be related parties (see Note 7).

**10. Income taxes**

The Company had no income tax expense for the year ended December 31, 2021 and 2020, due to its history of operating losses. During the years ended December 31, 2021 and 2020 the Company recorded a net loss of $192.0 million and $91.1 million, respectively.

The effective tax rate for the years ended December 31, 2021 and 2020 is different from the federal statutory rate primarily due to the tax benefit of the Company's net loss and comprehensive loss not being more likely than not to be realized. The following is a reconciliation of the statutory federal income tax rate to the Company's effective tax rate:

| | December 31, | |
|---|---|---|
| Effective income tax rate: | 2021 | 2020 |
| Expected income tax benefit at the federal statutory rate | 21.0% | 21.0% |
| State taxes, net of federal benefit | 7.7 | 7.7 |
| Research and development tax credits | 0.8 | 1.5 |
| Permanent differences | (0.2) | (0.8) |
| Change in valuation allowance | (29.3) | (29.4) |
| Total provision for income taxes | —% | —% |

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred income taxes are as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Deferred tax assets: | | |
| Federal and state operating loss carryforwards | $ 60,966 | $ 31,700 |
| Research and development tax credits | 6,655 | 4,444 |
| Lease liabilities | 4,221 | 208 |
| Manufacturing line and production equipment | 29,153 | 12,201 |
| Inventory related costs | 11,076 | 1,890 |
| Compensation related items | 2,877 | — |
| Other accruals | 141 | 1,070 |
| Total gross deferred tax asset | 115,089 | 51,513 |
| Valuation allowance | (111,024) | (51,291) |
| Net deferred tax asset | 4,065 | 222 |
| Deferred tax liabilities: | | |
| Property and equipment | (167) | (53) |
| Operating lease right-of-use asset | (3,898) | (169) |
| Total deferred tax liabilities | (4,065) | (222) |
| Net deferred tax asset | $ — | $ — |

The Company determines its valuation allowance on deferred tax assets by considering both positive and negative evidence in order to ascertain whether it is more likely than not that deferred tax assets will be realized. Realization of deferred tax assets is dependent upon the generation of future taxable income. Because of the Company's history of operating losses, the Company believes that the realization of its deferred tax assets is not more likely than not to be realized and, accordingly, has provided a valuation allowance. The valuation allowance increased by $59.7

million and $28.7 million for the years ended December 31, 2021 and 2020, respectively, primarily due to the increase in the Company's net loss and comprehensive loss.

NOLs and tax credit carryforwards as of December 31, 2021 are as follows (in thousands):

| | Amount | Expiration Years |
|---|---|---|
| NOLs, federal (post December 31, 2017) | $ 181,135 | Do not expire |
| NOLs, federal (pre January 1, 2018) | 30,901 | 2033 - 2037 |
| NOLs, state | 188,733 | 2033 to 2041 |
| Research and development tax credits, federal | 7,652 | 2035 to 2041 |
| Research and development tax credits, state | 6,247 | Do not expire |

Utilization of the NOL carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 as amended (Section 382) due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the NOL carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL carryforwards or research and development tax credit carryforwards before utilization. Until a study is completed and any limitation is known.

***Uncertain tax positions***

A reconciliation of the beginning and ending balance of total gross unrecognized tax benefits is as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Unrecognized tax benefits at the beginning of the period | $ 4,841 | $ 2,395 |
| Additions for current tax positions | 2,403 | 2,446 |
| Changes for previous tax positions | — | — |
| Unrecognized tax benefits at the end of the period | $ 7,244 | $ 4,841 |

During the years ended December 31, 2021 and 2020, the Company recognized no interest and penalties associated with unrecognized tax benefits. There are no tax positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within twelve months of the reporting date.

The Company files income tax returns in the U.S. federal and various tax jurisdictions. The federal and state income tax returns from inception through December 31, 2021 remain subject to examination by federal and state authorities, where applicable. There are currently no pending income tax examinations.

**11. Net loss per share**

***Net loss per share***

The basic and diluted loss per share are computed as follows (in thousands, except for share and per share data):

| | December 31, | |
|---|---|---|
| | 2021 | 2020 |
| **Numerator:** | | |
| Net loss - basic and diluted | $ (192,036) | $ (91,130) |
| **Denominator:** | | |
| Weighted-average number of shares of common stock outstanding - basic and diluted | 22,655,339 | 2,120,322 |
| Net loss per share - basic and diluted | $ (8.48) | $ (42.98) |

The Company was in a loss position for all periods presented, therefore 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 December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Historical convertible preferred stock | — | 37,419,127 |
| Series 1 convertible preferred stock | 29,863,674 | — |
| Options to purchase common stock | 8,590,411 | 7,737,095 |
| Shares estimated to be purchased under 2021 ESPP | 196,558 | — |
| Unvested RSUs | 407,720 | — |
| Total | 39,058,363 | 45,156,222 |

**12. Employee benefit plans**

The Company has a qualified deferred compensation plan under Section 401(k) of the Internal Revenue Code of 1986, as amended (401(k) Plan). Under the 401(k) Plan, employees may elect to defer a percentage of their salary, subject to Internal Revenue Service limits. The 401(k) Plan follows the Safe Harbor Deferral provisions, met with a Company Basic Matching Provision in which we provide an automatic matching contribution as follows: one-for-one with respect to the first 3% of an employee's contributions, and 50 cents on the dollar for the next 2% of the employee's contributions, up to a maximum company match of 4%. The matching contribution under this provision totaled $1.1 million and $0.5 million for the years ended December 31, 2021 and 2020.

The Company, at its sole discretion, may make discretionary profit-sharing contributions to the accounts of qualifying participants. There were no discretionary contributions to the 401(k) Plan for the years ended December 31, 2021 or 2020.

**13. Subsequent events**

In January 2022, in conjunction with the Company's Redwood City, CA operating lease, the Company entered into a standby LOC in the amount of $1.0 million to secure the lease through its expiration. The Company is required to maintain a cash balance of $1.0 million as collateral for the LOC, which will be classified in other long-term assets on the balance sheet. In exchange, $1.0 million in funds held with the landlord as a long-term deposit in other long-term assets on balance sheet as of December 31, 2021, was released.

On March 15, 2022, the Company announced a reduction in force and will be implementing further spending reductions to preserve cash given the uncertainty in timing of the Talis One system launch. The Company expects to recognize $1.0 million of expense related to these reductions during the three months ended March 31, 2022.

**Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.**

None.

**Item 9A. 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 amended (the Exchange Act)) as of the end of the period covered by this Annual Report on Form 10-K (this Annual Report) required by Exchange Act Rules 13a-15(b) or 15d-15(b).

Disclosure controls and procedures are designed to reasonably assure that information required to be disclosed in our reports filed or submitted under the Exchange Act, such as this Annual Report on Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures are also designed to reasonably assure that this information is accumulated and communicated to our management, including the CEO and CFO, to allow timely decisions regarding required disclosure. Based on this evaluation, the CEO and CFO concluded that, as of the end of the period covered by this Annual Report, the Company’s disclosure controls and procedures were effective at a reasonable assurance level.

*Management’s report on internal control over financial reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f) and 15d-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2021.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission for emerging growth companies that permit us to provide only management's report in this Annual Report on Form 10-K.

*Changes in internal control over financial reporting.*

During fiscal year 2021, we implemented internal control procedures which address a previously identified material weakness related to a lack of effective review of estimated vendor progress associated with our manufacturing scale-up project, which resulted in material adjustments to prepaid research and development expenses. During the fourth quarter of fiscal year 2021, we successfully completed the testing necessary to conclude that the material weakness has been remediated.

Except as noted above, there have been no changes in the Company's internal control over financial reporting that have materially affected, or that are reasonably likely to materially affect, the Company’s internal control over financial reporting.

**Item 9B. Other Information.**

Not applicable.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.**

Not applicable.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference to our Proxy Statement with respect to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K (the "2022 Proxy Statement"), under sections headed "Proposal 1. Election of Directors," "Information Regarding our Board of Directors and Corporate Governance," and "Information About our Executive Officers."

### Item 11. Executive Compensation.

The information required by this item is incorporated by reference to our 2022 Proxy Statement under the section headed "Executive and Director Compensation."

### Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference to our 2022 Proxy Statement under the section headed "Security Ownership of Certain Beneficial Owners and Management" and "Executive and Director Compensation—Securities Authorized for Issuance Under Equity Compensation Plans."

### Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated by reference to our 2022 Proxy Statement under the section headed "Transactions with Related Persons and Indemnification," "Information Regarding our Board of Directors and Corporate Governance—Independence of the Board of Directors," and "Information Regarding our Board of Directors and Corporate Governance—Information Regarding Committees of the Board of Directors."

### Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to our 2022 Proxy Statement under the section headed "Ratification of Selection of Independent Registered Public Accounting Firm—Principal Accountant Fees and Services."

## PART IV

**Item 15. Exhibit and Financial Statement Schedules.**

(a) List the following documents filed as a part of the report:

(1) Financial Statements. The financial statements are set forth under “Item 8. Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.

(2) Schedules. The financial statement schedules required by Item 15(a) are omitted because they are not applicable, not required or the required information is included in the financial statements or notes thereto as filed in Item 8 of this Annual Report on Form 10-K.

(3) Exhibits. An index of Exhibits can be found in the exhibit index on page 125 of this report.

| 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 | Description of Securities (incorporated by reference to Exhibit 4.4 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 30, 2021). |
| 4.5 | 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, filed with the SEC on March 30, 2021). |
| 10.1+ | Form of Indemnity Agreement, by and between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021). |
| 10.2+ | Talis Biomedical Corporation 2013 Equity Incentive Plan and Forms of Option Grant Notice, Option Agreement and Notice of Exercise thereunder, as amended (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021). |
| 10.3+ | Talis Biomedical Corporation 2021 Equity Incentive Plan and Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise thereunder (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (File No. 333-253218), filed with the SEC on February 17, 2021). |
| 10.4+ | Talis Biomedical Corporation 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8 (File No. 333-253218), filed with the SEC on February 17, 2021). |
| 10.5+ | Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the Talis Biomedical Corporation 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File no. 001-40047) filed with the SEC on November 15, 2021). |

| | |
|---|---|
| 10.6+ | Talis Biomedical Corporation 2021 Inducement Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K (File No. 001-40047), filed with the SEC on November 15, 2021). |
| 10.7+ | Talis Biomedical Corporation Amended and Restated Non-Employee Director Compensation Policy. |
| 10.8+ | Talis Biomedical Corporation Severance and Change in Control Plan and Amended Form of Participation Agreement thereunder. |
| 10.9+ | Separation and Consulting Agreement by and between the Registrant and Brian Coe, dated August 30, 2021 (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 November 15, 2021.) |
| 10.10+ | Offer Letter, dated April 3, 2020, by and between the Registrant and J. Roger Moody, Jr. (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021). |
| 10.11+ | Offer Letter, dated August 19, 2020, by and between the Registrant and Robert Kelley (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021). |
| 10.12+ | Offer Letter, dated December 8, 2021, by and between the Registrant and Robert J. Kelley (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-40047), filed with the SEC on December 9, 2021). |
| 10.13+ | Offer letter, dated November 1, 2021, by and between the Registrant and Brian Blaser (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-40047), filed with the SEC on November 15, 2021). |
| 10.14+ | Offer Letter, dated September 21, 2020, by and between the Registrant and Douglas Liu (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021). |
| 10.15 | Business Park Lease, dated December 14, 2015, by and between the Registrant and Facebook, Inc., as amended on April 4, 2018 (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021). |
| 10.16* | Supply Agreement, dated May 22, 2020, by and between the Registrant and thinXXS Microtechnology AG (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021). |
| 10.17 | Amended Supply Agreement, dated December 15, 2021, by and between the Registrant and thinXXS Microtechnology. |
| 10.18 | Lease, dated January 20, 2021, by and between the Registrant and Fulton Ogden Venture, LLC (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on February 8, 2021). |
| 10.19 | Lease Agreement, dated January 20, 2021, by and between the Registrant and Westport Office Park, LLC (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on February 8, 2021). |
| 10.20 | 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). |

| | |
|---|---|
| 23.1 | Consent of Independent Registered Public Accounting Firm. |
| 24.1 | Power of Attorney. Reference is made to the signature page hereto. |
| 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) |

| | |
|---|---|
| + | Indicates management contract or compensatory plan. |
| * | Certain portions of this exhibit (indicated by "[***]") have been omitted as the Registrant determined (i) the omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K. |
| ^ | Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. |

**Item 16. Form 10-K Summary**

Not applicable.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

TALIS BIOMEDICAL CORPORATION

Date: March 15, 2022

By: /s/ Robert J. Kelley
Robert J. Kelley
*Chief Executive Officer*

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Robert J. Kelley and J. Roger Moody, Jr., and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

| Name | Title | Date |
|---|---|---|
| /s/ Robert J. Kelley<br>**Robert J. Kelley** | Chief Executive Officer and Member of the Board of Directors<br>(*Principal Executive Officer)* | March 15, 2022 |
| /s/ J. Roger Moody, Jr.<br>**J. Roger Moody, Jr.** | Chief Financial Officer<br>(*Principal Financial and Accounting Officer*) | March 15, 2022 |
| /s/ Felix Baker, Ph.D.<br>**Felix Baker, Ph.D.** | Member of the Board of Directors | March 15, 2022 |
| /s/ Raymond Cheong, M.D., Ph.D.<br>**Raymond Cheong, M.D., Ph.D.** | Member of the Board of Directors | March 15, 2022 |
| /s/ Melissa Gilliam M.D., M.P.H.<br>**Melissa Gilliam M.D., M.P.H.** | Member of the Board of Directors | March 15, 2022 |
| /s/ Jeryl L. Hilleman<br>**Jeryl L. Hilleman** | Member of the Board of Directors | March 15, 2022 |
| /s/ Rustem F. Ismagilov, Ph.D.<br>**Rustem F. Ismagilov, Ph.D.** | Member of the Board of Directors | March 15, 2022 |
| /s/ Kimberly J. Popovits<br>**Kimberly J. Popovits** | Member of the Board of Directors | March 15, 2022 |
| /s/ Matthew L. Posard<br>**Matthew L. Posard** | Member of the Board of Directors | March 15, 2022 |
| /s/ Randal Scott, Ph.D.<br>**Randal Scott, Ph.D.** | Member of the Board of Directors | March 15, 2022 |

**TALIS BIOMEDICAL CORPORATION**

**NON-EMPLOYEE DIRECTOR COMPENSATION POLICY**
Effective Date: February 11, 2021
Amended and Restated: December 17, 2021

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of or consultant to Talis Biomedical Corporation (the "***Company***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy for his or her Board service. An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash may be paid or equity awards are to be granted, as the case may be. This policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

**Annual Cash Compensation**

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
    a. All Eligible Directors: $40,000
    b. Independent Chair of the Board Service Retainer (in addition to Eligible Director Service Retainer): $40,000
    c. Lead Independent Director Service Retainer (in addition to Eligible Director Service Retainer): $22,500

2. Annual Committee Chair Service Retainer:
    a. Chair of the Audit Committee: $20,000
    b. Chair of the Compensation Committee: $14,000
    c. Chair of the Nominating and Corporate Governance Committee: $10,000
    d. Chair of the Science, Technology and Clinical Affairs Committee: $10,000

3. Annual Committee Member Service Retainer (not applicable to Committee Chairs):
    a. Member of the Audit Committee: $10,000
    b. Member of the Compensation Committee: $7,000
    c. Member of the Nominating and Corporate Governance Committee: $5,000
    d. Member of the Science, Technology and Clinical Affairs Committee: $5,000

**Equity Compensation**

The equity compensation set forth below will be granted under the Company's 2021 Equity Incentive Plan (the "***Plan***"). All stock options granted under this policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock of the Company (the "***Common Stock***") on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan, provided that upon a termination of service other than by death or for cause, the post-termination exercise period will be 12 months from the date of termination).

1. Initial Grant: For each Eligible Director who is first elected or appointed to the Board, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or the Compensation Committee of the Board, granted a stock option to purchase shares of Common Stock with an aggregate Black-Scholes option value of $340,000 (the "***Initial Grant***"). The shares subject to each Initial Grant will vest in equal monthly installments over a three year period such that the option is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through each such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

2. Annual Grant: On the date of each annual stockholder meeting of the Company, each Eligible Director who continues to serve as a non-employee member of the Board following such stockholder meeting (excluding any Eligible Director who is first appointed or elected to the Board at such meeting) will be automatically, and without further action by the Board or the Compensation Committee of the Board, granted a stock option to purchase shares of Common Stock with an aggregate Black-Scholes option value of $170,000 (the "***Annual Grant***"). The shares subject to the Annual Grant will vest in equal monthly installments over the 12 months following the date of grant, provided that the Annual Grant will in any case be fully vested on the date of the Company's next annual stockholder meeting, subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date and will vest in full upon a Change in Control (as defined in the Plan). With respect to an Eligible Director who is first elected or appointed to the Board on a date other than the date of the Company's annual stockholder meeting, upon the Company's first annual stockholder meeting following such Eligible Director's first joining the Board, such Eligible Director's first Annual Grant will be pro-rated to reflect the time between such Eligible Director's election or appointment date and the date of such first annual stockholder meeting.

**Non-Employee Director Compensation Limit**

Notwithstanding the foregoing, the aggregate value of all compensation granted or paid, as applicable, to any individual for service as a Non-Employee Director (as defined in the Plan) shall in no event exceed the limits set forth in Section 3(d) of the Plan.

**Exhibit 10.8**

**TALIS BIOMEDICAL CORPORATION**
**SEVERANCE AND CHANGE IN CONTROL PLAN**

**a. INTRODUCTION.**

The Talis Biomedical Corporation Severance and Change in Control Plan (the "***Plan***") is hereby established by the Board of Directors of Talis Biomedical Corporation (the "***Company***") effective upon the IPO Date (as defined below). The purpose of the Plan is to provide for the payment of severance and/or Change in Control (as defined below) benefits to eligible employees of the Company. This Plan document also is the Summary Plan Description for the Plan.

For purposes of the Plan, the following terms are defined as follows:

**i.** "***Affiliate***" means any corporation (other than the Company) in an "unbroken chain of corporations" beginning with the Company, if each of the corporations other than the last corporation in the unbroken chain owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

**ii.** "***Base Salary***" means base pay (excluding incentive pay, premium pay, commissions, overtime, bonuses and other forms of variable compensation) as in effect prior to any reduction that would give rise to an employee's right to a resignation for Good Reason (if applicable).

**iii.** "***Cause***" means, with respect to a particular employee, the meaning ascribed to such term in any written employment agreement, offer letter or similar agreement between such employee and the Company defining such term, and, in the absence of such agreement, means with respect to such employee, the term "Cause" as defined in the Equity Plan. The determination whether a termination is for Cause shall be made by the Plan Administrator in its sole and exclusive judgment and discretion.

**iv.** "***Change in Control***" has the meaning ascribed to such term in the Equity Plan.

**v.** "***Change in Control Period***" means the period commencing three months prior to the Closing of a Change in Control and ending 12 months following the Closing of a Change in Control.

**vi.** "***Closing***" means the initial closing of the Change in Control as defined in the definitive agreement executed in connection with the Change in Control. In the case of a series of transactions constituting a Change in Control, "Closing" means the first closing that satisfies the threshold of the definition for a Change in Control.

**vii.** "***Code***" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

**viii.** "***Committee***" means the Board of Directors or the Compensation Committee of the Board of Directors of the Company.

**ix.** "***Company***" means Talis Biomedical Corporation or, following a Change in Control, the surviving entity resulting from such event.

**x.** "***Confidentiality Agreement***" means the Company's standard form of Proprietary Information and Invention Assignment Agreement or any similar or successor document.

**xi.** "***Covered Termination***" means, with respect to an employee, a termination of employment that is due to (1) a termination by the Company without Cause (and other than as a result of the employee's death or Disability) or (2) the employee's resignation for Good Reason, and in either case of (1) or (2), results in such employee's Separation from Service.

**xii.** "***Disability***" means any physical or mental condition which renders an employee incapable of performing the work for which he or she was employed by the Company or similar work offered by the Company. The Disability of an employee shall be established if (i) the employee satisfies the requirements for benefits under the Company's long-term disability plan or (ii) if no long-term disability plan, the employee satisfies the requirements for Social Security disability benefits.

**xiii.** "***Eligible Employee***" means an employee of the Company that meets the requirements to be eligible to receive Plan benefits as set forth in Section 2.

**xiv.** "***Equity Plan***" means the Talis Biomedical Corporation 2021 Equity Incentive Plan, as amended from time to time, or any successor plan thereto.

**xv.** "***Good Reason***" for an employee's resignation means the occurrence of any of the following are undertaken by the Company without the employee's written consent:

**1.** a material reduction in a such employee's base salary (unless pursuant to a salary reduction program affecting substantially all of the similarly situated employees of the Company and that does not adversely affect the employee to a greater extent than other similarly situated employees);

**2.** a material diminution of the employee's authority, duties or responsibilities;

**3.** a relocation of such employee's principal place of employment with the Company (or successor to the Company, if applicable) to a place that increases such employee's one-way commute by more than 50 miles as compared to such employee's then-current principal place of employment immediately prior to such relocation (excluding regular travel in the ordinary course of business); provided that (i) if such employee's principal place of employment is his or her personal residence, this clause (3) shall not apply and (ii) if the employee works remotely during any period in which such employee's regular principal office location is a Company office that is closed, then neither the employee's relocation to remote work or back to the office from remote work will be considered a relocation of such employee's principal office location for purposes of this definition; or

**4.** a material breach by the Company of any provision of this Plan or any other material agreement between such employee and the Company concerning the terms and conditions of such employee's employment with the Company.

Notwithstanding the foregoing, in order for the employee's resignation to be deemed to have been for Good Reason, the employee must (a) provide written notice to the Company of such employee's intent to resign for Good Reason within 30 days after the first occurrence of the event giving rise to Good Reason, which notice shall describe the event(s) the employee believes give rise to Good Reason; (b) allow the Company at least 30 days from receipt of the written notice to cure the event (such period, the "***Cure Period***"), and (c) if the event is not reasonably cured within the Cure Period, the employee's resignation from all positions held with the Company is effective not later than 30 days after the expiration of the Cure Period.

**xvi.** "***IPO Date***" means the date of the underwriting agreement between the Company and the underwriter(s) managing the initial public offering of the Company's Common Stock, pursuant to which the Common Stock is priced for the initial public offering.

**xvii.** "***Participation Agreement***" means an agreement between an employee and the Company in substantially the form of **Appendix A** attached hereto, and which may include such other terms as the Committee deems necessary or advisable in the administration of the Plan.

**xviii.** "***Plan Administrator***" means the Committee prior to the Closing and the Representative upon and following the Closing, as applicable.

**xix.** "***Representative***" means one or more members of the Committee or other persons or entities designated by the Committee prior to or in connection with a Change in Control that will have authority to administer and interpret the Plan upon and following the Closing as provided in Section 9(a).

**xx.** "***Section 409A***" means Section 409A of the Code and the treasury regulations and other guidance thereunder and any state law of similar effect.

**xxi.** "***Separation from Service***" means a "separation from service" within the meaning of Treasury Regulations Section 1.409A-1(h), without regard to any alternative definition thereunder.

**b.Eligibility for Benefits.**

**i.** **Eligible Employee**. An employee of the Company is eligible to participate in the Plan if (i) the Plan Administrator has designated such employee as eligible to participate in the Plan by providing such employee a Participation Agreement; (ii) such employee has signed and returned such Participation Agreement to the Company within the time period required therein; and (iii) such employee meets the other Plan eligibility requirements set forth in this Section 2. The determination of whether an employee is an Eligible Employee shall be made by the Plan Administrator, in its sole discretion, and such determination shall be binding and conclusive on all persons.

**ii. Release Requirement.** Except as otherwise provided in an individual Participation Agreement, in order to be eligible to receive benefits under the Plan, the employee also must execute a general waiver and release, in such a form as provided by the Company (the "***Release***"), within the applicable time period set forth therein, and such Release must become effective in accordance with its terms, which must occur in no event more than 60 days following the date of the applicable Covered Termination.

**iii. Plan Benefits Provided In Lieu of Any Previous Benefits.** Except as otherwise provided in an individual Participation Agreement, this Plan shall supersede any change in control or severance benefit plan, policy or practice previously maintained by the Company with respect to an Eligible Employee and any change in control or severance benefits in any individually negotiated employment contract or other agreement between the Company and an Eligible Employee. Notwithstanding the foregoing, the Eligible Employee's outstanding equity awards shall remain subject to the terms of the Equity Plan or other applicable equity plan under which such awards were granted (including the award documentation governing such awards) that may apply upon a Change in Control and/or termination of such employee's service and no provision of this Plan shall be construed as to limit the actions that may be taken, or to violate the terms, thereunder.

**iv. Exceptions to Severance Benefit Entitlement.** An employee who otherwise is an Eligible Employee will not receive benefits under the Plan in the following circumstances, as determined by the Plan Administrator in its sole discretion:

**1.** The employee is terminated by the Company for any reason (including due to the employee's death or Disability) or voluntarily terminates employment with the Company in any manner, and in either case, such termination does not constitute a Covered Termination. Voluntary terminations include, but are not limited to, resignation, retirement or failure to return from a leave of absence on the scheduled date.

**2.** The employee voluntarily terminates employment with the Company in order to accept employment with another entity that is wholly or partly owned (directly or indirectly) by the Company or an Affiliate.

**3.** The employee is offered an identical or substantially equivalent or comparable position with the Company or an Affiliate. For purposes of the foregoing, a "substantially equivalent or comparable position" is one that provides the employee substantially the same level of responsibility and compensation and would not give rise to the employee's right to a resignation for Good Reason.

**4.** The employee is offered immediate reemployment by a successor to the Company or an Affiliate or by a purchaser of the Company's assets, as the case may be, following a Change in Control and the terms of such reemployment would not give rise to the employee's right to a resignation for Good Reason. For purposes of the foregoing, "immediate reemployment" means that the employee's employment with the successor to the Company or an Affiliate or the purchaser of its assets, as the case may be, results in uninterrupted employment such that the employee does not incur a lapse in pay or benefits as a result of the change in ownership of the Company or the sale of its assets. For the avoidance of doubt, an employee who

becomes immediately reemployed as described in this Section 2(d)(4) by a successor to the Company or an Affiliate or by a purchaser of the Company's assets, as the case may be, following a Change in Control shall continue to be an Eligible Employee following the date of such reemployment.

**5.** The employee is rehired by the Company or an Affiliate and recommences employment prior to the date severance benefits under the Plan are scheduled to commence.

**v. Termination of Severance Benefits**. An Eligible Employee's right to receive severance benefits under this Plan shall terminate immediately if, at any time prior to or during the period for which the Eligible Employee is receiving severance benefits under the Plan, the Eligible Employee

**5.** willfully breaches any material statutory, common law, or contractual obligation to the Company or an Affiliate (including, without limitation, the contractual obligations set forth in the Confidentiality Agreement and any other confidentiality, non-disclosure and developments agreement, non-competition, non-solicitation, or similar type agreement between the Eligible Employee and the Company, as applicable);

**6.** fails to enter into the terms of the Confidentiality Agreement; or

**7.** without the prior written approval of the Plan Administrator, engages in a Prohibited Action (as defined below). In addition, if benefits under the Plan have already been paid to the Eligible Employee and the Eligible Employee subsequently engages in a Prohibited Action during the Prohibited Period (or it is determined that the Eligible Employee engaged in a Prohibited Action prior to receipt of such benefits), any benefits previously paid to the Eligible Employee shall be subject to recoupment by the Company on such terms and conditions as shall be determined by the Plan Administrator, in its sole discretion. The "***Prohibited Period***" shall commence on the date of the Eligible Employee's Covered Termination and continue for the number of months corresponding to the Severance Period set forth in such Eligible Employee's Participation Agreement. A "***Prohibited Action***" shall occur if the Eligible Employee: (i) breaches a material provision of the Confidentiality Agreement and/or any obligations of confidentiality, non-solicitation, non-disparagement, no conflicts or non-competition set forth in the Eligible Employee's employment agreement, offer letter, any other written agreement between the Eligible Employee and the Company, or under applicable law; (ii) encourages or solicits any of the Company's then current employees to leave the Company's employ for any reason or interferes in any other manner with employment relationships at the time existing between the Company and its then current employees; or (iii) induces any of the Company's then current clients, customers, suppliers, vendors, distributors, licensors, licensees, or other third parties to terminate their existing business relationship with the Company or interferes in any other manner with any existing business relationship between the Company and any then current client, customer, supplier, vendor, distributor, licensor, licensee, or other third parties.

**c.AMOUNT OF BENEFITS.**

**i. Benefits in Participation Agreement.** Benefits under the Plan shall be provided to an Eligible Employee as set forth in the Participation Agreement.

**ii. Additional Benefits.** Notwithstanding the foregoing, the Committee may, in its sole discretion, provide benefits to individuals who are not Eligible Employees ("***Non-Eligible Employees***") chosen by the Plan Administrator, in its sole discretion, and the provision of any such benefits to a Non-Eligible Employee shall in no way obligate the Company to provide such benefits to any other individual, even if similarly situated. If benefits under the Plan are provided to a Non-Eligible Employee, references in the Plan to "Eligible Employee" (and similar references) shall be deemed to refer to such Non-Eligible Employee.

**iii. Certain Reductions.** In addition to Section 2(e) above, the Company, in its sole discretion, shall have the authority to reduce an Eligible Employee's severance benefits, in whole or in part, by any other severance benefits, pay and benefits provided during a period following written notice of a business closing or mass layoff, pay and benefits in lieu of such notice, or other similar benefits payable to the Eligible Employee by the Company or an Affiliate that become payable in connection with the Eligible Employee's termination of employment pursuant to (i) any applicable legal requirement, including, without limitation, the Worker Adjustment and Retraining Notification Act or any other similar state law or (ii) any Company policy or practice providing for the Eligible Employee to remain on the payroll for a limited period of time after being given notice of the termination of the Eligible Employee's employment, and the Plan Administrator shall so construe and implement the terms of the Plan. Any such reductions that the Company determines to make pursuant to this Section 3(c) shall be made such that any severance benefit under the Plan shall be reduced solely by any similar type of benefit under such legal requirement, agreement, policy or practice (*i.e.*, any cash severance benefits under the Plan shall be reduced solely by any cash payments or severance benefits under such legal requirement, agreement, policy or practice). The Company's decision to apply such reductions to the severance benefits of one Eligible Employee and the amount of such reductions shall in no way obligate the Company to apply the same reductions in the same amounts to the severance benefits of any other Eligible Employee. In the Company's sole discretion, such reductions may be applied on a retroactive basis, with severance benefits previously paid being re-characterized as payments pursuant to the Company's statutory obligation.

**iv. Parachute Payments.** Except as otherwise provided in an individual Participation Agreement, if any payment or benefit an Eligible Employee will or may receive from the Company or otherwise (a "***Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then any such Payment shall be equal to the Reduced Amount. The "***Reduced Amount***" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Eligible Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject

to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "***Reduction Method***") that results in the greatest economic benefit for the Eligible Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "***Pro Rata Reduction Method***").

Notwithstanding any provisions in this Section above to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for the Eligible Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (*e.g.*, being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

The Company shall appoint a nationally recognized accounting or law firm to make the determinations required by this Section. The Company shall bear all expenses with respect to the determinations by such accounting or law firm required to be made hereunder. If the Eligible Employee receives a Payment for which the Reduced Amount was determined pursuant to clause (x) above and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Eligible Employee agrees to promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) above) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) above, the Eligible Employee shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

**d.Return of Company Property.**

An Eligible Employee will not be entitled to any severance benefit under the Plan unless and until the Eligible Employee returns all Company Property. For this purpose, "***Company Property***" means all paper and electronic Company documents (and all copies thereof) and other Company property which the Eligible Employee had in his or her possession or control at any time, including, but not limited to, Company files, notes, drawings, records, plans, forecasts, reports, studies, analyses, proposals, agreements, financial information, research and development information, sales and marketing information, operational and personnel information, specifications, code, software, databases, computer-recorded information, tangible property and equipment (including, but not limited to, computers, facsimile machines, mobile telephones, servers), credit cards, entry cards, identification badges and keys; and any materials of any kind which contain or embody any proprietary or confidential information of the Company (and all reproductions thereof in whole or in part). As a condition to receiving benefits under the Plan, an Eligible Employee must not make or retain copies, reproductions or summaries of any such Company documents, materials or property. However, an Eligible Employee is not required to return his or her personal copies of documents evidencing the Eligible Employee's hire,

termination, compensation, benefits and stock options and any other documentation received as a stockholder of the Company.

**e.Time of Payment and Form of Benefits.**

The Company reserves the right in the Participation Agreement to specify whether payments under the Plan will be paid in a single sum, in installments, or in any other form and to determine the timing of such payments. All such payments under the Plan will be subject to applicable withholding for federal, state, foreign, provincial and local taxes. All benefits provided under the Plan are intended to satisfy the requirements for an exemption from application of Section 409A to the maximum extent that an exemption is available and any ambiguities herein shall be interpreted accordingly; *provided, however*, that to the extent such an exemption is not available, the benefits provided under the Plan are intended to comply with the requirements of Section 409A to the extent necessary to avoid adverse personal tax consequences and any ambiguities herein shall be interpreted accordingly.

It is intended that (i) each installment of any benefits payable under the Plan to an Eligible Employee be regarded as a separate "payment" for purposes of Treasury Regulations Section 1.409A-2(b)(2)(i), (ii) all payments of any such benefits under the Plan satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9)(iii), and (iii) any such benefits consisting of COBRA premiums also satisfy, to the greatest extent possible, the exemption from the application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(9)(v). However, if the Company determines that any severance benefits payable under the Plan constitute "deferred compensation" under Section 409A and the Eligible Employee is a "specified employee" of the Company, as such term is defined in Section 409A(a)(2)(B)(i), then, solely to the extent necessary to avoid the imposition of the adverse personal tax consequences under Section 409A, (A) the timing of such severance benefit payments shall be delayed until the earlier of (1) the date that is six months and one day after the Eligible Employee's Separation from Service and (2) the date of the Eligible Employee's death (such applicable date, the "***Delayed Initial Payment Date***"), and (B) the Company shall (1) pay the Eligible Employee a lump sum amount equal to the sum of the severance benefit payments that the Eligible Employee would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the severance benefits had not been delayed pursuant to this paragraph and (2) commence paying the balance, if any, of the severance benefits in accordance with the applicable payment schedule.

In no event shall payment of any severance benefits under the Plan be made prior to an Eligible Employee's Separation from Service or prior to the effective date of the Release. If the Company determines that any severance payments or benefits provided under the Plan constitute "deferred compensation" under Section 409A, and the Eligible Employee's Separation from Service occurs at a time during the calendar year when the Release could become effective in the calendar year following the calendar year in which the Eligible Employee's Separation from Service occurs, then regardless of when the Release is returned to the Company and becomes effective, the Release will not be deemed effective, solely for purposes of the timing of payment of severance benefits under this Plan, any earlier than the latest permitted effective date (the "***Release Deadline***"). If the Company determines that any severance payments or benefits

provided under the Plan constitute "deferred compensation" under Section 409A, then except to the extent that severance payments may be delayed until the Delayed Initial Payment Date pursuant to the preceding paragraph, on the first regular payroll date following the effective date of an Eligible Employee's Release, the Company shall (1) pay the Eligible Employee a lump sum amount equal to the sum of the severance benefit payments that the Eligible Employee would otherwise have received through such payroll date but for the delay in payment related to the effectiveness of the Release and (2) commence paying the balance, if any, of the severance benefits in accordance with the applicable payment schedule.

**f. Transfer and Assignment.**

The rights and obligations of an Eligible Employee under this Plan may not be transferred or assigned without the prior written consent of the Company. This Plan shall be binding upon any entity or person who is a successor by merger, acquisition, consolidation or otherwise to the business formerly carried on by the Company without regard to whether or not such entity or person actively assumes the obligations hereunder and without regard to whether or not a Change in Control occurs.

**g. Mitigation.**

Except as otherwise specifically provided in the Plan, an Eligible Employee will not be required to mitigate damages or the amount of any payment provided under the Plan by seeking other employment or otherwise, nor will the amount of any payment provided for under the Plan be reduced by any compensation earned by an Eligible Employee as a result of employment by another employer or any retirement benefits received by such Eligible Employee after the date of the Eligible Employee's termination of employment with the Company.

**h. Clawback; Recovery.**

All payments and severance benefits provided under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Plan Administrator may impose such other clawback, recovery or recoupment provisions as the Plan Administrator determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of common stock of the Company or other cash or property upon the occurrence of a termination of employment for Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for Good Reason, constructive termination, or any similar term under any plan of or agreement with the Company.

**i. Right to Interpret and Administer Plan; Amendment and Termination.**

i. **Interpretation and Administration.** Prior to the Closing, the Committee shall be the Plan Administrator and shall have the exclusive discretion and authority to establish rules, forms, and procedures for the administration of the Plan and to construe and interpret the Plan and to decide any and all questions of fact, interpretation, definition, computation or administration

arising in connection with the operation of the Plan, including, but not limited to, the eligibility to participate in the Plan and amount of benefits paid under the Plan. The rules, interpretations, computations and other actions of the Committee shall be binding and conclusive on all persons. Upon and after the Closing, the Plan will be interpreted and administered in good faith by the Representative who shall be the Plan Administrator during such period. All actions taken by the Representative in interpreting the terms of the Plan and administering the Plan upon and after the Closing will be final and binding on all Eligible Employees. Any references in this Plan to the "Committee" or "Plan Administrator" with respect to periods following the Closing shall mean the Representative.

**ii. Amendment.** The Plan Administrator reserves the right to amend this Plan at any time; *provided, however,* that any amendment of the Plan will not be effective as to a particular employee who is or may be adversely impacted by such amendment or termination and has an effective Participation Agreement without the written consent of such employee.

**iii. Termination.** Unless otherwise extended by the Committee, the Plan will automatically terminate upon the earlier of (i) the third anniversary of the IPO Date and (ii) the satisfaction of all the Company's obligations under the Plan.

**j.No Implied Employment Contract.**

The Plan shall not be deemed (i) to give any employee or other person any right to be retained in the employ of the Company or (ii) to interfere with the right of the Company to discharge any employee or other person at any time, with or without cause, which right is hereby reserved. This Plan does not modify the at-will employment status of any Eligible Employee.

**k.Legal Construction.**

This Plan is intended to be governed by and shall be construed in accordance with the Employee Retirement Income Security Act of 1974 ("***ERISA***") and, to the extent not preempted by ERISA, the laws of the State of California.

**l.Claims, Inquiries and Appeals.**

**i. Applications for Benefits and Inquiries.** Any application for benefits, inquiries about the Plan or inquiries about present or future rights under the Plan must be submitted to the Plan Administrator in writing by an applicant (or his or her authorized representative). The Plan Administrator is:

Talis Biomedical Corporation
Compensation Committee of the Board of Directors or Representative
Attention to: Corporate Secretary
230 Constitution Drive
Menlo Park, California 94025

**ii. Denial of Claims.** In the event that any application for benefits is denied in whole or in part, the Plan Administrator must provide the applicant with written or electronic notice of the denial of the application, and of the applicant's right to review the denial. Any electronic

notice will comply with the regulations of the U.S. Department of Labor. The notice of denial will be set forth in a manner designed to be understood by the applicant and will include the following:

**1.** the specific reason or reasons for the denial;

**2.** references to the specific Plan provisions upon which the denial is based;

**3.** a description of any additional information or material that the Plan Administrator needs to complete the review and an explanation of why such information or material is necessary; and

**4.** an explanation of the Plan's review procedures and the time limits applicable to such procedures, including a statement of the applicant's right to bring a civil action under Section 502(a) of ERISA following a denial on review of the claim, as described in Section 12(d) below.

This notice of denial will be given to the applicant within 90 days after the Plan Administrator receives the application, unless special circumstances require an extension of time, in which case, the Plan Administrator has up to an additional 90 days for processing the application. If an extension of time for processing is required, written notice of the extension will be furnished to the applicant before the end of the initial 90 day period.

This notice of extension will describe the special circumstances necessitating the additional time and the date by which the Plan Administrator is to render its decision on the application.

**iii. Request for a Review.** Any person (or that person's authorized representative) for whom an application for benefits is denied, in whole or in part, may appeal the denial by submitting a request for a review to the Plan Administrator within 60 days after the application is denied. A request for a review shall be in writing and shall be addressed to:

Talis Biomedical Corporation
Compensation Committee of the Board of Directors or Representative
Attention to: Corporate Secretary
230 Constitution Drive
Menlo Park, California 94025

A request for review must set forth all of the grounds on which it is based, all facts in support of the request and any other matters that the applicant feels are pertinent. The applicant (or his or her representative) shall have the opportunity to submit (or the Plan Administrator may require the applicant to submit) written comments, documents, records, and other information relating to his or her claim. The applicant (or his or her representative) shall be provided, upon request and free of charge, reasonable access to, and copies of, all documents, records and other information relevant to his or her claim. The review shall take into account all comments, documents, records and other information submitted by the applicant (or his or her representative) relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination.

**iv.** **Decision on Review.** The Plan Administrator will act on each request for review within 60 days after receipt of the request, unless special circumstances require an extension of time (not to exceed an additional 60 days), for processing the request for a review. If an extension for review is required, written notice of the extension will be furnished to the applicant within the initial 60 day period. This notice of extension will describe the special circumstances necessitating the additional time and the date by which the Plan Administrator is to render its decision on the review. The Plan Administrator will give prompt, written or electronic notice of its decision to the applicant. Any electronic notice will comply with the regulations of the U.S. Department of Labor. In the event that the Plan Administrator confirms the denial of the application for benefits in whole or in part, the notice will set forth, in a manner calculated to be understood by the applicant, the following:

**1.** the specific reason or reasons for the denial;

**2.** references to the specific Plan provisions upon which the denial is based;

**3.** a statement that the applicant is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records and other information relevant to his or her claim; and

**4.** a statement of the applicant's right to bring a civil action under Section 502(a) of ERISA.

**v.** **Rules and Procedures.** The Plan Administrator will establish rules and procedures, consistent with the Plan and with ERISA, as necessary and appropriate in carrying out its responsibilities in reviewing benefit claims. The Plan Administrator may require an applicant who wishes to submit additional information in connection with an appeal from the denial of benefits to do so at the applicant's own expense.

**vi.** **Exhaustion of Remedies.** No legal action for benefits under the Plan may be brought until the applicant (i) has submitted a written application for benefits in accordance with the procedures described by Section 12(a) above, (ii) has been notified by the Plan Administrator that the application is denied, (iii) has filed a written request for a review of the application in accordance with the appeal procedure described in Section 12(c) above, and (iv) has been notified that the Plan Administrator has denied the appeal. Notwithstanding the foregoing, if the Plan Administrator does not respond to an Eligible Employee's claim or appeal within the relevant time limits specified in this Section 12, the Eligible Employee may bring legal action for benefits under the Plan pursuant to Section 502(a) of ERISA.

**m. Basis of Payments to and from Plan.**

The Plan shall be unfunded, and all cash payments under the Plan shall be paid only from the general assets of the Company.

**n. Other Plan Information.**

**i.** **Employer and Plan Identification Numbers.** The Employer Identification Number assigned to the Company (which is the "Plan Sponsor" as that term is used in ERISA) by

the Internal Revenue Service is 46-3122255. The Plan Number assigned to the Plan by the Plan Sponsor pursuant to the instructions of the Internal Revenue Service is 510.

**ii. Ending Date for Plan's Fiscal Year.** The date of the end of the fiscal year for the purpose of maintaining the Plan's records is December 31.

**iii. Agent for the Service of Legal Process.** The agent for the service of legal process with respect to the Plan is:

Talis Biomedical Corporation
Attention to: Corporate Secretary
230 Constitution Drive
Menlo Park, California 94025

In addition, service of legal process may be made upon the Plan Administrator.

**iv. Plan Sponsor.** The "Plan Sponsor" is:

Talis Biomedical Corporation
230 Constitution Drive
Menlo Park, California 94025
(650) 433-3000

**v. Plan Administrator.** The Plan Administrator is the Committee prior to the Closing and the Representative upon and following the Closing. The Plan Administrator's contact information is:

Talis Biomedical Corporation
Compensation Committee of the Board of Directors or Representative
230 Constitution Drive
Menlo Park, California 94025

The Plan Administrator is the named fiduciary charged with the responsibility for administering the Plan.

**o. Statement of ERISA Rights.**

Participants in this Plan (which is a welfare benefit plan sponsored by Talis Biomedical Corporation) are entitled to certain rights and protections under ERISA. If you are an Eligible Employee, you are considered a participant in the Plan and, under ERISA, you are entitled to:

**i. Receive Information About Your Plan and Benefits**

**1.** Examine, without charge, at the Plan Administrator's office and at other specified locations, such as worksites, all documents governing the Plan and a copy of the latest annual report (Form 5500 Series), if applicable, filed by the Plan with the U.S. Department of

Labor and available at the Public Disclosure Room of the Employee Benefits Security Administration;

**2.** Obtain, upon written request to the Plan Administrator, copies of documents governing the operation of the Plan and copies of the latest annual report (Form 5500 Series), if applicable, and an updated (as necessary) Summary Plan Description. The Administrator may make a reasonable charge for the copies; and

**3.** Receive a summary of the Plan's annual financial report, if applicable. The Plan Administrator is required by law to furnish each Eligible Employee with a copy of this summary annual report.

**ii. Prudent Actions by Plan Fiduciaries.** In addition to creating rights for Plan Eligible Employees, ERISA imposes duties upon the people who are responsible for the operation of the employee benefit plan. The people who operate the Plan, called "fiduciaries" of the Plan, have a duty to do so prudently and in the interest of you and other Eligible Employees and beneficiaries. No one, including your employer, your union or any other person, may fire you or otherwise discriminate against you in any way to prevent you from obtaining a Plan benefit or exercising your rights under ERISA.

**iii. Enforce Your Rights.** If your claim for a Plan benefit is denied or ignored, in whole or in part, you have a right to know why this was done, to obtain copies of documents relating to the decision without charge, and to appeal any denial, all within certain time schedules.

Under ERISA, there are steps you can take to enforce the above rights. For instance, if you request a copy of Plan documents or the latest annual report from the Plan, if applicable, and do not receive them within 30 days, you may file suit in a Federal court. In such a case, the court may require the Plan Administrator to provide the materials and pay you up to $110 a day until you receive the materials, unless the materials were not sent because of reasons beyond the control of the Plan Administrator.

If you have a claim for benefits which is denied or ignored, in whole or in part, you may file suit in a state or Federal court.

If you are discriminated against for asserting your rights, you may seek assistance from the U.S. Department of Labor, or you may file suit in a Federal court. The court will decide who should pay court costs and legal fees. If you are successful, the court may order the person you have sued to pay these costs and fees. If you lose, the court may order you to pay these costs and fees, for example, if it finds your claim is frivolous.

**iv. Assistance with Your Questions.** If you have any questions about the Plan, you should contact the Plan Administrator. If you have any questions about this statement or about your rights under ERISA, or if you need assistance in obtaining documents from the Plan Administrator, you should contact the nearest office of the Employee Benefits Security Administration, U.S. Department of Labor, listed in your telephone directory or the Division of Technical Assistance and Inquiries, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210. You may also obtain certain

publications about your rights and responsibilities under ERISA by calling the publications hotline of the Employee Benefits Security Administration.

## Appendix A

## Participation Agreement

**Name: _____**

**a.Eligibility.**

You have been designated as eligible to participate in the Talis Biomedical Corporation Severance and Change in Control Plan (the "***Plan***"), a copy of which is attached to this Participation Agreement (the "***Participation Agreement***"). Capitalized terms not explicitly defined in this Participation Agreement but defined in the Plan shall have the same definitions as in the Plan. You will receive the benefits set forth below if you meet all the eligibility requirements set forth in the Plan, including, without limitation, executing the required Release within the applicable time period set forth therein and allowing such Release to become effective in accordance with its terms. Notwithstanding the schedule for provision of benefits as set forth below, the schedule and timing of payment of any benefits under this Participant Agreement is subject to any delay in payment that may be required under Section 5 of the Plan.

**p.Change in Control Severance Benefits.**

If you are terminated in a Covered Termination that occurs during the Change in Control Period, you will receive the severance benefits set forth in this Section 2. All severance benefits described herein are subject to standard deductions and withholdings.

**i.** **Base Salary.** You shall receive a cash payment in an amount equal to [_____] months (the "***Severance Period***") of payment of your Base Salary. The Base Salary payment will be paid to you in a lump sum cash payment no later than the second regular payroll date following the later of (i) the effective date of the Release or (ii) the Closing, but in any event not later than March 15 of the year following the year in which your Separation from Service occurs.

**ii.** **Bonus Payment**. You will be entitled to [__] of the annual target cash bonus established for you, if any, pursuant to the annual performance bonus or annual variable compensation plan established by the Board of Directors or Committee (or any authorized committee or designee thereof) for the year in which your Covered Termination occurs. If at the time of the Covered Termination you are eligible for the annual target cash bonus for the year in which the Covered Termination occurs, but the target percentage (or target dollar amount, if specified as such in the applicable bonus plan) for such bonus has not yet been established for such year, the target percentage shall be the target percentage established for you for the preceding year (but adjusted, if necessary for your position for the year in which the Covered Termination occurs). For the avoidance of doubt, the amount of the annual target bonus to which you are entitled under this Section 2(b) will be calculated (1) assuming all articulated performance goals for such bonus (including, but not limited to, corporate and individual performance, if applicable), for the year of the Covered Termination was achieved at target levels; (2) as if you had provided services for the entire year for which the bonus relates; and (3) ignoring any reduction in your Base Salary that would give rise to your right to resignation for Good Reason (such bonus to which you are entitled under this Section 2(b), the "***Annual Target Bonus Severance Payment***"). The Annual Target Bonus Severance Payment shall be paid in a lump sum cash payment no later than the second

regular payroll date following the later of (i) the effective date of the Release or (ii) the Closing, but in any event not later than March 15 of the year following the year in which your Separation from Service occurs.

**iii. Payment of Continued Group Health Plan Benefits**. If you timely elect continued group health plan continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("***COBRA***") following your Covered Termination date, the Company shall pay directly to the carrier the full amount of your COBRA premiums on behalf of you for your continued coverage under the Company's group health plans, including coverage for your eligible dependents, until the earliest of (i) the end of the Severance Period following the date of your Covered Termination, (ii) the expiration of your eligibility for the continuation coverage under COBRA, or (iii) the date when you become eligible for substantially equivalent health insurance coverage in connection with new employment (such period from your termination date through the earliest of (i) through (iii), the "***COBRA Payment Period***"). Upon the conclusion of such period of insurance premium payments made by the Company, you will be responsible for the entire payment of premiums (or payment for the cost of coverage) required under COBRA for the duration of your eligible COBRA coverage period, if any. For purposes of this Section, (1) references to COBRA shall be deemed to refer also to analogous provisions of state law and (2) any applicable insurance premiums that are paid by the Company shall not include any amounts payable by you under an Internal Revenue Code Section 125 health care reimbursement plan, which amounts, if any, are your sole responsibility. You agree to promptly notify the Company as soon as you become eligible for health insurance coverage in connection with new employment or self-employment.

Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that it cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of paying COBRA premiums directly to the carrier on your behalf, the Company will instead pay you on the last day of each remaining month of the COBRA Payment Period a fully taxable cash payment equal to the value of your monthly COBRA premium for the first month of COBRA coverage, subject to applicable tax withholding (such amount, the "***Special Severance Payment***"), such Special Severance Payment to be made without regard to your election of COBRA coverage or payment of COBRA premiums and without regard to your continued eligibility for COBRA coverage during the COBRA Payment Period. Such Special Severance Payment shall end upon expiration of the COBRA Payment Period.

**iv. Equity Acceleration**. The vesting and exercisability of each outstanding unvested stock option and other stock award, as applicable, that you hold covering Company common stock as of the date of your Covered Termination (each, an "***Equity Award***") that is subject to time-vesting shall be accelerated in full and any reacquisition or repurchase rights held by the Company in respect of Company common stock issued pursuant to any time-vesting Equity Award granted to you shall lapse in full. To the extent your Covered Termination occurs prior to the Change in Control, the acceleration set forth in this Section 2(d) shall be contingent and effective upon the Change in Control and your Equity Awards will remain outstanding following your Covered Termination to give effect to such acceleration as necessary. For the avoidance of doubt, any Equity Awards subject to performance-vesting shall vest and become exercisable according to their individual award agreements.

**q.Non-Change in Control Severance Benefits**. If you are terminated in a Covered Termination that occurs at a time that is not during the Change in Control Period, you will receive:

**i.** the base salary cash payment described in Section 2(a) above, but the Severance Period for purposes of calculating such benefits shall be [_____] months; [and]

**ii.** [the Annual Target Bonus Severance Payment described in Section 2(b) above; and]

**iii.** the COBRA benefits described in Section 2(c) above, but the Severance Period for purposes of calculating such benefits shall be [_____] months.

You shall not be eligible to receive any other benefits under the Plan except as described in Section 2(a)[, Section 2(b)] and Section 2(c) above.

For the avoidance of doubt, in no event shall you be entitled to benefits under both Section 2 and this Section 3. If you are eligible for severance benefits under both Section 2 and this Section 3, you shall receive the benefits set forth in Section 2 and such benefits shall be reduced by any benefits previously provided to you under Section 3.

**r.Change in Control Acceleration Upon Acquiror's Failure to Assume, Continue or Substitute**. If (i) in connection with a Change in Control, any outstanding unvested Equity Award that you hold will not be assumed or continued by the successor or acquiror entity (or its parent company) in such Change in Control or substituted for a similar award of the successor or acquiror entity (or its parent company) (a "***Terminating Award***") and (ii) your continued employment with the Company has not terminated as of immediately prior to the effective time of such Change in Control, then you will become vested, with respect to any then unvested portion of such Terminating Award, effective immediately prior to, but subject to the consummation of such Change in Control. With respect to any such outstanding Terminating Award that is subject to performance-vesting, unless otherwise provided in the individual grant notice and award agreement evidencing such award, such performance-vesting award will accelerate vesting at 100% of the target level. For the avoidance of doubt, the benefits under this Section 4 are contingent on a Change in Control and do not require your Covered Termination or other termination of service. In addition, you may be eligible for benefits under this Section 4 in addition to benefits under Section 2 or Section 3 and in such case, you shall receive benefits under both sections, without duplication.

**s.Acknowledgements; Interaction with Prior Benefits.**

As a condition to participation in the Plan, you hereby acknowledge each of the following:

**i.** The benefits that may be provided to you under this Participation Agreement are subject to certain reductions and termination under Section 2 and Section 3 of the Plan.

**ii.** Your eligibility for and receipt of any severance benefits to which you may become entitled as described in Section 2 or Section 3 above is expressly contingent upon your execution of and compliance with the terms and conditions of the Plan, the Release and the Confidentiality Agreement. Severance benefits under this Participation Agreement shall immediately cease in the

event of your violation of the provisions of Confidentiality Agreement or any other written agreement with the Company.

**iii.** As further described in Section 2(c) of the Plan, this Participation Agreement and the Plan supersede and replace any change in control or severance benefits previously provided to you, including but not limited to any benefits under your employment or other written agreement or plan and by executing below you expressly agree to such treatment.

To accept the terms of this Participation Agreement and participate in the Plan, please sign and date this Participation Agreement in the space provided below and return it to _____ no later than _____, ____.

**Talis Biomedical Corporation**

By: _____

_____

**Eligible Employee**

_____

[Insert Name]

Date:____

**CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

# EXHIBIT A-1

**THIS EXHIBIT A-1 REPLACES EXHIBIT A TO THE SUPPLY AGREEMENT DATED MAY 22, 2020 BETWEEN THINXXS MICROTECHNOLOGY AG AND TALIS BIOMEDICAL CORPORATION ("TALIS")**

## PRODUCTS

[...***...]

[...***...]. In addition, and without limiting the foregoing, thX and Talis agree in good faith on cost reduction goals and shall work together to achieve such goals via process changes, material changes and other improvements to Products. The benefit of cost reductions shall be shared between the parties

2. Product Specifications (Including Acceptance Criteria)

Product Specifications are available as follows:

[...***...]

4. Key Performance Indicators (KPI's)

thX will provide Talis with the following reports on a quarterly basis for the following:

- On Time Delivery
- Cost Reductions
- Benchmarking (and lead time reduction to meet benchmarks)
- On Hand Inventory, Projected Available, Critical Items

ThX will start and/or maintain a continuous improvement strategy for Product quality, cost, delivery, inventory reduction and service including the above stated KPI's

[...***...]

[...***...]

| thinXXS Microtechnology AG | Talis Biomedical Corporation |
| --- | --- |
| By: /s/ Joe Rytell | By: /s/ Roger Moody |
| Name: Joe Rytell | Name: Roger Moody |
| Title: Managing Director | Title: Chief Financial Officer |

# PURCHASE AGREEMENT

This Purchase Agreement (the "Purchase Agreement"), entered into as of 13 December 2021 (the "Effective Date") sets forth the terms of the agreement between Talis Biomedical Corporation ("Talis" or the "Company") and thinXXS Microtechnology AG ("thX") (each a "Party" and together, the "Parties") regarding purchase commitments made under the Supply Agreement executed between the Parties as of August 12, 2020 (the "Supply Agreement").

## 1 Definitions

**1.1** Any capitalized terms not specifically defined in this Purchase Agreement shall be given the definition set forth in the Supply Agreement.

**1.2 "Raw Cards"** shall mean a Product that is a [...***...] as described in the Specifications contained in attached Exhibit 1 (the "Raw Card Specifications"), and the Parties acknowledge and agree that the Raw Card Specifications are hereby incorporated into Section 2 of Exhibit A-1 to the Supply Agreement.

## 2 Purchase Commitment.

**2.1** Talis shall purchase a minimum of [...***...] Raw Cards per [...***...] from thX during the period of [...***...] (the "Committed Quantity") at a purchase price of [...***...]. Upon execution of this Purchase Agreement, Talis shall issue a purchase order for [...***...]. For the sake of clarity, the Parties agree that the obligations, rights and remedies of each Party provided under the Supply Agreement shall apply to the Purchase PO. Subject to each Party's obligations, rights and remedies under the Supply Agreement, the purchase of the Committed Quantity is a [...***...]. Within [...***...] of the Effective Date of this Purchase Agreement, Talis will issue a Purchase Order (the "Purchase PO") in the amount of [...***...] for the remainder of the Committed Quantity. For clarity, subject to the terms of this Purchase Agreement, the Purchase PO constitutes a binding and noncancelable commitment on Talis to purchase and on thX to manufacture and supply the Committed Quantity of Raw Cards set forth in such Purchase PO. If thX fails to timely provide Raw Cards in accordance with the Specifications, the Quality Agreement, timing requirements, and all other requirements of the Supply Agreement, the Parties rights and responsibilities will be determined by the terms of the Supply Agreement, including that if there is any Chronic Supply Delay, the Parties agree that Talis may choose to waive the Committed Quantity for any [...***...] impacted by a Chronic Supply Delay.

**2.2**. The Parties acknowledge and agree that in order for Talis to receive the intended benefit and use of the Committed Quantity of Raw Cards, thX must manufacture and supply the requested quantity of reagent plugs in accordance with the applicable Specifications and the Quality Agreement. As such, the Parties further acknowledge and agree that [...***...]

[...***...].

## 3 Contract Revisions

**3.1 Purchase Order Number 2020112038.** The Parties agree to cancel existing Purchase Order Number 2020112038 dated 25 November 2020, including its reissuance on 16 March 2021 as PO-000204 (the “Raw Card PO”).

**3.2 Release of Claims.** Each Party, on behalf of itself and its parents, subsidiaries, affiliates, and insurers, successors, agrees to fully release and discharge the other Party from and for any and all rights, claims, controversies, damages, expenses, costs, obligations, causes of action, counterclaims, cross-claims, rights of set-off and recoupment, suits, debts, sums of money, accounts, breaches of duty, covenants, contracts, agreements, promises, judgments, executions, demands and liabilities of any nature whatsoever, in law or otherwise, whether known or unknown, that have ever existed, that now exist, or that may exist in the future, related in any way to the Raw Card PO.

**3.3 Supply Agreement**

**3.3.1 Completion of Production Lines.** The Parties have both met their obligations to design and establish semi-automated Production Lines in accordance with Section 2.3 of the Supply Agreement. At a future date, at Talis's request, the Parties shall enter into a mutually agreed upon Statement of Work under which thX will establish a Production Line that delivers complete cards at the Automated Product Price of [...***...], subject to the conditions set forth in Exhibit A-1.

**3.3.2 Raw Material Purchasing.** Upon (a) [...***...], and notwithstanding Section 4.1(b) of the Supply Agreement, Talis will transfer to thX the Third Party Supplier parts listed in Exhibit 2 to this Purchase Agreement that are in Talis's possession and on order by Talis ("Talis Third Party Supplier Parts") up to [...***...] to support its manufacture of Talis's Committed Quantity and any additional Talis Third Party Supplier Parts [...***...] in order to fulfill any future Talis order ("Transferred Inventory"). Talis acknowledges and agrees that thX will charge Talis [...***...] of the Transferred Inventory upon thX's receipt of any portion of the Transferred Inventory from a Third Party Supplier or Talis, as requested by thX. For clarification and not limitation, once Third Party Supplier Parts are entirely shipped to thX (upon its request), thX shall on a going-forward basis, purchase the Raw Materials listed in Exhibit 2 to this Purchase Agreement as well as all Third Party Supplier parts required to manufacture Consumables from Third Party Suppliers and thX shall bill Talis [...***...] of Third Party Supplier Parts it purchases directly from Third Party Suppliers plus [...***...] when invoiced by such Third Party Suppliers. The Parties agree that all Third Party Supplier Parts and Raw Materials which are the subject of this subsection 3.3.2 shall be considered "Talis-Supplied Materials" as defined under the Supply Agreement during the Term of this Purchase Agreement [...***...]. After the end of the Term of this Purchase Agreement, all Third Party Supplier Parts and Raw Materials shall be deemed thX supplied materials[...***...].

**3.3.3** [...***...] **Annual Commitment PO.** In view of the purchase commitment and associated Purchase Order set forth in Section 2 of this Purchase Agreement, [...***...]. The obligations associated with Section 3.4 of the Supply Agreement will [...***...].

**3.4 Rolling Monthly Forecasts.** In accordance with Section 3.3 of the Supply Agreement, on the first Business Day of each month, commencing on [...***...], Talis will provide thX with updated Rolling Monthly Forecasts. For clarity, other than as set forth in Section 2 of this Purchase Agreement or as secured by a binding Purchase Order as set forth in Section 3.5 of this Purchase Agreement, each Rolling Monthly Forecast shall be non-binding on both Parties; rather, the Rolling Monthly Forecasts will reflect Talis's good faith expectation, at the time of submission of the forecast, of the quantity of Products Talis expects to order during the applicable [...***...] period.

**3.5 Orders in Excess of Purchase PO.** During the Term, [...***...], Talis may place a Purchase Order for Products in excess of the Committed Quantity per [...***...] recited in Section 2 ( “Excess PO”) by submitting to thX a written purchase order using Talis’s standard purchase order form, which shall (a) specify any quantity of Products (by Product type) in excess of the quantities set forth in the Purchase PO, (b) provide delivery dates for any such Product, and (c) include any reasonable special shipping, storage or other instructions applicable to such order. thX shall promptly (in all cases within [...***...] send its acceptance, rejection, or counter-offer of each Excess PO to Talis in writing, and any acceptance will be a binding obligation on thX to fulfill such Purchase Order at the prices set forth in Exhibit A-1, provided however that the pricing set forth therein shall [...***...]. thX shall use [...***...] to implement a second shift in order to accommodate an Excess PO.

**3.6** Except as specifically set forth above and Exhibit A-1, in all other aspects, the Supply Agreement (and all of its terms and conditions contained therein) shall remain in full force and effect and continue to govern the parties’ ongoing relationship. To the extent any provisions in the Purchase Agreement conflict, other than those changes set forth in this Section 3 and Exhibit A-1 of this Purchase Agreement above, with any provisions in the Supply Agreement and cannot be read together in a consistent manner, then the terms of the Supply Agreement control.

**3.7 License to Finish Raw Cards Manufactured by thX.**

(a) During the term of the Supply Agreement and, further limited, to the period of time in which the Parties agree that Talis will Functionalize the Raw Cards, thX hereby grants to Talis a nonexclusive, worldwide, non-transferable, revocable, royalty-free and fully paid license to: (i) Functionalize, or sublicense to third parties that are not thX Competitors to Functionalize, the Raw Cards supplied by thX under the Supply Agreement to produce Consumables; and (ii) make, have made, use, sell, have sold, offer for sale, and import such Consumables Functionalized in accordance with subsection 3.9(a)(i). “Functionalize” shall mean [...***...]. No license is granted beyond the grant expressly set forth above.

b) In connection with the exercise of the license granted above, thX shall provide, [...***...], applicable technology transfer and related training to enable Talis to set up facilities to Functionalize the Raw Cards to produce Cartridge. For the avoidance of doubt, thX consultation with respect to the production Equipment shall include advice regarding the Specifications for and setup of such production Equipment.

**4** [...***...] **Payment.** As consideration for settlement of Talis’s cancellation of the Raw Card PO and the Release of Claims set forth in Section 3.2 Talis will (i) issue the Purchase PO and purchase of the Committed Quantity thereunder, and (ii) pay thX the total reconciliation amount of [...***...]

[...***...]. The Payment shall be paid electronically to the bank account as specified by thX with specific account information sufficient for Talis to pay the Payment electronically by such date.

**5** **Term.** This Purchase Agreement is effective as of the Effective Date and will extend until December 31, 2022, unless the Supply Agreement is terminated in accordance with the terms of Section 11.2 of the Supply Agreement, in which case Purchase Agreement will terminate on the same date as the Supply Agreement. Sections 6 and 7 shall survive any expiration or termination of this Purchase Agreement.

**6** **Miscellaneous.** This Purchase Agreement constitutes the complete, final and exclusive embodiment of the entire agreement between thX and the Talis with regard to its subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes all other such promises, warranties or representations. No amendment, modification or addition to this Purchase Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties. If any provision of this Purchase Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Purchase Agreement and the provision in question will be modified so as to be rendered enforceable. This Purchase Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of Illinois without regard to conflict of laws principles with venue and personal and subject matter jurisdiction agreed to be all exclusively in the state or federal courts located in Chicago, Illinois. Any ambiguity in this Purchase Agreement shall not be construed against either Party as the drafter. Any waiver of a breach of this Purchase Agreement shall be in writing and shall not be deemed to be a waiver of any successive breach.

**7** This Purchase Agreement may be separately executed in one or more separate counterparts, and all of such separately signed counterparts shall constitute one and the same agreement upon exchange. The Parties agree that facsimile or electronic signatures shall be as effective as if originals.

**IN WITNESS WHEREOF, the parties hereto have executed this Purchase Agreement as of the Effective Date.**

TALIS BIOMEDICAL CORPORATION

By: /s/ Roger Moody

Name: Roger Moody

Title: Chief Financial Officer

Date: Dec 15, 2021

thinXXS Microtechnology AG

By: /s/ Joe Rytell

Name: Joe Rytell

Title: Managing Director

Date: Dec 15, 2021

Exhibit 1

Raw Card Specifications

Product Specifications are available as follows:

[...***...]

Exhibit 2

**thX Purchase / Transfer from Talis of Third Party Supplier Parts**

[...***...]

**Exhibit 23.1**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the following Registration Statements:

- Registration Statement (Form S-8 No. 333-253218) pertaining to the 2013 Equity Incentive Plan, the 2021 Equity Incentive Plan and the 2021 Employee Stock Purchase Plan of Talis Biomedical Corporation, and
- Registration Statement (Form S-8 No. 333-261267) pertaining to the 2021 Inducement Plan of Talis Biomedical Corporation;

of our report dated March 15, 2022, with respect to the financial statements of Talis Biomedical Corporation included in this Annual Report (Form 10-K) of Talis Biomedical Corporation for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Chicago, Illinois

March 15, 2022

**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, Robert J. Kelley, certify that:

1. I have reviewed this Annual Report on Form 10-K 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: March 15, 2022

/s/ Robert J. Kelley
**Robert J. Kelley**
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 Annual Report on Form 10-K 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles

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

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

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

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

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

Date: March 15, 2022

/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 Annual Report on Form 10-K of Talis Biomedical Corporation (the "Company") for the year ending December 31, 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 results of operations of the Company.

Dated: March 15, 2022

/s/ Robert J. Kelley
**Robert J. Kelley**
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 Annual Report on Form 10-K of Talis Biomedical Corporation (the "Company") for the year ending December 31, 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 results of operations of the Company.

Dated: March 15, 2022

/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.