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, 2020

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	**94025**
(Address of principal executive offices)	(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 February 17, 2021, was $375,209,582.

The Registrant has elected to use February 17, 2021 as the calculation date, as this was the date the Registrant completed its initial public offering and on the last business day of the Registrant's most recently completed second fiscal quarter there was no public market for the Registrant's common stock. The calculation of the aggregate market value of voting and non-voting common equity excludes 10,138,055 shares of common stock of the Registrant and 29,863,674 shares of Series 1 convertible preferred stock of the Registrant held by executive officers, directors and stockholders that the Registrant concluded were affiliates of the Registrant on that 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 25, 2021, there were 55,501,277 shares of the Registrant's common stock and preferred stock outstanding, consisting of 25,637,603 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

None.

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Special note regarding forward-looking statements

This Annual Report on Form 10-K 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 expectations of the reliability, accuracy and performance of our products and services, as well as expectations of the benefits to patients, clinicians and providers of our products and services;
- future investments in our business, our anticipated capital expenditures and our estimates regarding our capital requirements, future revenues, expenses, reimbursement rates and needs for additional financing;
- impact from future regulatory, judicial, and legislative changes or developments in the United States and foreign countries;
- our ability to establish a sales force and acquire customers;
- our expectations regarding our sales models;
- the costs and success of our marketing efforts, and our ability to promote our brand;
- our ability to increase demand for our products and services, obtain favorable coverage and reimbursement determinations from third-party payers and expand geographically;
- our efforts to successfully develop and commercialize our products and services, including our ability to successfully conduct clinical trials;
- our ability to successfully develop additional revenue opportunities and expand our product and service offerings, including our recently launched offerings;
- the performance of our third-party suppliers and manufacturers;
- our ability to effectively manage our growth, including our ability to retain and recruit personnel, and maintain our culture;
- our ability to compete effectively with existing competitors and new market entrants;
- the impact on our business of economic or political events or trends;
- the size and growth potential of the markets for our products and services, and our ability to serve those markets; and
- the rate and degree of market acceptance of our products and services.

In some cases, you can identify these statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expects,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. These forward-looking statements reflect our management’s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this 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 the registration statement, of which this Annual Report is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this 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 on Form 10-K. 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 on Form 10-K as part of your evaluation of an investment in our common stock.

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

Part I

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 authorized, could be rapidly deployed to distributed diagnostic settings in the United States and around the world to diagnose infectious disease at the point-of care. The Talis One system comprises a compact instrument, single-use test cartridges and software, including a central cloud database, which work together and are designed to provide central laboratory levels of accuracy and be operated by an untrained user.

General

We are developing Talis One assay kits for respiratory infections, infections related to women’s health and sexually transmitted infections. In January 2021, we submitted a request for an EUA to the FDA for our Talis One system with COVID-19 molecular diagnostic assay in the Clinical Laboratory Improvement Amendments of 1988 (CLIA)-moderate settings. In late February 2021, the FDA informed the company that it cannot ensure the comparator assay used in the primary study has sufficient sensitivity to support our EUA application. On March 8, 2021 we announced that we withdrew our January application in favor of focusing on an application to authorize testing at the point-of-care. In late March 2021, we made certain changes to our clinical validation strategy in a point-of-care environment, and now intend to submit a request for EUA to the FDA for our Talis One system in non-laboratory settings in Q2 2021. 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, if authorization is received from the FDA, the Talis One COVID-19 assay kit may be used in either laboratory or non-laboratory settings.

We are also developing influenza A and influenza B tests to be included as part of a respiratory panel with our COVID-19 assay (COVID-Flu Panel). In addition, we plan to initiate a clinical trial to support clearance of a pre-market notification under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FDCA) of our Talis One system with a test cartridge for chlamydia and gonorrhea in the second half of 2021 and submit a 510(k) pre-market notification in the first half of 2022. To support our anticipated commercial launch of our COVID-19 assay kit, we have invested in automated cartridge manufacturing lines capable of producing one million cartridges per month, which began to come on-line in the first quarter of 2021 and we expect will scale to full capacity through 2021.

The COVID-19 crisis is accelerating 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 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. The Talis One system is designed to have the following capabilities which we believe would 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 that is 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 assay kit 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 to be operated 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 to support up to 14 separate assay chambers, which we believe could potentially enable a full menu of detection modes, from single organism to syndromic panel tests. The test cartridge for our anticipated commercial launch offers 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 is designed to 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. This 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. The cloud capability is also designed to 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. While we expect all instruments, if authorized for commercial sale, to be sold with cellular capability, the cloud database would not initially be available on devices distributed pursuant to our EUA, if obtained. This capability is expected to be enabled with an upcoming software upgrade in 2021 for all installed instruments.

Scalable for different throughput requirements—The Talis One system was 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 to 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 scale-up in manufacturing and provide a competitive advantage in cost-sensitive environments. We believe this could also facilitate customers acquiring multiple Talis One instruments to meet their volume requirements.

If we receive an EUA from the FDA for our Talis One system and COVID-19 assay kit, 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 pursue 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 marketing authorization and commercialization of our COVID-19 assay kit in the United States

- We are currently planning to seek an EUA for our COVID-19 test using our Talis One system in both laboratory and non-laboratory settings, for which we plan to submit in early Q2 2021.
- If we receive an EUA, we intend to commercialize the Talis One system through an enterprise account management 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) large elder care chains where vulnerable residents have unmet needs for millions of high sensitivity assays per year; (2) urgent care chains that serve on the front lines of COVID-19 diagnosis, needing millions of rapid tests to triage symptomatic patients; and (3) traditional medical establishments, including hospitals, ambulatory surgery centers, cancer treatment and dialysis centers, independent practice associations, accountable care organizations, and public health clinics that that need rapid and high-quality testing to best serve their patients.

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

- We have ordered 5,000 instruments from our instrument contract manufacturing partners to be delivered through the third quarter of 2021.
- We have invested in automated cartridge manufacturing lines that are scheduled to reach capacity of approximately one million tests per month in the second half of 2021 and we intend to invest in further scale-up in 2021.
- As we improve and scale manufacturing and automation, we expect to drive substantial reductions of cost of goods 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 influenza B, with the intention to pursue marketing authorizations and to commercialize a respiratory panel with our COVID-19 test. We have initiated discussions with the FDA and leveraging feedback from the FDA we intend to pursue the EUA pathway for this test panel. The current established pathway for marketing of a flu test is through the 510(k) clearance pathway. The FDA's marketing authorization requirements for the combination of an influenza A, influenza B and COVID-19 test will impact the timing to develop and commercialize this 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 test to detect chlamydia and gonorrhea (CT/NG), for which we plan to initiate a clinical study in the second half of 2021 to support a 510(k) submission in the first half of 2022. We are subsequently targeting other sexually transmitted infections (STIs), such as a panel for sexually transmitted inflection that would include CT/NG, *Trichomonas vaginalis* and *Mycoplasma genitalium*, a panel for bacterial vaginosis (BV), a panel for urinary tract

infections (UTI), and single target tests for infectious agents such as *Group B streptococcus*, or herpes simplex virus (HSV). If we obtain marketing authorization from the FDA, we intend to focus our commercialization efforts both on existing customers that 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 out tests to centralized laboratories.

Pursue marketing authorization and, if authorized, commercialize our products and expand our operations in selected geographies globally

- If we receive marketing authorization in the United States for our CT/NG test, we intend to pursue authorization to affix a CE Mark to enable commercialization of our test in Europe as early as the end of 2022 or approximately six months after U.S. clearance, if received. We also anticipate that we will pursue marketing authorization to commercialize our CT/NG test in selected countries in Asia, following our expansion into 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.

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 the available test menu.
- We intend to continue our research and development activities and 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, in 2020 the world has been 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 that are used 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 that can require 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 that 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 as well as 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 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 that is 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 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 are developing for the COVID-19 and CT/NG tests provides 5-fold multiplexing, which we believe is sufficient to meet our near-term 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, and we expect to make such features available with a planned post-launch software upgrade. 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 can be used by public health and research institutions 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 product sales. As reflected in the table below, we are developing Talis One assay kits for respiratory infections, infections related to women's health and sexually transmitted infections. We anticipate that our first test to be marketed 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 a respiratory panel test to detect influenza A and influenza B plus SARS-CoV-2. We intend to submit for a 510(k) clearance to commercialize our Talis One system with a test for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) in the first half of 2022. 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 which require high sensitivity and specificity and for which timely results provide significant clinical benefit. In addition to the project previously described, our women's and sexual health roadmap includes plans to develop seek marketing authorization for (1) a STI panel including CT, NG, *Trichomonas vaginalis and Mycoplasma genitalium*; (2) an assay for herpes simplex virus; (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 assay kit

The Talis One COVID-19 assay kit is our first product in development 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 assay kit. We submitted a request for an EUA to the FDA for our Talis One COVID-19 assay kit in CLIA-moderate settings in January 2021. In late February 2021, the FDA informed us that it cannot ensure the comparator assay used in the primary study has sufficient sensitivity to support our EUA application. On March 8, 2021, we announced that we withdrew our January application in favor of focusing on an application to authorize testing at the point-of-care. An EUA would allow us to market and sell our Talis One system and COVID-19 assay kit without 510(k) clearance or any other marketing authorization. The duration of any EUA we may receive is uncertain as the FDA may revoke an EUA when it determines the health emergency is over or no longer warrants such authorization or if we fail to comply with the conditions of the EUA. After the emergency period is declared to be over, we expect that the FDA will require companies operating under an EUA to submit a 510(k) pre-market notification for tests such as our COVID-19 assay kit, but we believe the FDA will provide a grace period for such submissions. Accordingly, we intend to complete the requirements for and submit a 510(k) pre-market notification to the FDA for our Talis One system and COVID-19 assay kit to enable continued marketing when the public health emergency period is declared to be over.

Respiratory panels

We also anticipate developing respiratory panels incorporating our COVID-19 test. We are developing tests targeting influenza A and influenza B. If we successfully commercialize the Talis One system for the diagnosis of COVID-19, we plan to incorporate these flu tests with the COVID-19 test in an upper respiratory panel on a single cartridge and seeking marketing authorizations for such multi-panel tests, whether through the EUA process, if available to us, or through a 510(k) clearance process once available to us.

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 sexually transmitted infections. We intend to complete clinical development of our Talis One system for CT/NG and submit a 510(k) pre-market notification to the FDA in the first half of 2022. We further intend to pursue authorization to affix a CE Mark from the European Medicines Agency (EMA) by the end of 2022 or 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 and could improve decision making and enable the provider to use this information to treat the patient in the same visit. We believe this could 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

We are currently developing the Talis One assay kit for COVID-19, other respiratory infections, and infections related to women's health and STIs. We estimate that the total potential annualized addressable market opportunity for COVID-19 tests in the United States exceeds $7.0 billion and exceeds $5.0 billion for our Talis One assay kits in development for infections related to women's health and STIs and our COVID-Flu Panel.

We believe that the demand for COVID-19 diagnostic testing will evolve over three phases as the pandemic progresses:

Initial phase: We believe 2020 epitomized the initial phase of the COVID-19 pandemic, characterized by diagnostic testing predominantly of individuals suspected of COVID-19 by their healthcare providers in high-volume centralized locations. In this initial phase, there was insufficient supply of tests to meet the demand and was primarily carried out through the use of centralized laboratories or rapid antigen tests with limited amount of point-of-care molecular testing. While the testing capacity using currently authorized options may ultimately surpass the daily testing need, we believe these current tests lack the capabilities to meet the testing needs as the COVID-19 pandemic evolves, most importantly due to limitations providing highly accurate and actionable diagnosis in a timely manner. We believe that the preferred approach for COVID-19 diagnostic testing will be to deliver the highest testing accuracy and results in a timely manner, which we believe can only be met by a point-of-care, molecular-based approach.

Second phase: We believe that the demand for products such as the Talis One COVID-19 assay kit will grow from the initial phase because vaccination will become more common and point-of-care testing will become increasingly available. As a result, testing will shift from high-volume centralized sites to the point-of-care. Included in the broader group of potential customers that will adopt point-of-care diagnostic technologies will be physicians' offices, institutions caring for vulnerable populations, urgent care centers, employers, and schools. We expect that this will drive a shift of testing towards the point-of-care and

significant demand for point-of-care technologies, with a high importance by customers placed on accuracy and speed.

Third phase: We believe that an additional phase of the COVID-19 pandemic may emerge and which could extend into the foreseeable future. In this phase, the presence of vaccines is expected to result in a lower incidence of COVID-19. However, we believe that there will continue to be a high focus on safety supporting demand for COVID-19 testing, especially as it relates to demand from potential customers testing individuals suspected of COVID-19 infection and of vulnerable populations. Additionally, there may be demand for rapid point-of-care testing as a means to determine eligibility for COVID-19 therapies that may be shown to be effective only in a narrow timeframe after initial exposure or onset of symptoms, and this could particularly apply to people who were not vaccinated or had an insufficient or waning vaccine response. We anticipate that this phase will drive demand for panel-based tests which incorporate additional respiratory viruses, for example a flu and COVID-19 panel. Respiratory infections, including COVID-19, can be difficult to diagnose and having a panel-based test to diagnose for and rule-out different pathogens can improve the chances of a definitive diagnosis on the first test.

Subject to receipt of marketing authorization for our COVID-19 assay kits using our Talis One system, our initial sales strategy will focus on increasing adoption of the Talis One system in two customer types: enterprise accounts and health care providers. We initially plan to launch the Talis One system through an enterprise account management team and a direct sales force with approximately 40 sales representatives dedicated to increasing adoption in both categories. With respect to direct sales, we intend to commercialize the Talis One system through a sales force focused initially on placing system with potential customers that place high value on accuracy and/or our broader test menu in development. Target customer segments include: (1) large elder care chains where vulnerable residents have unmet needs for millions of high sensitivity assays per year; (2) urgent care chains that serve on the front lines of COVID-19 diagnosis, needing millions of rapid tests to triage symptomatic patients; and (3) 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. These customers represent large and concentrated testing opportunities for COVID-19. For example, we estimate that a single large elder care chain could represent a COVID-19 testing opportunity of over a million tests per year. In addition, the sales team will directly target smaller accounts including obstetrician and gynecologist practices, primary care doctors and mid-sized physician networks. We may also consider sales to organizations such as schools and school districts as well as corporate customers.

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.

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. However, we believe our proprietary and adaptable technology platform, our process capabilities and our manufacturing scale will distinguish us from our competitors.

We anticipate facing competition primarily from centralized laboratories and diagnostic companies offering both point-of-care and at-home solutions. Competitors include those offering molecular, antibody and antigen tests. Competitors in the reference lab category include Laboratory Corporation of America Holdings (commonly referred to as LabCorp) and Quest Diagnostics Incorporated, along with many hospital laboratories. Competitors with point-of-care molecular diagnostic technology platforms that are either currently available or that are in development include Abbott Laboratories, Binx Health, Inc., BioFire Diagnostics, LLC, Cepheid (a subsidiary of Danaher Corporation), Cue Health Inc., Lucira Health, Inc., Mesa Biotech, Inc. (recently acquired by Thermo Fischer Scientific Inc.), Roche Molecular Systems, Inc., and Visby Medical, Inc.

Each of the preceding companies have received an EUA for a point-of-care COVID-19 test. 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.

We believe key competitive factors impacting our success include the accuracy, utility, turnaround time and economics of our products, and commercial execution. We also believe our success 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.

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, 2020, for the validation, approval, and scale-up of capacity for manufacturing of the Talis One instrument and test cartridges. Pursuant to the NIH Contract, we are required to obtain and maintain an EUA from the FDA for the Talis One system and COVID-19 assay kit. We are also required to provide data and reports to and meet regularly with NIH for evaluation of milestones and compliance with contractual obligations. Prices offered to consumers must ultimately be a fair market rate and consistent with the objective of increasing and improving testing in the US. Further, the testing capabilities produced are for utilization within the U.S. and its territories.

The term of the NIH Contract is one year. The NIH Contract can be terminated for convenience by the NIH at any time, or for cause upon a failure to perform the services as specified in the NIH Contract. In the latter circumstance, we would be required to repay the NIH 15.0% of the amounts already paid to us under the NIH Contract as liquidated damages, in place of any actual damages. Such repayment would not be required if a delay in delivery or performance was beyond our control and without fault or negligence on our part.

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. Our instrument contract manufacturer is scaling up to be able to make up to 500 instruments per week. We have various suppliers that provide molded parts and reagents that are assembled by two contract manufacturers

for the cartridge. We are investing approximately $119.8 million dollars to scale up cartridge manufacturing. This investment includes high cavity count molding capability and automation of significant portions of the cartridge assembly process. 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 industry-leading 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 plan to engage a third-party logistics company to manage the movement of materials between suppliers and for finished goods warehousing.

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.

Intellectual property

Patents

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). As of January 1, 2021, we solely own nine issued U.S. patents, 18 pending U.S. patent applications, 12 issued foreign patents, 59 pending foreign patent applications, and three pending PCT international patent applications. We co-own three issued U.S. patents, one pending U.S. patent application, and 11 pending foreign patent applications with Caltech. We exclusively in-license 10 issued U.S. patents, two pending U.S. patent applications, 17 issued foreign patents and four 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 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), *Chlamydia trachomatis*, and *Neisseria gonorrhoeae*. 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. Our trademark applications may not proceed to registration, and our intellectual property rights may be invalidated, circumvented or challenged. For instance, we are currently subject to ongoing opposition before the United States Patent and Trademark Office filed by Talis Clinical, LLC, which alleges that our application for registration of the trademark TALIS should not be registered because it is likely to be confused with the prior unregistered trademark TALIS used in connection medical software and related goods and services. In the event this opposition is successful, or if we enter into a settlement agreement with Talis Clinical, LLC, we could lose rights to this trademark. We cannot predict the outcome of this action or if we will be subject to similar claims in the future.

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.

We intend to pursue additional intellectual property protection to the extent we believe it would advance our business objectives. Notwithstanding these efforts, there can be no assurance that we will adequately protect our intellectual property or determine the likelihood that these efforts will provide any competitive advantage. We cannot provide any assurance that any patents will be issued from our pending or any future applications or that any issued patents will adequately protect our products or technology. Our intellectual property rights may be invalidated, circumvented or challenged. In addition, the laws of various foreign countries where our products are distributed may not protect our intellectual property rights to the same extent as laws in the United States. Furthermore, it may be difficult to protect our trade secrets. While we have confidence in the measures we take to protect and preserve our trade secrets, they may be inadequate and can be breached, and we may not have adequate remedies for violations of such measures. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. For more information regarding risks related to intellectual property, please see “Risk factors—Risks related to our intellectual property.”

Government regulation and product approval

Our products under development and our operations are subject to significant government regulation. In the United States, our products are regulated as medical devices by the FDA and other federal, state, and local regulatory authorities.

FDA regulation of medical devices

The FDA and other U.S. and foreign governmental agencies regulate, among other things, with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;

- product safety;
- marketing, sales and distribution;
- pre-market clearance and approval;
- record keeping procedures;
- advertising and promotion;
- recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market approval studies; and
- product import and export.

In the United States, numerous laws and regulations govern all the processes by which medical devices are brought to market and marketed. These include the FDCA and the FDA's implementing regulations, among others.

FDA pre-market clearance and approval requirements

Each medical device we seek to commercially distribute in the United States must first receive 510(k) clearance, *de novo* classification, or approval of a pre-market approval (PMA) application, from the FDA, unless specifically exempted. In addition, devices may receive EUAs, such as those issued for in vitro diagnostics to detect SARS-CoV-2, which are time-limited authorizations under the public health emergency provisions of the FDCA.

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 includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation (QSR), facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. 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 the device. These special controls can include performance standards, post-market surveillance, 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 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices are placed in Class III, requiring approval of a PMA application. Some pre-amendment devices are unclassified but are subject to the FDA's pre-market notification and clearance process in order to be commercially distributed.

In addition, EUAs and other forms of approval or clearance may be limited to use of 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.

Emergency Use Authorization

Section 564 of the FDCA authorizes the U.S. Secretary of the Department of Health and Human Services (HHS) to declare public health emergencies that have a significant potential to affect national security or the health and security of U.S. citizens. Before an EUA may be issued, the Secretary must declare an emergency based on one of the following grounds:

- a determination by the Secretary of the Department of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological or nuclear agent or agents;
- a determination by the Secretary of the Department of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or
- a determination by the Secretary of the HHS of a public health emergency that effects or has the significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

Prior such public health emergencies have included declarations regarding the Zika virus (2016), Ebola virus (2014), and Avian flu virus (2013). 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 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 applicant's request for an EUA includes available scientific evidence, and the FDA engages in interactive review of the request with the applicant. If and once authorized, products subject to an EUA must comply with the conditions of an EUA, including informing healthcare professionals and patients of the risks and benefits of the product, adverse event reporting and recordkeeping, and may include distribution and advertising controls and limitations. 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 device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of 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. 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. 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 of 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 documents, where feasible.

De novo classification process

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA) in July 2012, a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) pre-market notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) pre-market notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, FDA is required to classify the device within 120 days following receipt of the *de novo* application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

Pre-market approval process

A PMA application must be submitted if the medical device is in Class III (although the FDA has the discretion to continue to allow certain pre- amendment Class III devices to use the 510(k) process) or cannot be cleared through the 510(k) process. A PMA application must be supported by, among other things, extensive technical, preclinical, and clinical trials, as well as manufacturing and labeling data to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the manufacturing facility to ensure compliance with QSR, which imposes elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMA applications or supplements are required for significant modifications to the manufacturing process, labeling of the product and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an original PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical trials

A clinical trial is typically required to support a PMA application and is sometimes required for a 510(k) pre-market notification. Clinical trials generally require submission of an application for an Investigational Device Exemption (IDE), to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the investigational protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB), for each clinical site. The IRB is responsible for the initial and continuing review of the IDE and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Pervasive and continuing U.S. Food and Drug Administration regulation

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

- the 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 recall 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 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:

- untitled letters or 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, 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 and physician sunshine 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), 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. Beginning in 2022, applicable manufacturers will also be required to report such information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiology assistants, certified nurse anesthetists and certified nurse-midwives. 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.

Healthcare reform

In the United States and foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system seeking, among other things, to reduce healthcare costs that could affect our future results of operations as we begin to directly commercialize our products.

By way of example, in the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA) which was signed into law in March 2010, substantially changed the way healthcare is delivered and financed by both governmental and private insurers. Among other things, the ACA:

- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; and
- implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models.

There have been executive, judicial and political challenges to certain aspects of the ACA. For example, the Tax Cuts and Jobs Act of 2017 (TCJA), includes a provision repealing, effective January 1, 2019, 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 that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas (Texas District Court Judge), ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, although it is unclear when or how the Supreme Court will rule. Although the Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs 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 also unclear how the Supreme Court ruling, other such litigation and healthcare reform measures of the Biden administration will impact the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was enacted, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. In addition, 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, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure. For example, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Data privacy and security

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, processing, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations that govern the collection, use, processing, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder, imposes privacy, security and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business

associates and their subcontractors that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information (PHI), a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties.

Further, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. Where state laws are more protective, we may have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also may afford a private right of action to individuals who believe their personal information has been misused. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and our clients, and potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as PHI or personally identifiable information along with increased demands for enhanced data security infrastructure, could greatly increase our costs of providing our services, decrease demand for our services, reduce our revenue and/or subject us to additional risks.

Even when HIPAA does not apply, according to the Federal Trade Commission (FTC), violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain state laws, such as the California Consumer Privacy Act of 2018 (CCPA) may govern the privacy and security of health and other types of personal information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, the CCPA, which went into effect January 1, 2020, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Further, the California Privacy Rights Act (CPRA) was recently voted into law by California residents. The CPRA amends the CCPA, and imposes additional data protection obligations on covered companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which may result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The substantive requirements for businesses subject to the CPRA will go into effect on January 1, 2023, and become enforceable on July 1, 2023.

In Europe, the General Data Protection Regulation (GDPR) went into effect in May 2018 and introduced strict requirements for processing the personal data of individuals within the European Economic Area (EEA). In addition, the GDPR generally prohibits the transfer of personal data from the EEA to the United States many other countries unless the parties to the transfer have established a legal basis for the transfer and implemented specific safeguards to protect the transferred personal data. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Additionally, following the United Kingdom's withdrawal from the European Union and the

EEA, companies have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover.

Human capital resources

As of December 31, 2020, we had a total of 136 employees, 133 of whom were full-time employees. Our employees are located in Menlo Park, California 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.

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://talis.bio.

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.

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.talis.bio 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 on Form 10-K, 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

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

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

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

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

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

The FDA may also revoke an EUA when the circumstances justifying its issuance no longer exist, such as when an alternative is authorized for marketing through the standard procedures, such as through a 510(k) clearance. The FDA has stated that, given the magnitude of the COVID-19 health crisis and the testing capacity challenges in the United States, it has no intention of terminating EUAs for COVID-19 diagnostic tests based solely on a test

receiving 510(k) clearance. However, the FDA may change this position at any time and without notice. If granted, we cannot predict how long an EUA for the Talis One system and COVID-19 assay kit will remain in place. FDA policies regarding diagnostic tests, therapies and other products used to diagnose, treat or mitigate COVID-19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence. Changes to FDA regulations or requirements could require changes to our authorized test, necessitate additional measures, or make it impractical or impossible for us to market our test. The revocation of an EUA, if granted, could necessitate that we pursue the lengthy and expensive 510(k) clearance process, which is now available since a COVID-19 assay has received *de novo* 510(k) classification. Indeed, FDA has recommended that manufacturers of tests subject to an EUA pursue pre-market submissions such as a 510(k), *de novo* classification, or PMA, as applicable, during the declared public health emergency so that their devices can remain on the market after the emergency terminates. As a result, any such revocation could adversely impact our business, financial condition and results of operations.

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

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

We have focused our efforts on the development of the Talis One system for FDA clearance or other marketing authorization as a point-of-care testing platform for infectious diseases. A significant portion of our commercial strategy is dependent upon the initial commercialization of our Talis One system with COVID-19 assay kit pursuant to an EUA, if granted, and on receiving subsequent marketing authorizations with inclusion in clinical guidelines to strengthen our position in establishing coverage and reimbursement of our products with both public and private payors. If we are unable to receive marketing authorization pursuant to an EUA, or if any EUA we receive is later withdrawn or terminates at the conclusion of the public health emergency, we will be required to pursue marketing authorization through the FDA's standard pre-market review pathways, such as a 510(k) clearance, *de novo* classification, or PMA approval. The 510(k) clearance pathway may not be available to us if no suitable predicate device has previously received marketing authorization through the FDA's traditional marketing authorization pathways. In that case, we may be required to pursue a PMA approval or *de novo* classification, both of which are more onerous than the 510(k) clearance pathway. We cannot guarantee that we would be able to satisfy the requirements for marketing authorization under any of these pathways. If we do not receive such marketing authorizations in a timely manner, or at all, or we are not successful in receiving such guideline inclusion, we may not be able to commercialize our products successfully or at all. Additionally, third-party payors may be unwilling to provide sufficient coverage and reimbursement for our products necessary for hospitals and other healthcare providers to adopt our solutions as part of their treatment strategy.

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

market demand for the system, which would adversely affect our business. See "—Risks related to regulatory matters."

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

We do not have any commercial-scale manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of the Talis One system and our tests, as well as for commercial supply if any of our products are authorized for marketing. This reliance exposes us to significant risk that we will not have sufficient quantities of our products at an acceptable cost or quality, which could delay, prevent or impair our clinical trials and commercialization efforts. The manufacturing of our Talis One instrument and cartridge involves over 500 raw materials, intermediates and subassemblies. While we do not have any commercial-scale manufacturing facilities, we have invested in the development of multiple automated assembly lines for production of the test cartridges. The automated lines are required to meet the near-term volume commercial needs for the Talis One system, if we receive an EUA for our COVID-19 test. However, the lines are not complete and could incur substantial delays, costs and may not perform as anticipated, and any failure to perform as anticipated could require us to make significant capital expenditures to make adjustments. Any such delays or required expenditures could prevent us from launching our Talis One system with COVID-19 assay kit if we receive marketing authorization, which would adversely impact our business, financial condition and results of operations. The effects of any such delays would also be exacerbated if the demand for COVID-19 tests declines prior to our assembly lines becoming fully operational at scale.

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

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

Our third-party manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, or unstable political environments, or health pandemics or epidemics. For example, due to the health crisis of the COVID-19 pandemic, some of the suppliers of materials and components for our instrument and cartridges are facing extreme demand for their services. In particular, certain manufacturers of multiple components of our instrument are currently unable to provide such components to us, or are unable to provide such components on reasonable timelines, without a requirement from the government to do so pursuant to the Defense Production Act of 1950, as amended (DPA). Currently, our contract with the NIH for Phase 2 of its RADx initiative has been modified to incorporate a Health Resources Priorities and Allocations System (HRPAS) priority rating of DO pursuant to the DPA. This allows us to place the same priority rating on orders for industrial resources that we need to fulfill our rated order with our suppliers. If our suppliers do not comply with such mandates or the RADx contract is subsequently amended to remove the priority rating, we may be unable to manufacture our instruments in

sufficient quantities and such event would have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

Assuming we are successful in obtaining an EUA, we expect to initially market and sell the Talis One system with our COVID-19 assay kit in the United States. Substantially all of our revenue will initially be dependent upon such sales, which we expect will continue to be the case until such time as we obtain marketing authorization for subsequent tests. As a result, our future success will depend in large part on our ability to effectively launch the Talis One system with our COVID-19 assay kit and subsequently introduce enhanced or new tests for the Talis One system. The launch of new products is inherently uncertain and requires the completion of commercialization activities that are complex, costly, time-intensive and uncertain, and require us to accurately anticipate patients', providers' and, if applicable, payors' attitudes and needs and emerging technology and industry trends. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals on a timely basis, or at all.

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

- whether our customers are willing to incur the upfront costs associated with purchasing Talis One instruments;
- whether there is adequate utilization of our tests by clinicians, health systems and other target groups based on the potential and perceived advantages of our diagnostic tests over those of our competitors;
- the convenience and ease of use of our diagnostic tests relative to those currently on the market;
- the effectiveness of our sales and marketing efforts;
- our ability to provide incremental data that show the clinical benefits and cost effectiveness, and operational benefits, of our diagnostic tests;
- the coverage and reimbursement acceptance of our products and services;

- pricing pressure, including from group purchasing organizations (GPOs), seeking to obtain discounts on our diagnostic tests based on the collective bargaining power of the GPO members;
- negative publicity regarding our or our competitors' diagnostic tests resulting from defects or errors;
- the accuracy of our tests relative to those of our competitors;
- product labeling or product insert requirements by the FDA or other regulatory authorities; and
- limitations or warnings contained in the labeling cleared or approved by the FDA or other authorities.

With respect to our COVID-19 test, our commercial success could also depend on the availability and effectiveness of any vaccinations for COVID-19. Three vaccines for COVID-19 were authorized for emergency use as of March 2021. 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.

Additionally, even if our diagnostic tests achieve widespread market acceptance, they may not maintain that market acceptance over time if competing diagnostic tests or technologies, which are more cost effective or are received more favorably, are introduced. Failure to achieve or maintain market acceptance and/or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations.

We may experience research and development, regulatory, marketing and other difficulties that could delay or prevent our introduction of enhanced or new products and result in increased costs and the diversion of management's attention and resources from other business matters. For example, any molecular diagnostic tests that we may enhance or develop may not prove to be clinically effective, or may not meet our desired target product profile or be offered at acceptable cost and with the sensitivity, specificity and other test performance metrics necessary to address the relevant clinical need or commercial opportunity; our molecular diagnostic test performance in commercial settings may be inconsistent with our validation or other clinical data; we may not be successful in achieving market awareness and demand, whether through our own sales and marketing operations or entering into collaborative arrangements; the collaborative arrangements we enter into may not be successful or we may not be able to maintain those that are successful; healthcare providers may not use any tests that we may enhance or develop; or we may otherwise have to abandon a product or service in which we have invested substantial resources.

An important factor in our ability to commercialize our products is collecting data that supports the value proposition of our products, and in particular that our tests are just as accurate and reliable as central lab testing. The data collected from any studies we complete may not be favorable or consistent with our existing data or may not be statistically significant or compelling to the medical community or to third-party payors seeking such data for purposes of determining coverage for our products. Any of the foregoing could have a negative impact on our ability to commercialize our future products, which could have a material adverse effect on our business, financial condition and results of operations.

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

The DPA is a federal statute that confers upon the President of the United States a broad set of authorities to influence domestic industry in the interest of national defense. "National defense" can include emergency and disaster response and, since the start of the current COVID-19 crisis, the President of the United States has used this authority more than 30 times to address the public health crisis. Through the DPA, the executive branch has struck agreements with multiple companies to accelerate COVID-19 countermeasures, like N95 protective masks, testing swabs, and vaccine development, and, in September 2020, used the DPA to acquire point-of-care diagnostic testing instruments from two of our potential competitors for placement in nursing homes. The government has now also applied the DPA to our RADx contract to acquire our Talis One instrument, requiring us to prioritize their order over others. The government may similarly apply the DPA, or another law or program, to our other existing contracts or a new contract to acquire our testing instruments or to direct us to distribute our products in a particular

manner, and we may be likewise required to prioritize distribution to certain government agencies or other recipients, or to allocate inventory, supplies or facilities for government or government-directed use. The DPA provides that orders pursuant to the statute must "meet regularly established terms of sale or payment" and further provides that no person "shall be held liable for damages or penalties for any act or failure to act resulting directly or indirectly from compliance with a rule, regulation, or order" under the DPA. However, compliance with the DPA could potentially cause business disruption, interfere with our commercial sales and marketing efforts, and depending on the demand, could even prevent or delay our ability to sell our products commercially, or may have other implications that significantly affect our commercialization and development efforts and general ability to conduct our business operations as planned. For example, government directed use of our products under such a program may result in our instruments not being placed in settings where they will be used often for additional tests following the COVID-19 crisis which would adversely affect our long-term commercial plan that is based on the addition of multiple tests for use with the Talis One system. In addition, such government requirements may adversely affect our regular operations and financial results, result in differential treatment of customers and/or adversely affect our reputation and customer relationships. It is also possible that any change in the current administration could impact the manner in which the government uses the DPA and its other authorities, and result in additional or different risk to us.

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

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

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

Our success depends on physician and customer confidence that we can provide reliable and highly accurate diagnostic tests and enable better patient care. We believe that physicians and other healthcare providers are likely to be particularly sensitive to defects, errors or reliability issues in our products, including if our products fail to accurately diagnose infections with high accuracy from patient samples, and there can be no guarantee that our products will meet their expectations. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue as our product deliveries increase and our product portfolio expands.

Our products use a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors. For example, the Talis One system, comprised of a compact instrument, universal single-use assay cartridges and software, including a central cloud database, may contain

undetected errors or defects when first introduced or as new versions are released. Our diagnostic tests may contain errors or defects or be subject to reliability issues, and while we have made efforts to test them extensively, we cannot assure that our current diagnostic tests, or those developed in the future, will not have performance problems. An operational, technological or other failure in one of these complex processes or fluctuations in external variables may result in sensitivity or specificity rates that are lower than we anticipate or result in longer than expected turnaround times or they may cause our products to malfunction. Due to the complexity of our instrument and cartridge, it may be difficult or impossible to identify the reason for such performance. Performance issues would increase our costs in the near-term and accordingly adversely affect our business, financial condition and results of operations. In addition, failure to maintain high-quality customer support, or a market perception that we do not maintain high-quality customer support, could adversely affect our reputation and our ability to sell our Talis One system. We may also be subject to warranty claims or breach of contract for damages related to errors, defects or reliability issues in our products.

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

If our products do not perform, or are perceived to not have performed, as expected or favorably in comparison to competitive products, our operating results, reputation, and business will suffer, and we may also be subject to legal claims arising from product limitations, errors, or inaccuracies.

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

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

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

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

If we initiate a recall, including a correction or removal, for one of our commercialized products, issue a safety alert, or undertake a field action or recall to reduce a health risk, this could lead to increased scrutiny by the FDA, other governmental and regulatory enforcement bodies, and our customers regarding the quality and safety of our products, and to negative publicity, including FDA alerts, press releases, or administrative or judicial actions. Furthermore, the submission of these reports could be used against us by competitors and cause customers to delay purchase decisions or cancel orders, which would harm our reputation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our initial sales and marketing strategy is focused on enterprise accounts, including: (1) large elder care chains where vulnerable residents have unmet needs for millions of high sensitivity assays per year; (2) urgent care chains that serve on the front lines of COVID-19 diagnosis, needing millions of rapid tests to triage symptomatic patients; and (3) 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. Given the number of Talis One instruments we initially expect to have available for sale following any authorization, such strategy, may result in a customer base that is, initially, concentrated among one or a few customers. There are risks whenever a large percentage of total revenues are concentrated with a limited number of payers and customers. It is not possible for us to predict the level of demand for our diagnostic tests and services that will be generated by any of these customers in the future. If these largest customers were to significantly reduce their use of our instrument, leading to fewer cartridge sales than we are forecasting, it would have a material adverse effect on our business, financial condition and results of operations and could cause significant fluctuations in our results of operations.

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

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

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

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

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

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

We anticipate facing competition primarily from centralized laboratories and diagnostic companies offering both point-of-care and at-home solutions. Competitors include those offering molecular, antibody and antigen tests. Competitors in the reference lab category include Laboratory Corporation of America Holdings (commonly referred to as LabCorp) and Quest Diagnostics Incorporated, along with many hospital laboratories. Competitors with point-of-care molecular diagnostic technology platforms that are either currently available or that are in development include Abbott Laboratories, Binx Health, Inc., BioFire Diagnostics, LLC, Cepheid (a subsidiary of Danaher Corporation), Cue Health Inc., Lucira Health, Inc., Mesa Biotech, Inc. (recently acquired by Thermo Fischer Scientific Inc.), Roche Molecular Systems, Inc., and Visby Medical, Inc. Each of the preceding companies have received an EUA for a point-of-care COVID-19 test. There are also smaller or earlier-stage companies developing tests that may also prove to be significant competitors, in the COVID-19 market or in the women's health and/or sexual health markets. Many of our current or potential competitors, either alone or with their collaboration partners,

have significantly greater financial resources and expertise in research and development, manufacturing, regulatory clearance approval and compliance, and sales and distribution than we do. Mergers and acquisitions involving diagnostics companies may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies or customer networks. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize diagnostic products or services that are more accurate, more convenient to use or more cost-effective than our products or services. Our competitors also may obtain FDA or other regulatory clearance or approval for their products more rapidly than we may obtain clearance or approval or other marketing authorizations for ours, which could result in our competitors establishing a strong market position before we are able to enter a particular market.

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

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

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

Our estimates of the annual addressable markets for our COVID-19 test and the additional tests under development are based on a number of internal and third-party estimates as well as the assumed rates at which such products will be reimbursed, or the assumed prices at which we can sell our products for markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, including as a result of factors outside our control, thereby reducing the predictive accuracy of these underlying factors. Specifically, with respect to the market for our COVID-19 test, the market and competitive landscape are continuously changing. Any number of factors that are outside of our control could make our estimates invalid including the development and distribution of a safe and effective vaccine and/or effective therapies and interventions for COVID-19. Three vaccines for COVID-19 were authorized for emergency use by the FDA as of March 2021. 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.

If the actual number of patients who would benefit from our products, the price at which we can sell future products or the annual addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business, financial condition and results of operations.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For instance, legal, political and economic uncertainty surrounding the exit of the United Kingdom from the European Union (EU) may be a source of instability in international markets, adversely affect our operations in the EU and United Kingdom and pose additional risks to our business, financial condition, and results of operations. A severe or prolonged global economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our manufacturers and suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We are highly dependent on our senior management team and key personnel, and if we are unable to recruit, train and retain key personnel, we may not achieve our goals.

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

We do not maintain fixed-term employment contracts or key man life insurance with any of our employees. Competition for qualified personnel is intense. Our growth depends, in particular, on attracting, retaining and motivating highly skilled sales personnel with the necessary clinical background and ability to understand our systems at a scientific and technical level. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract, develop, retain and motivate qualified personnel could materially harm our operating results and growth prospects.

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

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

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

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

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

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

If the information technology systems of our third-party service providers and other contractors and consultants become subject to disruptions, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business, financial condition and results of operations.

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

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

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

Cyber-attacks are increasing in frequency and evolving in nature. We are at risk of attack by a variety of adversaries, including state-sponsored organizations, organized crime, hackers or "hacktivists" (activist hackers), through the use of increasingly sophisticated methods of attack, including long-term, persistent attacks referred to as advanced persistent threats. The techniques used to obtain unauthorized access or sabotage systems include, among other things, computer viruses, malicious or destructive code, ransomware, social engineering attacks (including phishing and impersonation), hacking and denial-of-service attacks. Furthermore, these techniques change frequently, and we may be unable to implement adequate preventative measures or stop security breaches while they are occurring. The recovery systems, security protocols, network protection mechanisms and other security measures that we have integrated into our applications, systems, networks and physical facilities, which are designed to protect against, detect and minimize security breaches, may not be adequate to prevent or detect service

interruption, system failure or data loss. Third parties may also exploit vulnerabilities in, or obtain unauthorized access to, platforms, applications, systems, networks and/or physical facilities utilized by our vendors. We have previously been, and may in the future become, the target of cyber-attacks by third parties seeking unauthorized access to our or our customers' data or to disrupt our operations or ability to provide our services. For example, we have been subject to phishing incidents and we may experience additional incidents in the future. Our applications, systems, networks and physical facilities are also subject to compromise from internal threats, such as theft, misuse, unauthorized access or other improper actions by employees, vendors and other third parties with otherwise legitimate access to our systems. Given the unpredictability of the timing, nature and scope of information technology disruptions, there can be no assurance that any security procedures and controls that we or our third-party service providers have implemented will be sufficient to prevent cyber-attacks from occurring. The latency of a compromise is often measured in months, but could be years, and we may not be able to detect a compromise in a timely manner. New techniques may not be identified until they are launched against a target, and we may be unable to anticipate these techniques or detect an incident, assess its severity or impact, react or appropriately respond in a timely manner or implement adequate preventative measures, resulting in potential data loss or other damage to our information technology systems.

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

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

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

We have contractual and legal obligations to notify relevant stakeholders of security breaches. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of security breaches involving certain types of data. In addition, our agreements with certain customers and partners may require us to notify them in the event of a security breach involving customer or partner data on our systems or those of subcontractors Processing customer or partner data on our behalf. Such mandatory disclosures are costly, could lead to negative publicity, may cause our customers to lose confidence in the effectiveness of our security measures, and require us to expend significant capital and other resources to respond to or alleviate problems caused by the actual or perceived security breach may cause us to breach customer contracts. Depending on the facts and

circumstances of such an incident, it may require us to spend material resources to investigate or correct the breach and to prevent future security breaches and incidents. The costs related to significant security breaches or disruptions could be material and exceed the limits of any cybersecurity insurance we maintain, increase our risk of regulatory scrutiny, expose us to legal liabilities, including litigation, regulatory enforcement, indemnity obligations or damages for contract breach, divert the attention of management from the operation of our business and cause us to incur significant costs, any of which could affect our financial condition, operating results and our reputation. Moreover, there could be public announcements regarding any such incidents and any steps we take to respond to or remediate such incidents, and if securities analysts or investors perceive these announcements to be negative, it could, among other things, have a substantial adverse effect on the price of our common stock. Such an event also could harm our reputation and result in litigation against us. In addition, our remediation efforts may not be successful. Any of the foregoing events could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

Our facilities are located in areas, which have experienced severe earthquakes and fires and are at risk for rolling or prolonged power outages. If these earthquakes, fires, other natural disasters, power outages health pandemics or epidemics, terrorism and similar unforeseen events beyond our control, including for example the ongoing COVID-19 pandemic, prevented us from using all or a significant portion of our facilities, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time and/or could result in the loss of commercial inventory or inventory and supplies required for our clinical trials. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence

or limited nature of our internal or third party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

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

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

- failure by us or our distributors to obtain regulatory clearance, authorization or approval for the use of our products in various countries;
- multiple, conflicting and changing laws and regulations such as privacy security and data use regulations, tax laws, export and import restrictions, economic sanctions and embargoes, employment laws, anti-corruption laws, regulatory requirements, reimbursement or payor regimes and other governmental approvals, permits and licenses;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining intellectual property protection and maintaining, defending and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- employment risks related to hiring employees outside the United States;
- logistics and regulations associated with shipping samples, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets if we are not able to sell our products locally;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act (FCPA), its books and records provisions, or its anti-bribery provisions, or laws similar to the FCPA in other jurisdictions in which we may now or in the future operate, such as the United Kingdom's Bribery Act of 2010 (U.K. Bribery Act); and
- onerous anti-bribery requirements of several member states in the EU, the United Kingdom, and other countries that are constantly changing and require disclosure of information to which U.S. legal privilege may not extend.

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

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

In order to eventually market any of our products in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding quality, safety, performance and efficacy. In addition, clinical trials or clinical investigations conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory clearance, authorization or approval in one country does not guarantee regulatory clearance, authorization or approval in any other country. For example, the performance characteristics of our products may need to be validated separately in specific ethnic and genetic populations. Marketing authorization processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking foreign regulatory clearance, authorization or approval could result in difficulties and costs for us and our collaborators and require additional preclinical studies, clinical trials or clinical investigations which could be costly and time-consuming. Regulatory requirements and ethical approval obligations can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The foreign regulatory clearance, authorization or approval process involves all of the risks and uncertainties associated with FDA clearance, authorization or approval. We have no experience in obtaining regulatory clearance, authorization or approval in international markets. If we or our collaborators fail to comply with regulatory requirements in international markets or to obtain and maintain required regulatory clearances, authorizations or approvals in international markets, or if those approvals are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

We may not have adequate insurance coverage.

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

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

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

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

The development and potential commercialization of products will require substantial additional capital to fund expenses. We may form or seek further strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to any products that we may develop and commercialize, including in territories outside the United States. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management’s time and attention in order to manage a collaboration or develop acquired technologies, incurrence of substantial debt or

dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or in-license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, or if there are materially adverse impacts on our or the counterparty's operations resulting from COVID-19, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement.

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

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

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

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

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

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

Risks related to regulatory matters

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

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

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our Talis One system and any tests we propose for use with it, are substantially equivalent to a legally marketed predicate device or safe or effective for their proposed intended uses, or meet other standards required to obtain relevant marketing authorizations;
- the disagreement of the FDA with the design or implementation of any clinical trials or the interpretation of data from preclinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from preclinical studies or clinical trials may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

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

- adverse publicity, warning letters, untitled letters, it has come to our attention letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure;
- operating restrictions, partial suspension or total shutdown of production;

- denial of our requests for regulatory clearance or PMA approval or other marketing authorization of new products, new intended uses or modifications to existing products;
- withdrawal of marketing authorization that have already been granted; or
- criminal prosecution.

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

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

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

The potential end-users of our Talis One system and diagnostic tests include 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. If these end-users do not receive adequate reimbursement for the cost of our products from their patients' healthcare insurers or payors, the use of our products could be negatively impacted. Furthermore, the net sales of our products could also be adversely affected by changes in reimbursement policies of government or private healthcare payors.

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

In the United States, if our products receive clearance or approval from the FDA, we expect that our customers will use standard industry billing codes, known as CPT codes, to bill for our tests. If these codes were to change, there is a risk of an error being made in the claim adjudication process. Such errors can occur with claims submission, third-party transmission or in the processing of the claim by the payer. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment received, either of which may materially impact the demand for our testing products. If we introduce new testing products, we may need to apply for new codes to describe our tests, which may not be approved or if approved, may not have adequate reimbursement rates, any of which could result in reduced demand for our tests or additional pricing pressures.

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

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

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

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

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

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

Modifications to any products for which we receive clearance, approval, or other marketing authorization may require new regulatory approvals, clearances, or marketing authorizations, including 510(k) clearances or PMA approvals, or in the case of our COVID-19 test, new EUAs, or require us to recall or cease marketing the modified systems until these clearances, approvals, or other marketing authorizations are obtained. The FDA requires device

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

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

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

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

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

- we may be required to submit an IDE application to the FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators and/or an Institutional Review Board (IRB), or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations (CROs), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- regulators, IRBs, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- approval policies or regulations of the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

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

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

engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

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

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

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

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

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

In addition, we are required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as the QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device

we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

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

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

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

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

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

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

Changes in funding or disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner, or at all,

or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

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

Disruptions at the FDA and other agencies may also slow the time necessary for new product applications to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including for 35 days beginning on December 22, 2018, the U.S. government shut down several times and certain regulatory agencies, including the FDA, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities. On March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. 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 resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

We do not have the ability to independently conduct clinical trials that may be required to obtain FDA and other regulatory clearance or approval for future diagnostic products. Accordingly, we expect that we would rely on third parties, such as, laboratories, clinical investigators, CROs, consultants, and collaborators to conduct such studies if needed. Our reliance on these third parties for clinical and other development activities would reduce our control over these activities but will not relieve us of our responsibilities. We will remain responsible for ensuring that each of our clinical studies is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us to comply with standards, commonly referred to as GCPs, for conducting, recording and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of patients in clinical studies are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to current GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, including on account of the outbreak of infectious disease, such as the COVID-19 pandemic, or otherwise, we may be affected by increased costs, program delays or both, any resulting data may be unreliable or unusable for regulatory purposes, and we may be subject to enforcement action.

If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised, our preclinical development activities or clinical trials may be extended, delayed, suspended or

terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected.

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

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

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

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

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

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

In the United States, Data Protection Laws include rules and regulations promulgated under the authority of the Federal Trade Commission, the Electronic Communications Privacy Act, the Computer Fraud and Abuse Act, the California Consumer Privacy Act of 2018, or CCPA, and other state and federal laws relating to privacy and data security. Many states in which we operate have laws that protect the privacy and security of sensitive and personal information, including health-related information. Certain of these laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, the CCPA, which increases privacy rights for California residents and imposes stringent data privacy and security obligations on companies that process their personal information, came into effect on January 1, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers about their data collection, use and sharing practices and provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This

private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CCPA has been amended from time to time, and it is possible that further amendments will be enacted, but even in its current form it remains unclear how various provisions of the CCPA will be interpreted and enforced. The CCPA may increase our compliance costs and potential liability. In addition, California voters recently approved the California Privacy Rights Act of 2020 (CPRA) that goes into effect on January 1, 2023. The CPRA would, among other things, give California residents the ability to limit the use of their sensitive information, provide for penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the law. The enactment of the CCPA is prompting a wave of similar legislative developments in other states in the United States, which could create the potential for a patchwork of overlapping but different state laws. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business, results of operations, and financial condition. Some countries also are considering or have passed legislation requiring local storage and Processing of data, or similar requirements, which could increase the cost and complexity of operating our business. The enactment of the CCPA is prompting a wave of similar legislative developments in other states in the United States, which could create the potential for a patchwork of overlapping but different state laws. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, and there is continuing discussion in Congress of a new federal data protection and privacy law to which we would become subject if it is enacted. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products involving data are offered, all of which may have a material and adverse impact on our business, financial condition and results of operations.

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

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

Further, following a referendum in June 2016 in which voters in the United Kingdom approved an exit from the EU, the United Kingdom government has initiated a process to leave the EU, known as Brexit. Following December 31, 2020, the GDPR's data protection obligations continue to apply to the United Kingdom in substantially unvaried form under the so called "UK GDPR" or more explicitly, the GDPR continues to form part of the laws in the United Kingdom by virtue of section 3 of the European Union (Withdrawal) Act 2018, as amended (including by the various Data Protection, Privacy and Electronic Communications (EU Exit) Regulations), which potentially exposes us to two parallel data protection regimes, each of which authorizes fines and the potential for divergent enforcement actions. In addition, it is still unclear whether the transfer of personal data from the EU to the United Kingdom will in the future continue to remain lawful under the GDPR. For example, pursuant to a post-Brexit agreement between the United Kingdom and the EU, the European Commission will continue to treat the United Kingdom as if it remained a member state of the EU in relation to transfers of personal data from the EEA to the United Kingdom, meaning such transfers may be made without a need for additional safeguards, for four months from January 1, 2021, with a potential additional two month extension. This "transition" period, however, will end if and when the European Commission adopts an adequacy decision in respect of the United Kingdom or the United Kingdom amends certain UK data protection laws, or relevant aspects thereof, without the EU's consent (unless those amendments are made simply to align those UK data protection laws with the EU's data protection regime). If the European Commission does not adopt an adequacy decision with regard to personal data transfers to the United Kingdom before the expiration of the transition period, from that point onwards, the United Kingdom will be a "third country" under the GDPR and such transfers will need to be made subject to GDPR-compliant safeguards (for example, the Standard Contractual Clauses). With substantial uncertainty over the interpretation and application of how United Kingdom will approach and address GDPR following the transition period, we may face challenges in addressing their requirements and making necessary changes to our policies and practices, and may incur significant costs and expenses in an effort to do so. Any failure or perceived failure by us to comply with applicable laws and regulations or any of our other legal obligations relating to privacy, data protection, or information security may result in governmental investigations or enforcement actions, litigation, claims, or public statements against us. Any of the foregoing could result in significant liability or cause our customers to lose trust in us, any of which could have an adverse effect on our reputation, operations, financial performance and business. Furthermore, the costs of compliance with, and other burdens imposed by, the laws, regulations, and policies that are applicable our businesses may require us to modify our data Processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products involving data are offered, all of which may have a material and adverse impact on our business, financial condition and results of operations.

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

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

We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation and application of health-related and data protection laws, regulations, standards and other obligations are still

uncertain, and often contradictory and in flux, it is possible that the scope and requirements of these laws may be interpreted and applied in a manner that is or is alleged to be inconsistent with our management and Processing practices and our efforts to comply with the evolving data protection rules may be unsuccessful.

Any failure or perceived failure by us to comply with our Privacy Policies and our privacy-, data protection-, or information security-related obligations to customers or other third parties or any of our other legal obligations relating to privacy, data protection, or information security may result in governmental investigations or enforcement actions, litigation, claims, or public statements against us by consumer advocacy groups or others, and could result in significant liability or cause our customers to lose trust in us, which could have an adverse effect on our reputation and business.

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

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

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

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

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

- the federal 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 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 ACA, which require certain manufacturers of drugs, devices, biologics and medical supplies to report to the CMS, information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, and certain ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and other transfers of value made to or at the request of physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including our planned reagent rental program or other sales and marketing practices, could be subject to challenge under one or more of such laws. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including, among others, significant administrative, civil and criminal penalties, damages, fines, disgorgement, imprisonment, integrity oversight and reporting obligations, and exclusion from participation in government funded healthcare programs such as Medicare and Medicaid. Additionally, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously 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 system *using our COVID-19 assay kit may harm our reputation in the marketplace, result in false test results that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.*

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

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

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

We have received grant funding from the U.S. federal government, including through a grant from the NIH, National Institute of Allergy and Infectious Diseases, a sub-award from the Biomedical Advanced Research and Development Authority Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) program, a sub-award from the NIH RADx program, and an NIH RADx grant. We anticipate that a portion of the funding for the development of our technologies will come from these agreements, which provide for grant funds ultimately from the government. Our ability to receive the remaining funding provided for under the agreements is dependent on the government and the higher-tier grantees in connection with our sub-awards exercising additional options under the agreements, which they may do or not do at their sole discretion. In addition, activities covered under the base periods and exercised options may ultimately cost more than is covered by the grants and sub-awards or require a longer performance periods to complete than are remaining on our agreements; if we are unable to secure additional funding or allow for additional time for completion, we would have to incur additional costs to complete the activities or terminate the activities before completion. Moreover, the continuation of our agreements depends in large part on our ability to meet development milestones previously agreed to and on our compliance

with certain operating procedures and protocols. For instance, work under the CARB-X program is subject to certain unique commercialization, regulatory approval, and access requirements related to developed products and technology, and public access to research results. These agreements may be suspended or terminated should we fail to achieve key milestones, or fail to comply with the operating procedures and processes approved by the government and its audit agencies. There can be no assurance that we will be able to achieve these milestones or continue to comply with these procedures and protocols. Moreover, changes in government budgets and agendas may result in a decreased and deprioritized emphasis on supporting the development of our programs. While the NIH has provided funding for and has indicated a potential for future funding for many activities associated with combating COVID-19, the availability and focus for any NIH funding will likely be finite and may require us to compete with other technologies, both similar and disparate. If our agreements are terminated or suspended, if there is any reduction or delay in funding under our agreements, or if the government or higher-tier grantees determine not to exercise some or all of the options provided for under the agreements, our revenues and cash flows would be significantly and negatively impacted and we may be forced to seek alternative sources of funding, which may not be available on non-dilutive terms, terms favorable to us or at all. If alternative sources of funding are not available, we may be forced to suspend or terminate certain of our related development activities. Furthermore, should we be unable to deploy personnel or derive a benefit from fixed study costs or generate data from clinical sites and studies reimbursed through the agreements, our cash flows would be negatively impacted or we may have to initiate furloughs and layoffs which would likely prove disruptive to our management and operations. This in turn would impair our ability to recommence and complete studies if and when the COVID-19 crisis subsides and we are able to restart many suspended or delayed activities.

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

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

- suspend or prevent us for a set period of time from receiving new government contracts or grants or extending our existing agreements based on violations or suspected violations of laws or regulations;
- claim and exercise nonexclusive, nontransferable rights to products manufactured and intellectual property and data developed and generated under the agreements and may, under certain circumstances, license such inventions to third parties without our consent;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such contracts and grants;
- cancel, terminate or suspend our agreements based on violations or suspected violations of laws or regulations;
- terminate our agreements in whole or in part for convenience for any reason or no reason, including if funds become unavailable;
- reduce the scope and value of our agreements;
- decline to exercise an option to continue the agreements;
- direct the course of the development of the programs in a manner not chosen by us;
- require us to perform the option periods provided for under the agreements even if doing so may cause us to forego or delay the pursuit of other program opportunities with greater commercial potential;
- take actions that result in longer development timelines than expected; and
- change certain terms and conditions in our agreements.

Generally, government contracts and grants, including our grant and sub-award agreements, contain provisions permitting unilateral termination or modification, in whole or in part. Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed, plus a portion of the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

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

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

On December 14, 2018, a Texas District Court Judge ruled that the entire ACA is invalid based primarily on the fact that the 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 December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the Texas District Court Judge's ruling that the individual mandate was unconstitutional and remanded the case back to the district court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, although it is unclear when a decision will be made. Although the Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs 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 unclear how the Supreme Court ruling, other such litigation and the healthcare reform measure of the Biden administration will impact the ACA or our business.

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

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

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

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

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

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

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

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

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

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

Risks related to our intellectual property

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

Our commercial success depends in part upon our ability to develop, manufacture, market and sell our products and use our technology without infringing, misappropriating or otherwise violating the patents, trademarks or other intellectual property or proprietary rights of third parties. We cannot assure you that technologies we may develop will not infringe existing or future patents owned by third parties. Litigation relating to infringement, misappropriation or other violations of intellectual property rights in biotechnology industry is common, unpredictable and generally expensive and time consuming, including patent infringement lawsuits, trade secret lawsuits, interferences, oppositions, and *inter-partes* review, post-grant review and reexamination proceedings

before the United States Patent and Trademark Office (USPTO), and corresponding international patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biotechnology industry, have employed intellectual property litigation as a means to gain an advantage over their competitors. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In the future, we may also be subject to third-party claims and adversarial proceedings or litigation regarding infringement, misappropriation or other violation by us of patent, trademark or other intellectual property rights of third parties. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties. If any such claim or proceeding is brought against us, our collaborators or our third-party service providers, our development, manufacturing, marketing, sales and other commercialization activities could be similarly adversely affected. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that third party patents asserted against us are valid, enforceable, and infringed, which could materially and adversely affect our ability to develop, manufacture, market, sell and commercialize any of our products. To successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe any third party's patents or other intellectual property rights, and we are unsuccessful in demonstrating that such patents or other intellectual property are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing, marketing, selling and commercializing our products. However, we may not be able to obtain any required license on commercially reasonable terms or at all, and if we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, our ability to commercialize our products may be impaired or delayed, which could in turn significantly harm our business. Even if we were able to obtain a license, it could be non-exclusive, which would give our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing, royalty and other payments. We also could be forced, including by court order, to cease developing, manufacturing, marketing, selling and commercializing the infringing product or technology. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

receive, and expect to receive, communications from various industry participants alleging our infringement of their patents, trade secrets or other intellectual property rights and/or offering licenses to such intellectual property.

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

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

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

If we were to initiate legal proceedings against any other third party to enforce a patent covering our technology, the defendant could assert that our patent is invalid or unenforceable. If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering our technologies, the defendant could counterclaim we infringe their patents or that the patent covering our technology is invalid or unenforceable, or both. In patent litigation in the United States and Europe, defendants alleging invalidity or unenforceability are common. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness, lack of written description or non-enablement. Third parties might allege unenforceability of our patents because during prosecution of the patent an individual connected with such prosecution withheld relevant information, or made a misleading statement. There is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. Third parties may also raise challenges to the validity of our patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter-partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or products and that we do not have the right to stop the other party from using the invention at issue. The outcome of proceedings involving assertions of invalidity and unenforceability, including during patent litigation, is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution, but that an adverse third party may identify and submit in support of such assertions of invalidity. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our

patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). Such a loss of patent protection could have a material adverse effect on our business. Our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights. Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of our licensors.

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

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

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

- we or our licensors may not have been the first to invent the technology covered by our pending patent applications or issued patents;
- we or our licensors may not be the first to file all patent applications covering our methods or products, as patent applications in the United States and most other countries are confidential for a period of time after filing;
- our products and related methods may not be patentable;

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

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

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

challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products and technology, or limit the duration of the patent protection of our products and technology. Such proceedings also may result in substantial cost and require significant time from our employees and management, even if the eventual outcome is favorable to us.

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

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

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

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

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

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

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

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

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

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

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

Patents relating to certain components of our Talis One cartridge are controlled by a third party. Such third party has rights to file, prosecute, maintain, and defend the patents we have licensed from such licensor. If our

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

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

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

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

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

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

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

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

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

similarly apply. Any exercise by the government of such rights could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

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

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

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

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

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

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

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

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

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

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

Furthermore, proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, subject our patents to the risk of being invalidated or interpreted narrowly, subject our patent applications to the risk of not issuing or provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies

awarded to us, if any, may not be commercially meaningful, while the damages and other remedies we may be ordered to pay such third parties may be significant. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

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

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

Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

We may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

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

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

agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

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

A portion of our products incorporate so-called "open source" software and we may incorporate open source software into other products or technologies in the future. Such open source software is generally licensed by its authors or other third parties under open source licenses. Some open source licenses contain requirements that we disclose source code for modifications we make to the open source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of our software in connection with open source software could require that we disclose and license some or all of our proprietary code in that software as well as distribute our products that use particular open source software at no cost to the user. We monitor our use of open source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code, however, there can be no assurance that such efforts will be successful. Open source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of certain of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding our products and technologies. Companies that incorporate open source software into their products have, in the past, faced claims seeking enforcement of open source license provisions and claims asserting ownership of open source software incorporated into their product. If an author or other third party that distributes such open source software were to allege that we had not complied with the conditions of an open source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our products. In addition, if we combine our proprietary software with open source software in certain ways, under some open source licenses we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than ours and otherwise have a material adverse effect on our business.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products or provide services that are similar to ours but that are not protected by our intellectual property;
- we or our licensors might not have been the first to make the inventions covered by our patents;
- we or our licensors might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- issued patents for which we have rights may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products in our commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;

- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may fail to adequately protect and police our trademarks and trade secrets;
- the patents of others may harm our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications; and
- we or our licensors may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks related to our financial condition and capital requirements

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

We have historically incurred substantial net losses, including net losses of $91.1 million and $27.5 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020 and 2019, we had an accumulated deficit of $172.9 million and $81.8 million, respectively. We expect our losses to continue as we continue to devote a substantial portion of our resources to efforts to the commercial launch of the Talis One system and COVID-19 assay kit, and thereafter to increase the adoption of our products, improve these products, scale our manufacturing capabilities and research, develop and commercialize new products. We 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 general and administrative expenses.

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

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

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

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

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

Risks related to ownership of our common stock

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

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

- actual or anticipated fluctuations in our financial condition or results of operations;
- variance in our financial performance from expectations of securities analysts;
- changes in the pricing of our products;
- changes in our projected operating and financial results;
- changes in laws or regulations applicable to our products;

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

These and other factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In recent years, stock markets in general, and the market for life science technology companies in particular (including companies in the genomics, biotechnology, diagnostics and related sectors), have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. From February 12, 2021 through March 26, 2021, the closing price of our common stock has ranged between $11.02 and $33.90 per share. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance.

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

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

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

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

In addition, there were 7,737,095 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2020. We registered all of the shares of common stock issuable upon exercise of such outstanding options or other equity incentives we may grant in the future, for public resale under the Securities Act of 1933, as amended (Securities Act). The shares of common stock will become eligible for sale in the public market to the extent such options are exercised, subject to the lock-up agreements described above and compliance with applicable securities laws.

Further, based on shares outstanding as of December 31, 2020, holders of approximately 37,419,106 shares, or 67.3% 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. In this Annual Report, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. 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 February 17, 2021, our executive officers, directors and five percent or greater stockholders and their respective affiliates, beneficially own, in the aggregate, approximately 72.5% of our outstanding voting stock. Further, 67.5% of our outstanding voting stock is owned by entities affiliated with Baker Bros. Advisors LP (Baker Bros.). In addition, the holders of our Series 1 convertible preferred stock, which, subject to certain limitations, is a voting common stock equivalent, may elect to convert shares of Series 1 convertible preferred stock into shares of Series 2 convertible preferred stock, which is a non-voting common stock equivalent. These shares of Series 2

convertible preferred stock are then convertible into shares of our common stock, subject to certain beneficial ownership limitations.

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

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

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

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

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

material weakness, we have begun undertaking specific remediation actions to address the material weakness in our financial reporting which are outlined elsewhere in this Annual Report on Form 10-K.

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

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

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

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

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

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that

our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66 2/3% of the voting power of all of our then outstanding capital stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

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

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

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

Item 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 October 2021. In January 2021, we

entered into a lease agreement that expires in May 2032 for approximately 37,500 square feet of office and laboratory space in Redwood City, California, with expected occupancy to commence in the fourth quarter of 2021. 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, with expected occupancy to commence in the second quarter of 2021. In addition, we also occupy office space in a number of rooms at a co-working facility in Chicago, Illinois, pursuant to a month-to-month agreement. 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. We are currently not a party to any material legal proceedings. Information with respect to certain legal matters is included within “Contingencies” in Note 7 to the financial statements contained in Item 8. Financial and Supplementary Data and is incorporated herein by reference.

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.

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, and during the year ended December 31, 2020, there was no public market for our common stock. As of March 26, 2021, we had approximately 97 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

During the year ended December 31, 2020, we sold and issued the following unregistered securities:

- 2,289,899 shares and 11,187,189 shares of our Series E-1 and Series E-2 convertible preferred stock, respectively, during the Series E initial closing for combined net proceeds of $99.7 million
- 4,859,897 and 9,958,539 shares of our Series F-1 and Series F-2 convertible preferred stock shares of our Series F-2 convertible preferred stock, each at a purchase price of $8.55 per share, and received net proceeds of approximately $123.5 million

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering, and the Registrant believes each transaction was exempt from the registration requirements of the Securities Act as stated above.

Use of Proceeds

On February 17, 2021, we completed our initial public offering of our common stock in which we sold 15,870,000 shares of common stock (including shares issued pursuant to the exercise in full of the underwriters' option to purchase additional shares). The shares sold in the offering were registered under the Securities Act pursuant to our Registration Statement on Form S-1 (File No: 333-252360), which was declared effective by the SEC on February 11, 2021. We incurred offering expenses of approximately $21.3 million for net proceeds of $232.6 million. There has been no material change in the planned use of proceeds from our IPO 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.

J.P. Morgan Securities LLC, BofA Securities, Inc. and Piper Sandler & Co. acted as joint book running managers of the offering and as representatives of the underwriters.

Securities authorized for issuance under equity incentive plans

We have granted stock options to purchase an aggregate of 8,181,521 shares of our common stock to employees, directors and consultants pursuant to the 2013 Equity Incentive Plan during the twelve months ending December 31, 2020 at a weighted average exercise price of $4.14 per share. During the twelve months ending December 31, 2020, there were 10,671 exercises of stock options at a weighted average price of $1.51 per share.

The 2021 Equity Incentive Plan, which became effective upon completion of the IPO on February 17, 2021, serves as the successor equity incentive plan to the Company's 2013 Equity Incentive Plan. Initially, the maximum number of shares of our common stock that may be issued under our 2021 Plan will not exceed 12,840,904 shares of

our common stock. In addition, the number of shares of our common stock reserved for issuance under our 2021 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2022 through January 1, 2031, in an amount equal to (i) 4% of the total number of shares of our common stock outstanding on December 31 of the preceding year, or (ii) a lesser number of shares determined by our board of directors prior to the applicable January 1. The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2021 Plan is 39,000,000 shares.

In addition, the Company adopted the 2021 Employee Stock Purchase Plan (ESPP), which became effective upon completion of our initial public offering. The maximum number of the Company's common stock which will be authorized for sale under the ESPP is equal to 550,000 shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2022, through January 1, 2031, by the lesser of (1) 1% of the total number of shares of our common stock outstanding on December 31st of the preceding year and (2) 1,550,000 shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (1) and (2). As of the date hereof, no shares of our common stock have been purchased under the ESPP.

Item 6. Selected Financial Data.

Not applicable.

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

Our products will require marketing authorization from the FDA prior to commercialization. Due to the COVID-19 global pandemic, we plan to pursue marketing authorization for our COVID-19 test 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 capable of producing one million Talis One cartridges per month for the COVID-19 assay, which are scheduled to begin to come on-line in the first quarter of 2021 and we expect will scale to full capacity through 2021. These manufacturing lines will be located at our contract manufacturers' sites and operated by our contract manufacturing partners. We have also ordered 5,000 Talis One instruments from our instrument contract manufacturer through the first half of 2021.

Since our inception in 2013, we have devoted substantially all our efforts to research and development activities, manufacturing capabilities, raising capital, building our intellectual property portfolio and providing general and administrative support for these operations. We have principally financed our operations through the

issuance and sale of shares of our convertible preferred stock to outside investors in private equity financings as well as the issuance of convertible promissory notes and receipts from government grants. Prior to our initial public offering we received $351.5 million from investors in our preferred stock financings and the sale of convertible promissory notes that converted in such financings. Additionally, on February 17, 2021, the Company raised $232.6 million through an initial public offering to finance operations going forward.

We have incurred recurring losses since our inception, including net losses of $91.1 million and $27.5 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $172.9 million. We expect to continue to generate operating losses and negative operating cash flows for the foreseeable future if and as we:

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

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

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

As of December 31, 2020, we had unrestricted cash of $138.5 million. We expect that our cash of $138.5 million as of December 31, 2020 along with the proceeds from our initial public offering will be sufficient to fund our operations through at least the next 12 months. We may need substantial additional funding to support our continuing operations and pursue our long-term business plan. We may seek additional funding through the issuance of our common stock, other equity or debt financings, or collaborations or partnerships with other companies. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our research efforts for our assays and development and manufacturing activities. We may not be able to raise additional capital on terms acceptable to us, or at all. Any failure to raise capital as and when needed would compromise our ability to execute on our business plan and may cause us to significantly delay or scale back our operations.

We outsource essentially all of our manufacturing. Design work, prototyping and pilot manufacturing are performed in-house before outsourcing to third party contract manufacturers. Our outsourced production strategy is intended to drive rapid scalability and avoid the high capital outlays and fixed costs related to constructing and operating a manufacturing facility. Certain of our suppliers of components and materials are single source suppliers.

To support our anticipated commercial launch, we have invested in automated cartridge manufacturing production lines for our Talis One cartridges. Those assets deemed to have an alternative future use have been capitalized as property and equipment while those assets determined to not have an alternative future use have been expensed. The automated cartridge manufacturing lines are capable of producing one million Talis One cartridges per month, which we expect will scale to full capacity through 2021.

COVID-19 pandemic

Since it was reported to have surfaced in December 2019, a novel strain of coronavirus (COVID-19) has spread across the world and has been declared a pandemic by the World Health Organization. Efforts to contain the spread of COVID-19 have intensified and governments around the world, including in the United States, Europe and Asia, have implemented travel restrictions, social distancing requirements, stay-at-home orders and have delayed the commencement of non-COVID-19-related clinical trials, among other restrictions. As a result, the current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as contributing to significant volatility and negative pressure on the U.S. economy and in financial markets.

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

As a result of the outbreak, many companies have experienced disruptions in their operations and in markets served. We are considered an essential business and therefore the impact to our operations has been limited. To date, we have initiated some and may take additional temporary precautionary measures intended to help ensure our employees' well-being and minimize business disruption. For the safety of our employees and their families, we have temporarily reduced the presence of our employees in our 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 2021. 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. If our development efforts for our system are successful and result in regulatory approval, 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 no additional charge 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 if, when, or to what extent we will generate revenue from the commercialization and sale of our system. We may never succeed in obtaining regulatory approval for our system. Growth and predictability of recurring revenue is impacted by the mix between these options. 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

To date, all of our revenue has been derived from government grants, which includes an April 2018 subaward grant from Boston University as part of the CARB-X initiative, a May 2018 grant from the NIH to support our advancement of a Diagnostics via Rapid Enrichment, Identification, and Phenotypic Antibiotic Susceptibility Testing of Pathogens from Blood project (NIH grant), a July 2020 subaward grant from the University of Massachusetts Medical School for Phase 1 of the NIH's RADx initiative and a $25.4 million contract from the NIH directly for Phase 2 of the RADx initiative. The CARB-X, NIH grant and RADx initiative included initial funding of $4.4 million through September 2019, $1.3 million through April 2019, and $10.1 million based on achieving certain milestones, respectively. The initial funding term of the CARB-X grant was extended through September 30, 2020 and our initial funding was increased by $1.2 million. We also exercised our second one-year option under the NIH grant, extending the term through April 30, 2021. Under the CARB-X and NIH grant there is the possibility of an additional $2.8 million of funding through June 2021 and an additional $2.2 million of funding through April 2023, respectively. Under RADx there is the possibility of an additional $16.5 million of funding through July 2021.

These grants are not in scope of Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers* (ASC 606) as the government entities and/or government-sponsored entities are not customers under the agreements.

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

Operating expenses

Research and development expenses

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

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

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

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

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

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

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate and business development and administrative functions. General and administrative expenses also include professional fees for legal, patent, accounting, information technology, auditing, tax and consulting services, travel expenses and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization and sales of our platform. We also expect to incur increased expenses associated with being a public company, including costs of

accounting, audit, legal, regulatory and tax compliance services, director and officer insurance costs, and investor and public relations costs.

Other income (expense)

Other income (expense), net primarily consists of interest expense on a convertible promissory note held during 2019 as well as the change in estimated fair value of our convertible notes. We elected the fair value option to account for these convertible notes and fluctuations in the estimated fair value of our convertible notes were based on the remeasurement at each reporting period until conversion and/or settlement. In December 2019, we converted the convertible notes' aggregate contractually calculated principal amount, plus accrued and unpaid interest, of $19.0 million into 6,937,252 shares of Series D-2 convertible preferred stock at a conversion price of $2.74 per share.

Results of operations

Comparison for the twelve months ended December 31, 2020 and 2019

The following table summarizes our results of operations:

	Twelve Months Ended December 31,		
(in thousands)	**2020**	**2019**	**Change**
Grant revenue	$ 10,938	$ 3,977	$ 6,961
Operating expenses:			
Research and development	89,019	23,812	65,207
General and administrative	13,103	6,864	6,239
Total operating expenses	102,122	30,676	71,446
Loss from operations	(91,184)	(26,699)	(64,485)
Other (expense) income, net	54	(775)	829
Net loss and comprehensive loss	$ (91,130)	$ (27,474)	$ (63,656)

Grant revenue

Our revenue for the twelve months ended December 31, 2020 and 2019 relates to the CARB-X and NIH grants and the RADx initiative. During the twelve months ended December 31, 2020, $0.6 million, $1.1 million and $9.3 million of revenue was recognized related to the CARB-X, NIH and RADx grants, respectively. During the twelve months ended December 31, 2019, $3.1 million and $0.8 million of revenue was recognized related to the CARB-X and NIH grants, respectively. The changes in revenue recognized for the grants period over period were primarily a result of achieving RADx development targets during the twelve months ended December 31, 2020 offset by a reduction in revenue as a result of the expiration of the CARB-X grant. The increase in revenue of $9.3 million relating to the RADx initiative was offset by approximately $2.6 million between December 31, 2019 and 2020 as a result of the completion of the CARB-X grant in 2020.

Research and development expenses

Substantially all of our research and development expenses incurred for the twelve months ended December 31, 2020 were related to the development of our first potential commercial product utilizing the Talis One system, a rapid, point-of-care molecular diagnostic test to detect COVID-19 directly from a patient sample.

Research and development expenses were $89.0 million for the twelve months ended December 31, 2020, compared to $23.8 million for the twelve months ended December 31, 2019, an increase of $65.2 million. The increase was primarily due to increases of $40.9 million related to the ramp up of manufacturing efforts, an increase of $11.9 million in instrument expenses, an increase $6.6 million relating to Talis One cartridges for the COVID-19 assay, and an increase of $6.4 million related to personnel related expenses, including stock compensation expenses, as we increased full-time and temporary headcount. These increases were offset by a $0.8 million decrease in contracting expenses relating to research and development. We expect our research and development expenses to

increase over the near term as we continue to scale up our manufacturing capacity in anticipation of commercial launch of the Talis One system.

The ramp up of the Company's manufacturing efforts, which began in the middle of 2020, is expected to result in a significant increase in our research and development expenses through regulatory approval and launch of our initial products is achieved. As of December 31, 2020, we have incurred approximately $40.9 million related to such manufacturing scale-up costs. We expect to incur approximately $72.8 million of additional costs in the near term, of which we expect approximately $52.8 million to be recognized in research and development expense until we receive an EUA, at which point we will start capitalizing these costs. The Company plans to submit an EUA application for the Talis One system and COVID-19 assay cartridges in Q2 2021. See "Liquidity and capital resources- Future funding requirements" below for additional information.

General and administrative expenses

General and administrative expenses were $13.1 million for the twelve months ended December 31, 2020, compared to $6.9 million for the twelve months ended December 31, 2019, an increase of $6.2 million. The increase was primarily due to increased personnel related expenses of $3.9 million, including salaries and wages and stock compensation expenses, as we hired new administrative employees, and increased outside services, audit, legal and other expenses of $2.2 million related to corporate and intellectual property activities.

Other income (expense)

Other income was $0.1 million for the twelve months ended December 31, 2020, compared to other expense of $0.8 million for the twelve months ended December 31, 2019. The change of $0.8 million was primarily due to the change in the estimated fair value of the convertible notes of $0.8 million between their issuance and settlement in 2019. The overall change in fair value was primarily driven by the change in the estimated fair value of our preferred stock over this period.

Liquidity and capital resources

Sources of liquidity

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 $232.6 million after deducting underwriting discounts and commissions and other offering expenses.

Since inception and through December 31, 2020, we have raised $351.5 million from the sale of convertible preferred stock and the issuance of convertible promissory notes, which we have used to fund our operations. In the first half of 2020, we received net proceeds of $24.9 million related to issuances of our Series C-1, D-1, and D-2 convertible preferred stock. In the second half of 2020, we issued and sold 2,289,899 shares and 11,187,189 shares of our Series E-1 and Series E-2, for net proceeds of $99.7 million and 4,859,897 and 9,958,539 shares of our Series F-1 and Series F-2 convertible preferred stock, respectively, for net proceeds of $123.6 million.

In the second half of 2020, we were awarded a $25.4 million contract from the NIH for Phase 2 of its RADx initiative, of which, $8.9 million had been received as of December 31, 2020.

Between June 2020 and August 2020, we executed and amended a standby letter of credit (LOC) loan with JPMorgan Chase Bank, N.A. (JPMC) for up to $33.0 million, as terms of collateral that were required by one of our contract manufacturing organizations. The LOC was set to expire on December 31, 2020 but automatically extended to December 31, 2021 when we did not terminate the agreement 90 days prior to the original expiration date. Interest on any borrowings under the LOC agreement is equal to the lesser of (a) Prime plus 2% and (b) the highest rate permitted by applicable law and is payable on demand. The LOC requires us to maintain a cash balance of $34.7 million as collateral.

As of December 31, 2020, we had unrestricted cash of $138.5 million. We believe our cash balance as of December 31, 2020 and our proceeds from IPO of $232.6 million 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.

Future funding requirements

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

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

To date, our primary uses of cash have been to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We currently have no other ongoing material financing commitments, such as other lines of credit or guarantees. We have recently increased our spending on automated cartridge manufacturing scale-up and instrument manufacturing, and expect expenses related to manufacturing to increase significantly as we prepare for a potential commercial launch as early as the second quarter of 2021. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our platform. In addition, if we obtain marketing approval for our platform, we expect to incur significant commercialization expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of any future collaborators. We expect to incur additional costs associated with operating as a public company. Accordingly, we may choose to obtain additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Since our inception, we have incurred significant losses and negative cash flows from operations. We have an accumulated deficit of $172.9 million through December 31, 2020. We expect to incur substantial additional losses in the future as we conduct and expand our research and development, manufacturing and commercialization activities. Based on our planned operations, we expect that our unrestricted cash of $138.5 million as of December 31, 2020, together with the proceeds from our February 2021 initial public offering, will be sufficient to fund our operations for at least 12 months after these financial statements are issued. However, we may need to raise additional capital through equity or debt financing, or potential additional collaboration proceeds prior to achieving commercialization of our products. Our ability to continue as a going concern is dependent upon our ability to successfully secure sources of financing and ultimately achieve profitable operations.

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

- our ability to receive, and the timing of receipt of, an EUA for our COVID-19 test;
- the effectiveness and availability of the three vaccines that were authorized as of March 2021;

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

Cash flows

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

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Cash used in operating activities	$ (87,024)	$ (24,326)
Cash used in investing activities	(8,201)	(578)
Cash provided by financing activities	246,754	39,613
Net increase in cash and restricted cash	$ 151,529	$ 14,709

Operating activities

During the year ended December 31, 2020, cash used in operating activities was $87.0 million, resulting primarily from our net loss of $91.1 offset by non-cash items of $5.1 million (primarily made up of stock-based compensation of $3.7 million and depreciation expense of $0.8 million), an increase in prepaid research and development of $11.5 million and increases in accounts payable of $3.2 million and accrued expenses and other current liabilities of $7.3 million.

During the year ended December 31, 2019, cash used in operating activities was $24.3 million, resulting primarily from our net loss of $27.5 million, partially offset by non-cash items of $2.5 million (primarily changes in the estimated fair value of convertible notes of $0.8 million, stock-based compensation of $1.0 million, and depreciation expense of $0.7 million) and a net increase of $0.6 million in accounts payable and accrued expenses and other current liabilities.

Investing activities

During the years ended December 31, 2020 and 2019, we used $8.2 million and $0.6 million of cash, respectively, for investing activities related to purchases of property and equipment.

Financing activities

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 consisting of net proceeds of $24.9 million from the second tranche payment of 2019 issuance of Series C-1 convertible preferred stock, Series D-1 and D-2 convertible preferred stock, net proceeds of $99.7 million from our issuance of Series E-1 and E-2 convertible preferred stock, and $123.6 million from the issuance of our Series F-1 and F-2 convertible preferred stock offset by $1.5 million of deferred initial public offering costs.

During the year ended December 31, 2019, net cash provided by financing activities was $39.6 million, primarily consisting of $15.0 million of proceeds from the issuance of convertible notes that were subsequently converted into Series D-2 convertible preferred stock, $18.1 million of net proceeds from the sale of our Series C-1 convertible preferred stock in, $1.9 million of net proceeds from the sale of our Series D-1 convertible preferred stock, and $4.6 million of net proceeds from the sale of our Series D-2 convertible preferred stock.

Contractual obligations and commitments

The following table summarizes our non-cancellable contractual obligations at December 31, 2020, and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments due by period		
(in thousands)	**Total**	**Less than 1 year**	**1 to 3 years**
Operating leases(1)(4)	$ 698	$ 693	$ 5
Purchase commitments(2)	60,361	60,361	—
Manufacturing production lines(3)	41,615	41,615	—
Total	$ 102,674	$ 102,669	$ 5

(1) Represents minimum contractual lease payments on our real estate lease in Menlo Park, California

(2) Represents firm purchase commitments in the normal course of business of $26.5 million and $33.9 million of Talis One instruments and Talis One cartridges, respectively.

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

(4) In January 2021, we entered into a lease agreement that expires in May 2032 for office space in Redwood City, California, with expected occupancy to commence in the fourth quarter of 2021. In January 2021, we also entered into a lease that expires in February 2033 for laboratory space in Chicago, Illinois, with expected occupancy to commence in the second quarter of 2021.

Between June 2020 and August 2020, we executed and amended a LOC with JPMC for up to $33.0 million, as terms of collateral that were required by one of our contract manufacturing organizations. The LOC was set to expire on December 31, 2020 but automatically extended to December 31, 2021 when we did not terminate the agreement 90 days prior to the original expiration date.

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

Critical accounting policies and significant judgments and estimates

This management's discussion and analysis of financial condition and results of operations 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.

Equity transactions

We record convertible preferred stock at fair value on the dates of issuance, net of issuance costs. We have classified convertible preferred stock as temporary equity in the accompanying balance sheets due to terms that may require redemption of the shares in cash upon certain change in control events that are not solely within our control, including our sale or transfer. The carrying values of the convertible preferred stock will be adjusted to their liquidation preferences at such time it becomes probable that such a redemption triggering event will occur. We also evaluate our convertible preferred stock to determine where any of their contractual terms require bifurcation and separate recognition from the underlying shares in accordance with the embedded derivative accounting guidance.

Between November 2019 and December 2019, we entered into a series of transactions (Equity Transactions) with our existing preferred equity stockholders and other investors to (i) raise new capital in a sale of three new series of convertible preferred stock and (ii) restructure our capital structure. All existing holders of our convertible preferred stock were given the opportunity to participate in the new financing but existing convertible preferred stockholders that did not participate in the financing were subject to dilution. The steps of the Equity Transactions that impacted the existing stockholders were evaluated as a single transaction because they occurred concurrently and in contemplation of each other. We concluded that the these combined transactions resulted in the extinguishment of our Series A convertible preferred stock, Series B convertible preferred stock, and Series C convertible preferred stock because the Series C-1 convertible preferred stock, Series D-1 convertible preferred stock and Series D-2 convertible preferred stock issued to our existing investors were considered to be substantially different from the Series A convertible preferred stock, Series B convertible preferred stock and Series C convertible preferred stock. In determining if an extinguishment or modification of these shares occurred, we elected a policy to evaluate if changes to the preferred shares adds, removes, or significantly changes a substantive contractual term (e.g., one that is at least reasonably possible of being exercised), or fundamentally changes the nature of the preferred shares. This evaluation includes the consideration of both the expected economics as well as the business purpose for the amendment. More specifically, the Series C-1 convertible preferred stock received by existing stockholders has a significantly higher liquidation preference than the Series A convertible preferred stock, Series B convertible preferred stock and Series C convertible preferred stock, respectively. Together with the Series C-1 convertible preferred stock, existing stockholders also received common stock and paid additional cash through the Equity Transactions, causing the equity investments held by our preferred stockholders after the Equity Transaction to be substantially different than their equity investments prior to the Equity Transactions.

When mezzanine equity-classified preferred shares are extinguished, the difference between (1) the fair value of the consideration transferred to the holders of the preferred shares (i.e., the cash or the fair value of new instruments issued) and (2) the carrying amount of the preferred shares (net of issuance costs) are subtracted from (or added to) net income (loss) to arrive at income available to common stockholders in the calculation of earnings per share attributable to our common stockholders. In addition to the effect on earnings per share attributable to our common stockholders, extinguishment accounting will result in adjustments within equity but will not result in recognition of any amounts in net income (loss).

The estimated fair value of our convertible preferred stock, for purposes of evaluating the extinguishment resulting from the Equity Transactions, was based on the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The estimated fair value of the convertible preferred stock was based on a hybrid between the probability weighted expected return and option pricing methods, estimating the probability weighted value across multiple scenarios, but using the option pricing method to estimate the allocation of value within one or more of those scenarios. The assumptions we use in the valuation model are based on future expectations combined with management judgment. In the absence of a public trading market for our convertible preferred stock, our management exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of convertible preferred stock, including the following factors:

- a contemporaneous independent valuation of our common stock performed at periodic intervals by an independent third-party valuation firm;
- prices at which we sold shares of convertible preferred stock and the superior rights and preferences of the convertible preferred stock relative to our common stock;
- timing and likelihood of achieving a liquidity event, such as an initial public offering or sale of our company in light of prevailing market conditions;
- volatility as estimated based on the average volatility for comparable publicly traded diagnostic companies over a period equal to the expected term of a liquidity event (comparable companies are chosen based on their similar size, stage in the life cycle or area of specialty); and
- a risk-free interest rate based on the U.S. Treasury zero coupon issues corresponding with the estimated period of time to a liquidity event.

The assumptions underlying these valuations represent our management's best estimates based on application of these approaches and careful consideration of advice from a third-party valuation firm. Such estimates involve inherent uncertainties and the application of significant judgment.

Grant revenue

Grants awarded to us for research and development by government entities are outside the scope of the contracts with customers and contributions guidance. This is because these granting entities are not considered to be customers and are not receiving reciprocal value for their grant support provided to us. These grants provide us 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, our 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 our statements of operations and comprehensive loss.

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

Research and development expenses

Research and development costs are expensed as incurred. Research and development expenses include certain payroll and personnel expenses, laboratory supplies, consulting costs, external contract research and development expenses, allocated overhead and facility occupancy costs. Costs to develop our 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. These expenses relate to both our sponsored programs as well as costs

incurred pursuant to grants. Non-refundable advance payments made for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as expense as the goods are received or the related services are rendered.

We do 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 clearance or 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 as research and development expenses, or if used in marketing evaluations records such costs as 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.

In 2020, we began developing production lines to automate the production of our Talis One cartridges for the COVID-19 assay with the intention to scale up our manufacturing capabilities to meet the high demand expected in response to the COVID-19 pandemic. In Q2 2021, we plan to submit a request for EUA to the FDA for our Talis One system with COVID-19 molecular diagnostic assay for the automated detection of nucleic acid from the SARS-CoV-2 virus in nasal swab samples from individuals suspected of COVID-19 by their healthcare provider Approximately $40.9 million of the high capacity production equipment, purchased as part of our effort to scale up our manufacturing capacity, is highly specialized for the manufacturing of our Talis One cartridges and was determined not to have an alternative future use. 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. 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.

Fair value option

We have elected the fair value option to account for our convertible notes that were issued during and settled during 2019 and recorded these convertible notes at fair value with changes in fair value recorded as a component of other income (expense), net in the statement of operations and comprehensive loss. As a result of applying the fair value option, direct costs and fees related to the convertible notes were expensed as incurred and were not deferred. We concluded that it was appropriate to apply the fair value option to the convertible notes because there were no non-contingent beneficial conversion options related to the convertible notes. The probability-adjusted model used in valuing the fair value of our convertible debt is based on significant unobservable inputs, including but not limited to:

- Timing and probability of a qualified financing event, which is defined as financing event through the issuance of shares for total gross proceeds of at least $45.0 million in cash;
- discount rates; and

- fair value of the underlying convertible preferred stock.

Increases or decreases in the fair value of the convertible notes can result from updates to assumptions such as the expected timing or probability of a qualified financing event, or changes in discount rates. Judgment is used in determining these assumptions as of the initial valuation date and at each subsequent reporting period. Updates to assumptions could have a significant impact on our results of operations in any given period. The convertible notes were settled in December 2019.

Stock-based compensation

We measure stock-based compensation expense for stock options 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. Our stock-based payments include stock options. Stock-based compensation expense is recognized over the requisite service period, which is generally the vesting period, on a straight-line basis. 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. Stock-based compensation expense is classified in the accompanying statements of operations and comprehensive loss based on the function to which the related services are provided. We recognize stock-based compensation expense for the portion of awards that have vested. Forfeitures are recorded as they occur.

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. For granted “at-the-money” stock options, we estimate the expected term by using the simplified method. The simplified method 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.

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 initial public offering, 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. In accordance with the Practice Aid, our board of directors considered the following methods:

- *Current value method.* Under the Current Value Method, our value is determined based on our balance sheet. This value is then first allocated based on the liquidation preference associated with preferred stock issued as of the valuation date, and then any residual value is assigned to the common stock.
- *Option-pricing method.* Under the option-pricing method, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these options.
- *Probability-weighted expected return method.* The probability-weighted expected return method, is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

The assumptions we use in the valuation model are 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.

The assumptions underlying these valuations represented our board of directors and management develop best estimates based on application of these approaches and the assumptions underlying these valuations, giving careful consideration to the advice from our third-party valuation expert. Such estimates involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our equity-based compensation could be materially different. Following the closing of our initial public offering, our board of directors will 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.

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, $1.51. 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 and $0.1 million of the incremental expense relating to the unvested shares remained unrecognized as of December 31, 2020.

The intrinsic value of all outstanding options as of December 31, 2020 was approximately $91.1 million, based on the assumed initial public offering price of $16.00 per share, of which approximately $14.8 million is related to vested options and approximately $76.3 million is related to unvested options.

Off-balance sheet arrangements

As of December 31, 2020, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

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, 2020 and 2019, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, 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.

Redwood City, California
March 30, 2021

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash	$ 138,483	$ 21,604
Restricted cash	34,650	—
Grant receivables	238	—
Unbilled grant receivables	233	1,806
Prepaid research and development expenses	12,014	267
Prepaid expenses and other current assets	3,106	430
Total current assets	188,724	24,107
Property and equipment, net	9,114	1,535
Operating lease right-of-use-assets	567	—
Other long term assets	—	91
Total assets	$ 198,405	$ 25,733
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 4,906	$ 1,566
Accrued expenses and other current liabilities	10,427	2,471
Current operating lease liabilities	693	—
Total current liabilities	16,026	4,037
Other non-current liabilities	5	81
Total liabilities	16,031	4,118
Commitments and contingencies (Note 7)		
Convertible preferred stock, $0.0001 par value—229,296,908 and 127,144,422 shares authorized as of December 31, 2020 and 2019, respectively; 53,509,351 and 37,871,430 shares issued and outstanding as of December 31, 2020 and 2019, respectively; aggregate liquidation preference of $475,617 as of December 31, 2020 and $62,678 as of December 31, 2019, respectively	290,945	42,755
Stockholders' deficit:		
Common stock, $0.0001 par value; 230,000,000 shares authorized at December 31, 2020 and 82,000,000 and 20,000,000 Class A common stock and Class B common stock authorized at December 31, 2019, respectively, 2,126,254 common shares issued and outstanding at December 31, 2020 and 2,115,583 shares of Class A common stock and no Class B common stock issued and outstanding at December 31, 2019	—	—
Additional paid-in capital	64,335	60,636
Accumulated deficit	(172,906)	(81,776)
Total stockholders' deficit	(108,571)	(21,140)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 198,405	$ 25,733

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,	
	2020	**2019**
Grant revenue	$ 10,938	$ 3,977
Operating expenses:		
Research and development	89,019	23,812
General and administrative	13,103	6,864
Total operating expenses	102,122	30,676
Loss from operations	(91,184)	(26,699)
Other income (expense):		
Change in estimated fair value of convertible notes	—	(817)
Interest income, net	54	42
Total other income (expense), net:	54	(775)
Net loss and comprehensive loss	$ (91,130)	$ (27,474)
Net (loss) income attributable to common stockholders	$ (91,130)	$ 26,382
Net (loss) income per share attributable to common stockholders:		
Basic	$ (42.98)	$ 34.34
Diluted	$ (42.98)	$ (12.77)
Weighted average shares used in the calculation of net (loss) income per share attributable to common stockholders:		
Basic	2,120,322	768,366
Diluted	2,120,322	2,150,644

See accompanying notes to the financial statements

Talis Biomedical Corporation
Statements of convertible preferred stock and stockholders' deficit
(in thousands, except for share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid in	Accumulated	Stockholders'
	Shares	Value	Shares	Value	Capital	Deficit	Deficit
Balance at December 31, 2018	2,333,837	59,696	525,632	—	2,300	(54,302)	(52,002)
Equity Transactions - conversion of Series A, B, C convertible preferred stock into Series D-1 convertible preferred stock; issuance of Series C-1 convertible preferred stock, net of issuance costs of $338; conversion of Series D-1 convertible preferred stock into Common Stock	20,447,071	(38,132)	1,588,726	—	56,241	—	56,241
Issuance of Series D-1 convertible preferred stock, net of issuance costs of $36	2,330,899	1,536	—	—	319	—	319
Issuance of Series D-2 convertible preferred stock, net of issuance costs of $87	5,822,371	3,838	—	—	792	—	792
Settlement of convertible notes into Series D-2 convertible preferred stock	6,937,252	15,817	—	—	—	—	—
Issuance of Common Stock upon exercise of stock options	—	—	1,225	—	19	—	19
Stock-based compensation expense	—	—	—	—	965	—	965
Net loss	—	—	—	—	—	(27,474)	(27,474)
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)

See accompanying notes to the financial statements

Talis Biomedical Corporation
Statements of cash flows
(in thousands)

	Year ended December 31,	
	2020	**2019**
Operating activities		
Net loss	$ (91,130)	$ (27,474)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,683	965
Depreciation and amortization	763	726
Changes in estimated fair value of convertible notes	—	817
Non-cash lease expense	611	—
Changes in operating assets and liabilities:		
Unbilled grant receivables	1,572	192
Grants receivable	(238)	—
Prepaid expenses and other current assets	(295)	(255)
Prepaid research and development	(11,747)	—
Accounts payable	3,200	185
Accrued expenses and other liabilities	7,262	378
Lease liabilities	(796)	—
Other long term assets	91	140
Net cash used in operating activities	$ (87,024)	$ (24,326)
Investing activities		
Purchase of property and equipment	(8,201)	(578)
Net cash used in investing activities	$ (8,201)	$ (578)
Financing activities		
Proceeds from the issuance of convertible preferred stock, net of issuance costs	248,189	24,594
Proceeds from issuance of convertible note	—	15,000
Payment of deferred initial public offering costs	(1,451)	—
Proceeds from stock option exercises	16	19
Net cash provided by financing activities	$ 246,754	$ 39,613
Net increase in cash and restricted cash	151,529	14,709
Cash and restricted cash at beginning of year	21,604	6,895
Cash and restricted cash at end of year	$ 173,133	$ 21,604
Supplemental disclosure of noncash investing and financing activities		
Property and equipment purchases included in accounts payable and accrued expenses	$ 140	$ —
Right-of-use assets obtained in exchange for operating lease liabilities	$ 743	$ —
Remeasurement of operating lease right-of-use asset for lease modification	$ 417	$ —
Deferred initial public offering costs included in accrued expenses	$ 928	$ —
Noncash impact of Equity Transactions (see Note 9)	$ —	$ 56,241
Gain on issuance of Series D-1 convertible preferred stock	$ —	$ 319
Gain on issuance of Series D-2 convertible preferred stock	$ —	$ 792
Conversion of convertible notes into series D-2 convertible preferred stock	$ —	$ 15,817

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

	December 31,	
	2020	2019
Cash	$ 138,483	$ 21,604
Restricted cash	34,650	—
Total cash and restricted cash	$ 173,133	$ 21,604

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 transforming diagnostic testing through innovative molecular diagnostic products that enable customers to deploy accurate, reliable, low cost and rapid point-of-care testing for infectious diseases and other conditions. The Company is developing the Talis One system, a sample-to-answer, cloud-enabled molecular diagnostic platform that, once authorized, could be rapidly deployed to distributed diagnostic settings in the United States and around the world to diagnose infectious disease at the point-of care. The Talis One system comprises a compact instrument, single-use test cartridges and software, including a central cloud database, which work together and are designed to provide central laboratory levels of accuracy and be operated by an untrained user. The Company was incorporated in 2013 under the general laws of the State of Delaware and is based in Menlo Park, California and Chicago, Illinois.

Initial Public Offering and Reverse Stock Split

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

In February 2021, the Company completed an initial public offering (IPO) in which the Company issued and sold 13,800,000 shares of common stock at a public offering price of $16.00 per share, with an additional 2,070,000 shares sold pursuant to the underwriter's full exercise of their option to purchase additional shares. The aggregate proceeds received by the Company from the IPO was $232.6 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. The related carrying value of these preferred shares of $65.6 million was reclassified to common stock and additional paid in capital.

Liquidity

The Company has incurred significant losses and negative cash flows since inception, including net losses of $91.1 million for the year ended December 31, 2020. As of December 31, 2020, the Company had unrestricted cash of $138.5 million and $34.7 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. 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 as of December 31, 2020 together with the proceeds from its initial public offering 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 restricted and unrestricted cash and through strategic financing opportunities that could include, but are not limited to, future offerings of its equity, grant agreements, or the incurrence of debt. However, there is no guarantee that any of these strategic or financing opportunities will be executed or realized on favorable terms, if at all, and some could be dilutive to existing stockholders. The Company's ability to raise additional capital through either the issuance of equity or debt, is dependent on a number of factors including, but not limited to, the demand for the Company, which itself is subject to a number of development and business risks and uncertainties, as well as the uncertainty that the Company would be able to raise such additional capital at a price or on terms that are favorable to the Company.

2. Summary of significant accounting policies

Basis of presentation

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

Reclassifications

The accompanying balance sheet as of December 31, 2020 and 2019 and the statements of cash flows for the twelve months ended December 31, 2020 and 2019 reflect the Company's reclassification of prepaid research and development expenses from prepaid expenses and other current assets in order to conform to the presentation of the current period.

Fair value of financial instruments

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. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3 (see Note 3). 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.

Fair value option

The Company elected the fair value option to account for its convertible notes (the Notes) that were issued and settled during 2019 (see Note 8). The Company recorded these Notes at their estimated fair value with changes in estimated fair value recorded as a component of other income (expense), net in the statement of operations and comprehensive loss unless the change is a result of a change in credit risk of the Notes, in which case such change in estimated fair value is recorded within other comprehensive income (loss). As the Notes were issued and settled during the year ended December 31, 2019, any estimated fair value changes related to the credit risk of the Notes were recognized as part of other income (expense) upon settlement of the Notes. No material change to the credit risk of the Notes occurred during the period the Notes were outstanding. As a result of applying the fair value option, direct costs and fees related to the Notes were insignificant and expensed as incurred and were not deferred. The Company concluded that it was appropriate to apply the fair value option to the Notes because no component of the Notes was required to be recognized as a component of stockholders' deficit.

Cash

Cash consists of deposits held at financial institutions and is stated at fair value. The Company limits its credit risk associated with cash by maintaining its bank accounts at major financial institutions.

Restricted cash

Restricted cash consists of cash that serves as collateral for the Company's standby letter of credit (see Note 7). 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 other 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, restricted cash, and grant receivables. The Company's cash is deposited in accounts at large financial institutions. Such deposits may be in excess of federally insured limits. The Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash is held and government grant funded nature of the Company's grant receivables.

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

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

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

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

Property and equipment, net

Property and equipment, net 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

The Company reviews the carrying amount of its long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets 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 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. Management believes that no revision to the remaining useful lives or write-down of long-lived assets is required as of and for the year ended December 31, 2020.

Leases

Prior to January 1, 2020, the Company accounted for leases under Accounting Standards Codification (ASC) 840, *Leases* (ASC 840). The Company, as the lessee in its operating lease arrangements, recorded monthly rent expense on a straight-line basis, equal to the total of the payments due over the lease term, divided by the number of months of the lease term. The difference between rent expense recorded and the amount paid was charged to deferred rent. Effective January 1, 2020, the Company adopted Accounting Standards Update (ASU) 2016-

02, Leases (Topic 842) (ASC 842), using the modified retrospective transition method. Under this method, financial statements for reporting periods after adoption are presented in accordance with ASC 842 and prior-period financial statements continue to be presented in accordance with ASC 840, the accounting standard originally in effect for such periods.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement, including whether the Company controls the use of identified assets. Under ASC 842, the Company classifies leases with a term greater than one year as either operating or finance leases at the lease commencement date and records a right-of-use assets and current and non-current lease liabilities, as applicable on the balance sheet. The Company has elected not to recognize leases with terms of one year or less on the balance sheet. If a lease includes options to extend the lease term, the Company does not assume the option will be exercised in its initial lease term assessment unless there is reasonable certainty that the Company will renew based on an assessment of economic factors present as of the lease commencement date. The Company monitors its plans to renew its material leases each reporting period.

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 the Company utilizes its incremental borrowing rate (IBR), which reflects the fixed rate at which the Company 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. Variable costs associated with the lease, such as maintenance and utilities, are not included in the measurement of right-to-use assets and lease liabilities but rather are expensed when the events determining the amount of variable consideration to be paid have occurred.

The Company enters into certain manufacturing and supply arrangements with third-party suppliers that may contain embedded leases for the manufacturing of its Talis One cartridges, which require highly specialized production lines. The Company must assess its involvement with the design and construction of the production lines. If determined to control 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. Upon completion of the construction, the Company is required to perform a sale-leaseback analysis to assess whether control is transferred, in which case the Company should de-recognize the capitalized project costs, if any, and account for the arrangement as a lease. If the sale-leaseback criteria are not met, the capitalized project costs will remain on the Company’s balance sheet to be depreciated over the estimated useful life of the underlying assets.

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses include certain payroll and personnel expenses, laboratory supplies, consulting costs, external contract research and development expenses, allocated overhead and facility occupancy costs. Costs to develop the Company’s technologies, including software, are recorded as research and development expense except for costs that meet the criteria to be capitalized as internal-use software costs. These expenses relate to both Company sponsored programs as well as costs incurred pursuant to grants. Non-refundable advance payments made for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as expense as the goods are received or the related services are rendered.

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

In 2020, the Company began developing production lines to automate the production of its Talis One cartridges for the COVID-19 assay with the intention to scale up its manufacturing capabilities to meet the high demand expected in response to the COVID-19 pandemic. The Company has expensed $40.9 million of high capacity production equipment as part of the Company's effort to scale up its manufacturing capacity to date. This equipment is highly specialized and designed specifically for the commercial scale-up manufacturing of the Company's Talis One COVID-19 assay cartridges and was determined not to have an alternative future use. All materials, equipment, and external consulting costs associated with developing aspects of the production line that do not have an alternative future use are expensed as research and development costs until regulatory approval is obtained. Materials, equipment, and external consulting costs associated with developing aspects of the production line that are deemed to have an alternative future use are capitalized as property and equipment, assessed for impairment and depreciated over their related useful lives. These research and development costs, including expenditures for property and equipment with no alternative future use, are classified as operating cash outflows within the Company's statements of cash flows.

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

Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to the Company's prior estimates of accrued research and development expenses.

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.

Convertible preferred stock

The Company records convertible preferred stock at fair value on the dates of issuance, net of issuance costs. The Company has classified convertible preferred stock, which is redeemable, as temporary equity in the

accompanying balance sheets 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 convertible preferred stock which could trigger redemption of the shares.

The carrying values of the 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 convertible preferred stock to the redemption values since a future change in control event was not considered probable as of December 31, 2020 or December 31, 2019. Subsequent adjustments of the carrying values to the ultimate redemption values will be made only when it becomes probable that such liquidation events will occur, causing the shares to become redeemable.

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

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.

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.

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, 2020; 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 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 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 is 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 attributable to holders of common stock (common stockholders) is computed by dividing the net loss attributable to Common Stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration of potential dilutive securities. The convertible preferred stock are non-participating securities. Stock options, the Notes and convertible preferred stock are considered potentially dilutive common stock. The Company computes diluted net loss per share attributable to common stockholders 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 year ended December 31, 2020, the Company reported a net loss attributable to common stockholders. 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.

During the year ended December 31, 2019, the Company reported net income attributable to common stockholders. The stock options, convertible preferred stock and the Notes were therefore assessed to determine whether they were antidilutive. The Company's Series A convertible preferred stock (Series A Preferred), Series B convertible preferred stock (Series B Preferred), and Series C convertible preferred stock (Series C Preferred) (collectively, the Pre-Existing Preferred Stock) were determined to be dilutive and were therefore included in the diluted net loss per share attributable to Common Stockholders calculation. The Company's Series C-1 convertible preferred stock (Series C-1 Preferred), Series D-1 convertible preferred stock (Series D-1 Preferred), Series D-2 non-voting convertible preferred stock (Series D-2 Preferred), Series E-1 convertible preferred stock (Series E-1 Preferred), Series E-2 non-voting convertible preferred (Series E-2 Preferred), Series F-1 convertible preferred stock (Series F-1 Preferred), Series F-2 non-voting convertible preferred (Series F-2 Preferred), the Notes and the options to purchase common stock were determined to be antidilutive and, therefore, excluded from the calculation.

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 year 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 primarily relating to the Company's IPO, are capitalized and were offset against proceeds within stockholders' equity 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 February 2016, the Financial Accounting Standards Board (FASB) issued ASC 842 which supersedes the guidance in ASC 840. The new standard, as amended by subsequent ASUs, requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine the recognition pattern of lease expense over the term of the lease. A lessee is also required to record (i) a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification and (ii) lease expense on its statement of operations for operating leases and amortization and interest expense on its statement of operations for financing leases. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases under ASC 840.

Effective January 1, 2020, the Company adopted ASC 842, using the required modified retrospective approach and utilized the effective date as its date of initial application, with prior periods presented in accordance with previous guidance under ASC 840. ASC 842 provides several optional practical expedients in transition. The Company applied the package of practical expedients to leases that commenced prior to the effective date whereby the following are not required to be reassessed: (i) whether any expired or existing contracts are or contain leases;

(ii) the lease classification for any expired or existing leases; and (iii) the treatment of initial direct costs for existing leases. The Company also elected the short-term lease expedient for all leases that qualified based on a lease term of 12 months or less, and consequently a right-of-use asset or lease liability was not recognized for short-term leases.

Upon its adoption of ASC 842, the Company recorded lease liabilities and their corresponding right-of-use assets based on the present value of lease payments over the remaining lease term. The relevant IBR at January 1, 2020, specific to each lease and based on the remaining lease term, was used to calculate the present value of the Company's leases as of that date. Adoption of this standard resulted in the recording of operating lease right-of-use assets of $0.8 million and current and noncurrent operating lease liabilities of $0.8 million and $0.3 million, respectively, on the Company's balance sheet and the de-recognition of deferred rent liabilities of $0.3 million on the date of adoption. The adoption of the standard had no impact on the Company's statements of operations and comprehensive loss or to its cash flows from or used in operating, financing, or investing activities on its statements of cash flows. No cumulative-effect adjustment within accumulated deficit was required to be recorded as a result of adopting this standard. Refer to Note 7 for right-of-use assets and liabilities recorded during the year ended December 31, 2020.

In August 2018, the FASB issued ASU 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract*. This pronouncement clarifies the requirements for capitalizing implementation costs in cloud computing arrangements and aligns them with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The guidance can be adopted retrospectively or prospectively to all cloud computing arrangement implementation costs incurred after the date of adoption. The Company adopted the new guidance on January 1, 2020 on a prospective basis and it did not have a material impact on the Company's financial statements and related disclosures.

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

Management believes that the carrying amounts of the Company's financial instruments, including grant receivables, prepaid expenses and other current assets, prepaid research and development expenses, accounts payable and accrued expenses approximate fair value due to the short-term nature of those instruments.

In March 2019 and August 2019, the Company issued $10.0 million and $5.0 million in Notes (see Note 8). In December 2019, the Notes were converted into 6,937,252 shares of Series D-2 Preferred with a conversion price of $2.74 per share. The Company elected the fair value option to account for the Notes that were issued and settled during 2019. The Company recorded these Notes at their estimated fair value with changes in estimated fair value recorded as a component of other income (expense), net in the statement of operations and comprehensive loss unless the change was a result of a change in credit risk of the Notes, in which case such change in estimated fair value was recorded within other comprehensive income (loss). No financial instruments measured at fair value on a recurring basis were outstanding as of December 31, 2020 or 2019. The fair value of the Notes was determined based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy.

The Notes were valued using a scenario-based analysis. Two primary scenarios were considered: the qualified financing scenario and the default scenario. The value of the Notes under each scenario were probability weighted to arrive at the estimated fair value for the Notes. The qualified financing scenario considers the value impact of

conversion at the stated discount to the issue price if the Company has a qualifying financing event, i.e. raised $45.0 million in an equity financing before the maturity date. The default scenario assumes the qualified financing event does not occur and the Company is in distress, resulting in a partial or no recovery of the Notes. A recovery rate on the Notes in the default scenario gives consideration to the Company's net asset value relative to the size of the Note. As of the issuance date of the Notes, the probability of default was calculated such that the probability-weighted value of the Notes was equal to the principal investment amount. The implied probability of default of previously issued Notes is carried forward and used as the probability of default for subsequent valuation dates. It is assumed that the probability of the Notes reaching contractual maturity was not material at the valuation dates, given the proximity to the qualified financing and the Company's financing needs.

The following table summarizes the significant unobservable inputs used in the fair value measurement of the Notes during the years ended December 31, 2019:

Fair Value Range (in thousands)	Valuation Technique	Unobservable Input	Input Range
$15,231 - $15,817	Scenario-based analysis	Discount Rate	15.0% - 15.0%
		Timing of the scenarios	0.2 years - 0.8 years
		Probability of Qualified Financing	82.8% - 82.8%
		Probability of Default	17.2% - 17.2%
		Recovery Rate	0.0% - 0.0%

In December 2019, upon the occurrence of a non-qualified financing (see Note 9), the Company estimated the fair value of the Notes considering that a market participant would factor in the conversion upon the settlement and the terms of the Notes, including the rate at which the Notes converted into the qualified financing securities. The assumptions impacting the fair value measurement as of the settlement date included a 100% probability of conversion of the Notes into Series D-2 Preferred, the number of shares of Series D-2 Preferred received as a part of the conversion, and the conversion price of $2.74 for the Notes.

The fair value of the Notes upon settlement in December 2019 was $15.8 million. The Company recorded a loss of $0.8 million for changes in the estimated fair value of the Notes in the statements of operations and comprehensive loss for the year ended December 31, 2019.

The following table provides a roll forward of the estimated fair value of the Notes, for which fair value was determined using Level 3 inputs (in thousands):

	Convertible Notes
Balance as of December 31, 2018	$ —
Issuance of convertible notes	15,000
Change in estimated fair value immediately prior to settlement	817
Settlement of convertible notes	(15,817)
Balance as of December 31, 2019	$ —

During the years ended December 31, 2020 and 2019, there were no transfers between Level 1, Level 2 and Level 3 of the fair value hierarchy.

4. Property and equipment, net

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

	December 31,	
	2020	2019
Lab equipment	$ 3,874	$ 2,293
Office and computer equipment	456	325
Furniture and fixtures	392	338
Leasehold improvements	814	814
Total	5,536	3,770
Less accumulated depreciation	(2,998)	(2,235)
Total	2,538	1,535
Construction in progress	6,576	—
Property and equipment, net	$ 9,114	$ 1,535

Depreciation expense for the years ended December 31, 2020 and 2019 was $0.8 and $0.7 million.

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.

All of the Company's property and equipment is located in the U.S. and Switzerland, with $6.1 million of the construction in progress being located in Switzerland.

5. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2020	2019
Accrued research and development activities	$ 6,360	—
Compensation and benefits	2,738	1,908
Deferred rent, current	—	235
Professional fees	608	223
Other liabilities	721	105
	$ 10,427	$ 2,471

6. Grant revenue and receivables

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. Under the subaward agreement, there is a possibility of an additional $2.8 million of funding through June 2021 based on the discretion of CARB-X and the achievement of certain project milestones. During the years ended December 31, 2020 and 2019, the Company recognized $0.6 million and $3.2 million of revenue respectively, of which no reimbursable

expenses had been incurred and paid as of December 31, 2020 and $1.6 million had been incurred and paid but not yet invoiced and were included in unbilled grant receivables as of December 31, 2019. The unbilled grant receivables at December 31, 2019 were subsequently invoiced and collected by February 2020.

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 March 2019, the Company exercised its first one-year option under the grant, extending the term through April 2020. In April 2020, the Company exercised its second one-year option under the grant, extending the term through April 2021.

During the years ended December, 31 2020 and 2019, the company recognized $1.1 million and $0.9 million of revenue related to this grant, respectively, of which $0.2 million and $0.2 million of reimbursable expenses had been incurred and paid but were not yet invoiced and were included in unbilled grant receivables as of December 31, 2020 and 2019, 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 subaward agreement required the Company to produce functional Talis One COVID-19 assay cartridges in order to assess the Talis One instrument's capability of successfully detecting COVID-19. During the twelve months ended December 31, 2020, the Company fulfilled its contractual obligations for the subaward grant and all $0.4 million of revenue related to the grant had been recognized and received.

The NIH contract for Phase 2 of the RADx initiative is subject to meeting certain milestones and is comprised of five stages. 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. The Phase 2 RADx contract has a performance period of one year beginning July 2020 and contains key deliverables and milestones that directly support the upgrade and addition of new manufacturing lines which will support the Company's expansion of its manufacturing capacity to produce and distribute its COVID-19 assay cartridge. If the NIH contract is terminated by the NIH for cause upon the Company's failure to perform as specified in the NIH contract, the Company would be required to repay the NIH 15.0% of the amounts previously received as liquidating damages, in place of any actual damages. Such repayment would not be required if a delay in delivery or performance was beyond the Company's control. During the year ended December 31, 2020, the Company recognized and received $8.9 million relating to completing the first stage of the contract, with the remaining $16.5 million being contingent upon the Company meeting agreed-upon contractual milestones. There were no unbilled receivables recorded for this contract as of December 31, 2020.

7. Commitments and contingencies

Operating leases

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. This modification resulted in an increase to the right-of-use asset and lease liability of $0.4 million, with the lease remaining classified as an operating lease. The lease payments increase by 3.0% in each year. The lease included $0.8 million in tenant inducements, which has been fully utilized through qualifying tenant improvements and rental credits. Monthly rent expense is recognized net of the tenant inducement amount on a

straight-line basis over the lease term. As of December 31, 2020, the Company did not have an option to extend the term of the lease. The Company also leases office space on a month-to-month basis in Chicago, Illinois.

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 were as follows (in thousands):

	Twelve Months Ended December 31, 2020
Lease Costs	
Operating lease costs	$ 626
Short-term lease costs	22
Total operating lease costs	$ 648
Cash flows	
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows used for operating leases	$ 811

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

	December 31, 2020
Weighted-average remaining lease term	0.9 years
Weighted-average discount rate	1.2%

The undiscounted future lease payments for operating leases as of December 31, 2020 were as follows (in thousands):

Year ending December 31,	Operating Leases
2021	$ 696
2022	6
Total future minimum lease payments	702
Less: imputed interest	(4)
Present value of operating lease liabilities	698
Less: current portion of lease liabilities	(693)
Noncurrent portion of lease liabilities	$ 5

The Company recognized rent expense of $0.7 million for the year ended December 31, 2020 and future minimum lease payments under operating leases as of December 31, 2020 were as follows (in thousands):

Year ending December 31,	Operating Leases
2021	271
Total minimum lease payments	$ 271

Prior to January 1, 2020, the Company accounted for leases under ASC 840. The Company, as the lessee in its operating lease arrangements, recorded monthly rent expense on a straight-line basis, equal to the total of the payments due over the lease term, divided by the number of months of the lease term. Rent expense was $0.6 million for the year ended December 31, 2019.

Standby letter of credit

Between June 2020 and August 2020, the Company executed and amended a $33.0 million standby letter of credit (LOC) with JPMorgan Chase (JPMC) as terms of collateral that were required by one of the Company's contract manufacturing organizations. The LOC was set to expire on December 31, 2020 but automatically extended to December 31, 2021 when the Company did not terminate the agreement 90 days prior to the original expiration date. Interest on any borrowings under the LOC agreement is equal to the lesser of (a) Prime plus 2.0% and (b) the highest rate permitted by applicable law and is payable on demand. The Company is required to maintain a cash balance of $34.7 million as collateral for the LOC, which is classified as restricted cash as of December 31, 2020 in the balance sheet. As of December 31, 2020, the LOC had not been exercised.

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. These indemnities include indemnities to the 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.

Unconditional purchase obligations

In the normal course of business, the Company enters into various firm purchase commitments. As of December 31, 2020, these commitments are approximately $102.0 million and are primarily related to the build out of manufacturing production lines of $41.6 million and purchase commitments relating to the Talis One instruments and Talis One cartridges of $60.4 million, expected to be incurred in 2021.

8. Convertible notes due to related party

In March 2019 (Effective Date), the Company executed a Convertible Note Purchase Agreement under which the Company agreed to issue an aggregate principal amount of up to $15.0 million (First Tranche Funding) and up to an additional $5.0 million (Second Tranche Funding) of Notes to an existing investor and related party. The Notes were subject to adjustments to their principle balances whereby upon the issuance of the Notes under the First Tranche Funding and the Second Tranche Funding, the principal owed increased by 10.0% of the face value of the Notes. The Company issued, taking into the effect of the 10.0% increment, $11.0 million of Notes under the First Tranche Funding and $5.5 million under the Second Tranche Funding in March 2019 and August 2019, respectively.

An additional 5.0% installment adjustment was applied to the outstanding First Tranche Funding principal and accrued interest on the 150th day after the Effective Date, the 180th day after the Effective Date, and the 210th day after the Effective Date.

The Notes bore interest at a fixed per annum rate of 6.5% compounded monthly until their maturity date of December 31, 2019, at which time all outstanding principal and interest became due and payable in cash if not already converted.

In the event of a qualified financing, whereby the Company issued and sold its convertible preferred stock and raised capital of at least $45.0 million of total gross proceeds in cash, the Notes would automatically convert into convertible preferred stock at a price equal to the issue price per share of the shares issued in the qualified financing and on the same terms and conditions of such qualified financing. In the event of a non-qualified financing, the holders of the Notes had the option to convert the outstanding principal and unpaid interest of the Notes into such financing at a conversion price equal to the issue price per share of the financing shares and on the same terms and conditions of such non-qualified financing.

Upon a change of control in the company, the holders of the Notes could elect to either declare the Notes payable in an amount equal to 200% multiplied by the outstanding principal plus all unpaid interest or convert the outstanding principal and unpaid interest into shares of Series C Preferred at a conversion price equal to the Series C Preferred original issue price. Upon an event of default, including failure to comply with the Company's payment and other obligations under the Notes, the outstanding principal and unpaid interest would become due and payable.

In December 2019, upon the occurrence of a non-qualified financing (see Note 9), the holders of the Notes exercised their option and converted the Notes into 6,937,252 shares of the Company's Series D-2 Preferred at a conversion price of $2.74 per share, which was equal to the cash issuance price of the Series D-2 Preferred. The then outstanding principal and accrued interest amount of $19.0 million was converted and reclassified to Series D-2 Preferred. The Company elected to account for the Notes at estimated fair value pursuant to the fair value option and recorded the change in estimated fair value in the statement of operations and comprehensive loss until the Notes were converted into Series D-2 Preferred in December 2019. The estimated fair value of the Notes immediately prior to conversion was $15.8 million. The Company recorded a loss of $0.8 million relating to the change in estimated fair value of the Notes in the statement of operations and comprehensive loss for the year ended December 31, 2019. As the Notes were converted in December 2019, there was no fair value change recorded during year ended December 31, 2020.

9. Convertible preferred stock and stockholders' 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 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 Equity Transactions were accomplished through the following steps:

- Filing of the Company's Fourth Amended and Restated Certificate of Incorporation to authorize the issuance of shares of convertible preferred stock designated as Series C-1 Preferred, Series C-2 non-voting convertible preferred stock (Series C-2 Preferred), Series D-1 Preferred, and Series D-2 Preferred
- Execution of a Series C-1 Preferred Stock and Series D-1 Preferred Stock Purchase Agreement (Series C-1 and D-1 SPA) which authorized the sale and issuance of up to an aggregate of 23,338,437 shares of Series C-1 Preferred and up to an aggregate of 40,233,774 shares of Series D-1 Preferred, and up to an aggregate of 40,233,774 shares of Series D-2 Preferred. The Company's majority stockholder had the option to purchase one share of Series C-2 Preferred instead of each share of Series C-1 Preferred purchased and an option to purchase one share of Series D-2 Preferred in lieu of each share of Series D-1 Preferred purchased. A majority of the existing preferred stockholders participated in the Series C-1 and D-1 SPA. Pursuant to the Series C-1 and D-1 SPA, the Company:

    (i) Reclassified all shares of the Pre-Existing Preferred Stock for shares of Series D-1 Preferred on a 1-to- 1 basis based on terms of the Fourth Amended and Restated Certificate of Incorporation (Reclassification). Pursuant to the Series C-1 and D-1 SPA, the shares of Series D-1 Preferred

resulting from the Reclassification held by any investor who purchased Series C-1 Preferred had their Series D-1 Preferred automatically convert to shares of Class A Common Stock on a 1.43-to-1 basis. Existing Series D-1 Preferred stockholders that did not participate in the Series C-1 and D-1 SPA retained their Series D-1 Preferred. The Company automatically converted 2,271,892 shares of Series D-1 Preferred into Class A Common Stock upon the closing of the existing stockholders' respective purchases of Series C-1 Preferred. The Company concurrently sold 22,718,963 shares of Series C-1 Preferred at a purchase price of $2.74 per share to these existing stockholders;

(ii) Sold 2,330,899 shares of Series D-1 Preferred at a purchase price of $2.74 per share to new investors in the Company;

(iii) Sold 5,822,371 shares of Series D-2 Preferred at a purchase price of $2.74 per share to the Company's majority stockholder;

- Conversion of the Company's Notes (see Note 8) into 6,937,252 shares of Series D-2 Preferred at a price of $2.74 per share.

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. The first tranche was due and payable upon the respective closing date of the sale and issuance of the stock (First Tranche Payment) while the second and third tranches are due and payable upon the Company's completion of sufficient technical and operational progress, respectively, as determined by the Company's majority stockholder, in its sole and absolute discretion (Second Tranche Payment and Third Tranche Payment, respectively). The Company determined that the Second Tranche Payment and Third Tranche Payment each did not meet the definition of a freestanding financial instrument because the obligation on the applicable stockholder was not legally detachable from the host share.

The following table provides the cash payment per share due and payable upon the First Tranche Payment, Second Tranche Payment and Third Tranche Payment:

	First Tranche	Second Tranche	Third Tranche	Total
Series C-1 Preferred Stock	$ 0.81	$ 0.81	$ 1.12	$ 2.74
Series D-1 Preferred Stock	$ 0.81	$ 0.81	$ 1.12	$ 2.74
Series D-2 Preferred Stock	$ 0.81	$ 0.81	$ 1.12	$ 2.74

As of December 31, 2019, the First Tranche Payment of $25.0 million had been received and the Second Tranche Payment and Third Tranche Payment remained outstanding for issuances of the Company's Series C Preferred and Series D Preferred. During the second quarter of 2020, the Company received the Second Tranche Payment, resulting in net proceeds of $24.9 million, net of issuance costs of less than $0.1 million.

As part of the Equity Transactions, the Company issued the following shares and received the following proceeds (in thousands):

	Shares	First Tranche Proceeds	Issuance Costs	Net Proceeds
Series C-1 Preferred Stock	22,718,963	$ 18,447	$ (338)	$ 18,109
Series D-1 Preferred Stock	2,330,899	1,890	(35)	1,855
Series D-2 Preferred Stock	5,822,371	4,716	(87)	4,629
Series D-2 Preferred Stock - Notes conversion (see Note 8)	6,937,252	—	—	—
	37,809,485	$ 25,053	$ (460)	$ 24,593

The steps of the Equity Transactions that impacted the existing stockholders were evaluated as a single transaction because they occurred concurrently and in contemplation of each other. These combined transactions resulted in the extinguishment of the Pre-Existing Preferred Stock because the existing stockholders after this

transaction, held equity instruments which were considered to be substantially different from the Pre-Existing Preferred Stock.

The Equity Transactions had the following net impact on the Company's additional paid-in capital and net (loss) income attributable to Class A common stockholders:

(in thousands)	Additional paid in capital	Net (loss) income attributable to Class A common stockholders
Carrying value of Pre-Existing Preferred Stock	$ 59,696	$ 59,696
Estimated fair value of Series D-1 Preferred issued	(5,321)	(5,321)
Deemed contribution related to the extinguishment of the Pre-Existing Preferred Stock	54,375	54,375
Series C-1 Preferred gross proceeds received	18,447	18,447
Estimated fair value of Series D-1 Preferred received	5,179	5,179
Estimated fair value of Series C-1 Preferred issued	(21,760)	(21,760)
Estimated fair value of Class A Common Stock issued	(2,385)	(2,385)
Inducement	(519)	(519)
Fair value of Class A Common Stock issued	2,385	—
Total	$ 56,241	$ 53,856

The deemed contribution related to the extinguishment of the Pre-Existing Preferred Stock and inducement were computed separately because all Pre-Existing Preferred Stock was extinguished and exchanged into Series D-1 Preferred but only a subset of Series D-1 Preferred stockholders elected to participate in the Series C-1 Preferred issuance. The net impact of the Equity Transactions was a credit of $56.2 million, which represents a capital contribution and was recorded to additional paid-in capital in accordance with the accounting guidance on preferred stock modifications and extinguishments and earnings per share.

The Equity Transactions also resulted in a $53.9 million change to the net (loss) income attributable to Class A common stockholders for the year ended December 31, 2019 (see Note 13). The $2.4 million fair value of the Class A common Stock issued by the Company does not represent income to Class A common stockholders and was therefore excluded from the basic and diluted net (loss) income per share calculation for the year ended December 31, 2019.

The excess of cash paid over the fair value of the Series D-1 Preferred and Series D-2 Preferred sold to new investors and the Company's majority stockholder as a part of Equity Transactions were recorded as an increase to additional paid-in-capital.

The estimated fair value of the Series C-1 Preferred, Series D-1 Preferred and Series D-2 Preferred for purposes of evaluating the extinguishment resulting from the Equity Transactions was based on a hybrid option pricing method model, which is a market approach that utilizes certain assumptions including probability weighting of events, volatility, time to an exit event, and a risk-free interest rate, which are based on Level 2 and Level 3 inputs.

As of December 31, 2019, as a result of only the First Tranche Payment having been received, the liquidation preference for the shares of Series C-1 Preferred, Series D-1 Preferred, and Series D-2 Preferred that were not subject to forfeiture was $36.9 million, $2.1 million, and $23.7 million, respectively.

During the second quarter of 2020, the Company received the Second Tranche Payment, 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 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. 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	121,758	6,964,012
Series 1 convertible preferred stock	57,324,227	—	—	—	57,324,227
Series 2 convertible non-voting preferred stock	57,324,227	—	—	—	57,324,227
	229,296,908	53,509,351	$ 290,945	$ 475,617	152,067,534

December 31, 2019	Preferred authorized	Preferred shares issued and outstanding	Carrying value	Liquidation preference	Common shares issuable upon conversion
Series C-1 convertible preferred stock	23,338,437	22,718,963	$ 21,423	$ 124,500	4,607,400
Series C-2 convertible preferred stock	23,338,437	—	—	—	—
Series D-1 convertible preferred stock	40,233,774	2,392,844	1,677	6,556	516,034
Series D-2 convertible preferred stock	40,233,774	12,759,623	19,655	34,961	6,031,990
	127,144,422	37,871,430	$ 42,755	$ 166,017	$ 11,155,424

The convertible preferred stock also has 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 convertible preferred stock are as follows:

Voting rights

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.

As of the year ended December 31, 2019, the holders of Series C-1 Preferred and Series D-1 Preferred, 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 and Series D-2 Preferred is non-voting. Any additional members of the Board shall be elected by the holders of common stock and Series C-1 Preferred and Series D-1 Preferred, voting together as a single class. Each holder of Series C-1 Preferred and Series D-1 Preferred shall be entitled to the number of votes equal to the applicable number of shares of common stock into which the shares convert.

Dividends

The Series C-1 Preferred, Series D-1 Preferred, Series D-2 Preferred, Series E-1 Preferred and Series E-2 Preferred, Series F-1 Preferred and Series F-2 Preferred outstanding as of December 31, 2020 and the Series C-1 Preferred, Series D-1 Preferred, Series D-2 Preferred outstanding as of December 31, 2019 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, 2020 and 2019, no such dividends had been declared or accrued.

Liquidation distributions

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 and the holders of Series C-1 Preferred, Series C-2 Preferred, Series D-1 Preferred, and Series D-2 Preferred at December 31, 2019 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 and an amount per share of $5.48 per share of Series C-1 Preferred and Series C-2 Preferred and $2.74 per share of Series D-1 Preferred and Series D-2 Preferred plus any declared but unpaid dividends as of December 31, 2019 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 convertible preferred stock outside of stockholders' deficit because the shares contain liquidation features that are not solely within the Company's control.

Redemption rights

No shares of 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.

Conversion rights

Each share of the Company's 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. As of December 31, 2019, the conversion price was $7.84 per share for Series C-1 Preferred and Series C-2 Preferred and $3.92 per share for Series D-1 Preferred and Series D-2 Preferred.

Each share of the Company's 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 and December 31, 2019, 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 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 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. Series 1 convertible preferred stock can, at any time following the three year anniversary of the Company's IPO, convert the shares into fully paid and nonassessable Series 2 non-voting preferred, on a one-for-one basis.

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 preferred shares 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.

Registration rights

Holders of the Company's convertible preferred stock have the right to request the Company to file certain registration statements with the Securities and Exchange Commission for the registration of shares related to the convertible preferred stock. The obligations of the Company regarding such registration rights include, but are not limited to, 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.

Common Stock

In November 2019, the Company's Board of Directors (Board) approved and the Company filed its Fourth Amended and Restated Certificate of Incorporation to authorize the issuance of up to 82,000,000 shares of the Company's Class A Common Stock (Class A Common Stock) and 20,000,000 shares of the Company's Class B Non-Voting Common Stock (Class B Common Stock), each with a par value of $0.0001 per share. In conjunction with the amended and restated certificate of incorporation, the Company exchanged all outstanding shares of the Company's common stock and options to purchase common stock for an equal number of shares of Class A Common Stock and options to purchase Class A Common Stock. There were no changes in rights and privileges between the legacy common stock and Class A Common Stock. The accompanying financial statements and related

notes has been retroactively revised to reflect the common stock as Class A Common Stock to reflect this change in capital structure.

In October 2020, the Company filed its Seventh Amended and Restated Certificate of Incorporation, pursuant to which, each share of Class A Common Stock issued and outstanding immediately prior to the filing was automatically renamed and reclassified as one share of Common Stock. No shares of Class B Common Stock were outstanding immediately prior to the filing. Class A Common Stock and Class B Common Stock ceased to exist upon the filing of the Seventh Amended and Restated Certificate of Incorporation. The amended and restated certificate of incorporation increased the number of s common shares the Company is authorized to issue to 230,000,000 shares of common stock each with a par value of $0.0001 per share. No dividends have been declared or paid during the years ended December 31, 2020 or 2019.

The Company has reserved the following shares of common stock for future instances of Voting Preferred Stock and Non-Voting Preferred Stock and Common Stock for stock options as of:

	December 31,	
	2020	2019
Shares reserved for conversion of outstanding Series C-1 Preferred Stock	9,373,556	15,887,375
Shares reserved for conversion of outstanding Series D-1 Preferred Stock	1,005,013	1,673,310
Shares reserved for conversion of outstanding Series D-2 Preferred Stock	7,253,461	8,922,811
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 Preferred Stock	57,324,227	—
Shares reserved for conversion of outstanding Series 2 Non-Voting Preferred Stock	57,324,227	—
Shares reserved for options to purchase Common Stock under the 2013 Stock Option and Grant Plan	7,737,095	437,922
Shares reserved for issuance under the 2013 Stock Option and Grant Plan	1,928,256	6,410,201
Total	161,732,885	33,331,619

10. Stock-based compensation

2013 Equity Incentive Plan

The 2013 Equity Incentive Plan (2013 Plan) provides the Board the discretion to grant stock options and other equity-based awards to employees, directors, and consultants of the Company. The Board administers the 2013 Plan and has discretion to delegate some or all of the administration of the 2013 Plan to a committee or committees or an officer. To date, the Company has only granted Incentive Stock Options (ISOs) and Non-statutory Stock Options (NSOs) to employees, consultants, and directors. Therefore, the below discussion is limited to the terms applicable to ISOs and NSOs (collectively, stock options or options). As of December 31, 2020, there were 9,665,351 shares of common stock reserved by the Company for grants under the 2013 Plan and an aggregate of 1,928,256 shares of common stock remained available for future grants. In October 2020, the Board of Directors of the Company adopted the sixth and seventh amendments to the 2013 Plan and the number of shares available for issuance under the plan automatically increased by 2,812,205 shares.

The exercise prices, vesting, and other restrictions are determined at the discretion of the Board, except that the exercise price per share of stock options may not be less than 100% of the estimated fair market value of the common stock on the date of grant and not less than 110% if the employee owns more than 10% of the total combined voting power of all classes of the Company's stock. Stock options awarded under the 2013 Plan expire ten years after the grant date and five years after the grant date if the stockholder employee owns more than 10% of the total combined voting power of all classes of the Company's capital stock, unless the Board sets a shorter term. Vesting periods for awards under the 2013 Plan are determined at the discretion of the Board but in general vest over four years. Stock option exercises are settled with shares reserved under the 2013 Plan. Upon termination of

employment, the option holders' vested shares are subject to repurchase at the lower of (i) the estimated fair market value as of the date of repurchase or (ii) the original exercise price. The 2013 Plan allows for early exercise of certain options prior to vesting. No stock options were early exercised in the years ended December 31, 2020 or 2019. Unvested shares upon termination of employment are forfeited back to the Company and increase the number of shares available for future grants.

2021 Equity Incentive Plan

Our board of directors adopted our 2021 Equity Incentive Plan (2021 Plan), and our stockholders approved our 2021 Plan, on February 17, 2021. Our 2021 Plan is a successor to and continuation of our 2013 Plan. No further grants will be made under the 2013 Plan following the effectiveness of the 2021 Plan.

2021 Employee Stock Purchase Plan

Our board of directors adopted our 2021 Employee Stock Purchase Plan (ESPP), and our stockholders approved our ESPP, in February 2021. The purpose of the ESPP is to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. The ESPP includes two components. One component is designed to allow eligible U.S. employees to purchase our common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. In addition, purchase rights may be granted under a component that does not qualify for such favorable tax treatment because of deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the United States while complying with applicable foreign laws.

Stock option activity

In March 2020, the Company 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 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 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 and $0.1 million of the incremental expense relating to the unvested shares remained unrecognized as of December 31, 2020.

Prior to December 31, 2019, the Company had only granted common stock options with service based vesting conditions. During the year ended December 31, 2020, the Chief Executive Officer of the Company received stock options for the purchase of 241,958 shares of common stock that vest based on a performance condition that was initially tied to the regulatory approval of the Company's Talis One system for chlamydia and gonorrhea. The original award had a grant date fair value of $0.3 million. The Company modified the performance condition in August 2020 to be tied to the first sale by the Company of a regulatory approved product (considered to be an improbable to improbable modification). The modified grant date fair value of the award was $1.4 million. As of December 31, 2020, there was $1.4 million of unrecognized compensation expense related to these stock options as the achievement of the performance condition was not yet deemed probable. As of December 31, 2019, the Company had 184,258 non-vested options.

A summary of option activity under the 2013 Plan during the twelve months ended December 31, 2020 is as follows:

	Number of Units Outstanding	Weighted Average Strike Price per Unit	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2019	437,922	$ 15.38	7.2	$ 696
Granted	8,181,521	$ 4.14		
Exercised	(10,671)	$ 1.51		
Forfeited/Expired	(871,677)	$ 9.11		
Outstanding at December 31, 2020	7,737,095	$ 4.22	9.3	$ 16,374
Exercisable at December 31, 2020	1,039,225	$ 1.76	8.2	$ 4,483
Nonvested at December 31, 2020	6,697,870	$ 4.61	9.5	$ 11,891

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the estimated fair value of common stock for those stock options that had exercise prices lower than the estimated fair value of common stock. The total intrinsic value of options exercised during the years ended December 31, 2020 and 2019 was immaterial. The weighted-average estimated fair value of options granted during the years ended December 31, 2020 and 2019 was $2.80 and $1.43 per share, respectively.

As of December 31, 2020, the total unrecognized stock-based compensation expense for unvested stock options was $21.3 million, which is expected to be recognized over 3.2 years.

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,	
	2020	2019
Expected term (in years)	1.6 - 6.3	6.1
Expected Volatility	80.0%	80.0%
Risk-free interest rate	0.3% - 1.5%	1.6%-2.5%
Expected Dividend yield	—%	—%

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.

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,	
	2020	2019
Research and development	$ 1,480	$ 430
General and administrative	2,203	535
Total equity-based compensation	$ 3,683	$ 965

11. 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, 2020 and 2019, 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, 2020 and 2019.

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 9).

During the year ended December 31, 2019, the Company sold Series C-1 Preferred and Series D-2 Preferred for total proceeds of $21.6 million to stockholders who are considered to be related parties (see Note 9). The Company also entered into a Convertible Note Purchase Agreement with a stockholder considered to be a related party during the year ended December 31, 2019 (see Note 8).

12. Income taxes

The Company had no income tax expense for the years ended December 31, 2020 and 2019, due to its history of operating losses. During the years ended December 31, 2020 and 2019 the Company recorded a net loss of $91.1 million and $27.4 million, respectively.

The effective tax rate for the years ended December 31, 2020 and 2019 is different from the federal statutory rate primarily due to the valuation allowance against deferred tax assets as a result of insufficient sources of income. The following is a reconciliation of the statutory federal income tax rate to the Company's effective tax rate:

	December 31,	
	2020	2019
Effective income tax rate:		
Expected income tax benefit at the federal statutory rate	21.0%	21.0%
State taxes, net of federal benefit	7.7	7.8
Research and development tax credits	1.5	1.3
Change in estimated fair value related to convertible notes	—	(0.6)
Permanent differences	(0.8)	(0.8)
Change in valuation allowance	(29.4)	(28.7)
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 and operating losses and tax credit carryforwards. Significant components of the Company's deferred income taxes are as follows (in thousands):

	December 31,	
	2020	2019
Deferred tax assets:		
Federal and state operating loss carryforwards	$ 31,700	$ 20,118
Research and development tax credits	4,444	1,998
Lease liabilities	208	—
Manufacturing line and production equipment	12,201	—
Inventory related costs	1,890	—
Other accruals	1,070	574
Total gross deferred tax asset	51,513	22,690
Valuation allowance	(51,291)	(22,639)
Net deferred tax asset	222	51
Deferred tax liabilities:		
Depreciation	(53)	(51)
Operating lease right-of-use asset	(169)	—
Total deferred tax liabilities	(222)	(51)
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, if any, the timing and amount of which are uncertain. Because of the Company's recent history of operating losses, the Company believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has recognized a full valuation allowance on its deferred tax assets. The valuation allowance increased by $28.7 million and $10.2 million for the years ended December 31, 2020 and 2019, respectively, primarily due to the increase in the Company's net operating losses (NOL) during the period.

NOLs and tax credit carryforwards as of December 31, 2020 are as follows (in thousands):

	Amount	Expiration Years
NOLs, federal (post December 31, 2017)	$ 84,259	Do not expire
NOLs, federal (pre January 1, 2018)	30,901	2033 - 2037
NOLs, state	85,022	2033 to 2040
Research and development tax credits, federal	4,789	2035 to 2040
Research and development tax credits, state	4,496	Indefinite

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, no amounts are being presented as an uncertain tax position.

Uncertain tax positions

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

	December 31,	
	2020	2019
Unrecognized tax benefits at the beginning of the period	$ 2,395	$ 1,712
Additions for current tax positions	2,446	746
Changes for previous tax positions	—	(63)
Unrecognized tax benefits at the end of the period	$ 4,841	$ 2,395

During the years ended December 31, 2020 and 2019, 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, California and Illinois tax jurisdictions. The federal and state income tax returns from inception through December 31, 2020 remain subject to examination by federal and state authorities, where applicable. There are currently no pending income tax examinations.

13. Net (loss) income per share attributable to Common Stockholders

For the year ended December 31, 2020, the Company reported a net loss attributable to common stockholders of $91.1 million. For the year ended December 31, 2019, as a result of the Equity Transactions, the Company reported net income attributable to common stockholders of $26.4 million. The basic and diluted (loss) income per share attributable to common stockholders are computed as follows (in thousands, except for share and per share data):

	December 31,	
	2020	2019
Numerator:		
Net loss	$ (91,130)	$ (27,474)
Effect of Equity Transactions (Note 9)	—	53,856
Net (loss) income attributable to common stockholders -basic	$ (91,130)	$ 26,382
Effect of dilutive securities:		
Exclude effect of Equity Transactions	—	(53,856)
Numerator for diluted loss per share attributable to common stockholders	$ (91,130)	$ (27,474)
Denominator:		
Weighted-average number of common stock outstanding - basic	2,120,322	768,366
Weighted-average effect of dilutive securities:		
Assumed conversion of Series A, B and C Preferred Stock	—	1,382,278
Denominator for diluted loss per share attributable to common stockholders	2,120,322	2,150,644
Net (loss) income per share attributable to common stockholders - basic	$ (42.98)	$ 34.34
Net (loss) per share attributable to common stockholders - diluted	$ (42.98)	$ (12.77)

For the year ended December 31, 2020, the Company reported a net loss attributable to Common Stockholders. The potential Common Stock would have been anti-dilutive and therefore basic and diluted loss per share were the same. During the year ended December 31, 2019, the Company reported net income attributable to Class A Common Stockholders. The Company's stock options, convertible preferred stock and Notes were therefore assessed to determine whether they were antidilutive. Series A Preferred, Series B Preferred and Series C Preferred

were determined to be dilutive and were therefore included in the diluted net loss per share attributable to Common Stockholders calculation. The Series C-1 Preferred, Series D-1 Preferred and Series D-2 Preferred and the options to purchase Class A Common Stock were determined to be antidilutive and, therefore, excluded from the calculation.

The following common stock equivalents were excluded from the computation of diluted net loss per share attributable to Common Stockholders because including them would have been antidilutive:

	Year ended December 31,	
	2020	2019
Convertible Preferred Stock	53,509,351	10,471,311
Options to purchase Common Stock	7,737,095	437,922
Total	61,246,446	10,909,233

14. 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 $0.5 million and $0.3 million for the years ended December 31, 2020 and 2019.

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, 2020 or 2019.

15. Subsequent events

The Company has evaluated all subsequent events that occurred after December 31, 2020 through March 30, 2021, the date on which the financial statements were filed with the Securities and Exchange Commission.

Chicago laboratory lease

In January 2021, the Company entered a new operating lease for laboratory and office space in Chicago, IL. The lease 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 dollars annually with fixed escalations of 2.5% per annum. The Company is required to hold a letter of credit in the amount of $0.8 million to secure this lease through the expiration of the lease. The Company holds collateral of $0.8 million to secure the letter of credit.

Redwood City office lease

In January 2021, the Company entered a new operating lease for laboratory and office space in Redwood City, CA. 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 dollars annually with fixed escalations of 3.0% per annum.

NIH Rapid Acceleration of Diagnostics - RADx Initiative contracts

In February and March 2021, the Company completed certain contractual milestones related to Phase 2 requirements of our RADx initiative resulting in a total of $7.0 million being billed to the NIH of which $1.2 million had been collected. There were no unbilled receivables recorded for this contract as of December 31, 2020.

Registration Rights Agreement, with Baker Brothers Life Sciences, L.P. and 667, L.P

On March 26, 2021, we entered into a registration rights agreement (Registration Rights Agreement) with Baker Brothers Life Sciences, L.P. and 667, L.P. (the Baker Funds), pursuant to which the Baker Funds are entitled to certain resale registration rights with respect to shares of our common stock held by the Baker Funds (Registrable Securities). Under the Registration Rights Agreement, following a request by the Baker Funds, we are obligated to file a resale registration statement on Form S-3, or other appropriate form, covering Registrable Securities. 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.

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 of December 31, 2020.

Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2020 due to the material weakness in our internal control over financial reporting described below. In light of this fact, our management has performed additional analyses, reconciliations, and other post-closing procedures and has concluded that, notwithstanding the material weakness in our internal control over financial reporting, the financial statements for the periods covered by and included in this Annual Report on Form 10-K fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with GAAP.

Material weaknesses in internal control over financial reporting.

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

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

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

Changes in internal control over financial reporting.

Other than the changes intended to remediate the material weakness noted above, there were no changes in our internal control over financial reporting during the year ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Entry into Registration Rights Agreement

On March 26, 2021, we entered into a registration rights agreement (Registration Rights Agreement) with Baker Brothers Life Sciences, L.P. and 667, L.P., or the Baker Funds, pursuant to which the Baker Funds are entitled to certain resale registration rights with respect to shares of our common stock held by the Baker Funds (Registrable Securities). Under the Registration Rights Agreement, following a request by the Baker Funds, we are obligated to file a resale registration statement on Form S-3, or other appropriate form, covering Registrable Securities. 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. The rights of the Baker Funds under the Registration Rights Agreement terminate automatically upon the earlier to occur of the following events: (i) all Registrable Securities covered by the Registration Rights Agreement have been sold pursuant to an effective registration statement; (ii) all Registrable Securities covered by the Registration Rights Agreement have been sold pursuant to Rule 144, or other similar rule; (iii) at any time after the Baker Funds become an affiliate of the Company, all Registrable Securities covered by the Registration Rights Agreement may be resold by the Baker Funds without limitations as to volume or manner of sale pursuant to Rule 144; or (iv) ten (10) years after the date of the Registration Rights Agreement.

The foregoing is only a brief description of the terms of the Registration Rights Agreement and the transactions contemplated thereby and is qualified in its entirety by reference to the Agreement that is filed as Exhibit 4.5 hereto.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

INFORMATION ABOUT OUR EXECUTIVE OFFICERS AND DIRECTORS

The names, ages, and positions of all executive officers and directors as of March 29, 2021 are listed below.

Name	Age	Position(s)
Executive Officers		
Brian Coe	52	Chief Executive Officer and Director
J. Roger Moody, Jr.	53	Chief Financial Officer
Karen E. Flick, J.D., Ph.D.	52	Chief of Staff, Senior Vice President, Legal
Robert Kelley	49	Chief Commercial Officer
Douglas Liu	59	Senior Vice President, Operations
Ramesh Ramakrishnan, Ph.D.	61	Senior Vice President, Research and Development
Non-Employee Directors		
Felix Baker, Ph.D.	52	Director
Raymond Cheong, M.D., Ph.D.	39	Director
Melissa Gilliam, M.D., M.P.H.(2) (3)	55	Director
Jeryl L. Hilleman (1)	63	Director
Rustem F. Ismagilov, Ph.D.	47	Director
Kimberly J. Popovits (2) (3)	62	Director
Matthew L. Posard (1)(2)	53	Director
Randal Scott, Ph.D.(1)(3)	63	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

Brian Coe is one of our co-founders and has served as our Chief Executive Officer and a member of our board of directors since our reorganization into a corporate entity in June 2013. From July 1995 until its acquisition by The Laboratory Corporation of America (LabCorp) in November 2006, Mr. Coe was the co-founder and Chief Executive Officer of Litholink Corporation, a CLIA laboratory focused on kidney stone disease. From November 2006 to August 2012, Mr. Coe was employed by LabCorp, most recently as Senior Vice President. Mr. Coe received a B.A. in Neuroscience and Psychology from Brandeis University and an M.B.A. from the University of Chicago. Our board of directors believes that Mr. Coe's experience as our Chief Executive Officer and expertise in the medical diagnostics field qualify him to serve on our board of directors.

J. Roger Moody, Jr. has served as our Chief Financial Officer since May 2020. From August 2017 to May 2020, Mr. Moody was Chief Financial Officer of Clinical Genomics, Inc., a colorectal cancer diagnostics company. From July 2015 to August 2017, Mr. Moody was Chief Executive Officer and a member of the board of directors of GlySure Limited, a medical device company, and from February 2015 to July 2015 he was Chief Operating Officer of GlySure. Prior to GlySure, Mr. Moody served as the Chief Financial Officer and Vice President of Finance & Administration of Nanosphere, Inc., a publicly held molecular diagnostics platform company, from May 2007 to February 2015. Mr. Moody received a B.S. in Finance from Syracuse University and an M.B.A. from the University of Chicago.

Karen E. Flick, J.D., Ph.D. has served as our Chief of Staff and Senior Vice President, Legal since February 2020. Previously, Dr. Flick served as our Vice President, Legal from April 2019 to February 2020 and as our Intellectual Property Counsel from January 2015 to April 2019. Prior to joining us, Dr. Flick practiced law as a patent agent from 1998 to 2002 and as a patent attorney from 2002 to December 2014 at several prominent law firms, including Foley & Lardner LLP, Fish & Richardson P.C. and Cooley LLP. Dr. Flick received an A.B. in

Biochemistry from Harvard University and a J.D. and a Ph.D. in Molecular and Cell Biology from the University of California, Berkeley.

Robert Kelley has served as our Chief Commercial Officer since September 2020. From October 2017 to August 2020, Mr. Kelley was Vice President, Sales and Commercial Development of Genalyte, Inc., a healthcare analytics and point-of-care diagnostics company. Prior to Genalyte, Mr. Kelley was Vice President, Marketing of Cardiff Oncology, Inc. (formerly Trovagene, Inc.), a publicly held liquid biopsy company (Cardiff), from March 2015 to May 2017. From December 2008 to March 2015, Mr. Kelley held various positions of increasing responsibility with Illumina Inc., a publicly held biotechnology company (Illumina), including Global Sales Manager for clinical applications of NGS and Director, Market Development, New and Emerging Opportunities. Mr. Kelley received a B.S. in Biology from Duke University and an M.B.A. from the UCLA Anderson School of Management.

Douglas Liu has served as our Senior Vice President, Operations since September 2020. From July 2005 to September 2020, Mr. Liu was Senior Vice President, Global Operations at QIAGEN N.V., a publicly held biotechnology company. From July 1996 to July 2005, Mr. Liu was Director of Operations at Bayer AG, a publicly held pharmaceutical company. Prior to Bayer AG, Mr. Liu served as Project Manager, Research and Development at Abbott Laboratories, a publicly held medical device and healthcare company, from May 1986 to July 1996. Mr. Liu received a B.S. in Agriculture from the University of Illinois at Urbana-Champaign and an M.B.A. from Boston University.

Ramesh Ramakrishnan, Ph.D. has served as our Senior Vice President, Research and Development since May 2019. From August 2017 to March 2019, Dr. Ramakrishnan was Senior Vice President, Research and Development at Dovetail Genomics LLC, a genomics company. From January 2005 to August 2017, Dr. Ramakrishnan held various positions of increasing responsibility with Fluidigm Corporation, a publicly held biological research equipment company, most recently as Executive Vice President of Research and Development. Dr. Ramakrishnan received a B.Sc. from National College in Bangalore, an M.S. from the University of Baroda in India and, as a Fulbright Scholar, a Ph.D. in Zoology from the University of Poona, India and Georgetown University. Dr. Ramakrishnan completed his molecular biology postdoctoral work in the human genetics department at the University of Michigan, Ann Arbor.

Non-Employee Directors

Felix Baker, Ph.D. has served as a member of our board of directors since June 2013. Dr. Baker is a Managing Member of Baker Bros. Advisors LP ("BBA") a biotechnology-focused investment adviser to fund partnerships whose investors are primarily endowments and foundations. Dr. Baker founded BBA, together with his brother Julian Baker, in 2000. Dr. Baker holds a B.S. and a Ph.D. in Immunology from Stanford University, where he also completed two years of medical school. He serves on the boards of Seagen, Inc., Kodiak Sciences, Inc., Kiniksa Pharmaceuticals, Ltd., IGM Biosciences, Inc., and Talis Biomedical.

Raymond Cheong, M.D., Ph.D. has served on our board of directors since June 2020. Dr. Cheong is a Principal at Baker Bros., where he has worked since 2013. Dr. Cheong has also served on the board of directors of Istari Oncology, Inc., a biotechnology company focused on immuno-oncology and immunotherapy platforms, since December 2018. Dr. Cheong received a B.S. in Chemical Engineering from the University of Maryland, College Park, and an M.D. and a Ph.D. in Biomedical Engineering from Johns Hopkins University, where he was awarded the Michael A. Shanoff Award for best thesis research. Our board of directors believes Dr. Cheong's scientific and medical background and experience in the biotechnology industry qualify him to serve on our board of directors.

Jeryl L. Hilleman has served on our board of directors since March 2021. Ms. Hilleman brings extensive experience in life sciences and has served as a public company Chief Financial Officer for close to 20 years. Most recently, From June 2014 to November 2019, Ms. Hilleman served as the Chief Financial Officer for Intersect ENT, Inc., a publicly-traded commercial drug delivery company focusing on patients with ear, nose and throat conditions. Ms. Hilleman has served as a member of the board of directors and chair of the Audit Committee of NovoCure Limited and of Minerva Neurosciences, Inc. since July 2018 and of SI-Bone, Inc. since December 2019. From January 2005, Ms. Hilleman served as a member of the board of directors of Xenoport, Inc., a biopharmaceutical company, until it was acquired in July 2016. Ms. Hilleman received a B.A. in History from Brown University and an

M.B.A. from the Wharton School at the University of Pennsylvania. We believe Ms. Hilleman's financial experience, experience with medical device companies and her knowledge of our company qualify her to serve on our board of directors.

Rustem F. Ismagilov, Ph.D. is one of our co-founders and has served on our board of directors since June 2013. Dr. Ismagilov is a Professor of Chemistry and Chemical Engineering and the Director of the Jacobs Institute for Molecular Engineering for Medicine at the California Institute of Technology, where he has been employed since July 2011. From July 2001 to June 2011, Dr. Ismagilov held various positions of increasing responsibility at the University of Chicago, including as a Professor in the Department of Chemistry. Dr. Ismagilov received a B.S. from the Russian Academy of Sciences and a Ph.D. from the University of Wisconsin, Madison. Our board of directors believes Dr. Ismagilov's experience as one of our co-founders, as well has his deep scientific expertise, qualify him to serve on our board of directors.

Melissa Gilliam, M.D., M.P.H. has served on our board of directors since December 2020. Dr. Gilliam is the Ellen H. Block Distinguished Service Professor of Health Justice and Vice Provost at the University of Chicago, where she has taught as a Professor of Obstetrics and Gynecology and Pediatrics since 2005. Dr. Gilliam is also the founder and Director of the University of Chicago's Center for Interdisciplinary Inquiry and Innovation in Sexual and Reproductive Health, which conducts research to improve the health, education and wellbeing of adolescents. Prior to joining the University of Chicago, Dr. Gilliam was an Assistant Professor of Obstetrics and Gynecology at the University of Illinois at Chicago, where she also served as Adjunct Faculty to the Division of Epidemiology and Biostatistics in the School of Public Health. Dr. Gilliam received a B.A. in English from Yale University, an M.A. in Philosophy and Politics from the University of Oxford, an M.D. from Harvard Medical School and an M.P.H. in Epidemiology and Biostatistics from the University of Illinois at Chicago. Our board of directors believes Dr. Gilliam's medical leadership experience and expertise, including her deep expertise in issues of women's health and sexually transmitted infections, qualify her to serve on our board of directors.

Kimberly J. Popovits has served on our board of directors since March 2020. Ms. Popovits served as President and Chief Executive Officer of Genomic Health from January 2009, and as Chair of the board of directors from March 2012, until its acquisition by Exact Sciences Corporation in November 2019. Ms. Popovits has served on the board of directors of 10x Genomics, Inc., a public biotechnology company, since March 2020 and Kiniksa Pharmaceuticals, a public biopharmaceutical company, since February 2018. Ms. Popovits also served on the board of directors of ZS Pharma Inc., a public biopharmaceutical company and MyoKardia, Inc., a public clinical-stage biopharmaceutical company, from March 2017 until its acquisition in November 2020. Ms. Popovits received a B.A. in Business from Michigan State University. Our board of directors believes Ms. Popovits' significant leadership, operations and commercial experience qualify her to serve on our board of directors.

Matthew L. Posard has served on our board of directors since March 2016. Mr. Posard is a Founding Principal at Explore-DNA, Inc., a life sciences and diagnostics consulting firm, a position he has held since March 2016. Mr. Posard served as President and Chief Commercial Officer of GenePeeks, Inc., a genetic research company, from February 2017 to April 2018 and as Executive Vice President and Chief Commercial Officer of Cardiff from March 2015 to May 2016. Mr. Posard also held various executive roles at Illumina from February 2006 to February 2015, including most recently as Senior Vice President, General Manager of New and Emerging Markets. Mr. Posard has served on the board of directors of Halozyme Therapeutics, Inc. since March 2013, DermTech, Inc. since July 2016, and Nautilus Biotechnology, Inc. since January 2019. Mr. Posard has also served as the Executive Chair of both Stemson Therapeutics, LLC since March 2019 and GALT, Inc. since February 2020. Mr. Posard received a B.A. in Management Science from the University of California, San Diego. Our board of directors believes Mr. Posard's extensive experience as an executive and director of multiple biotechnology companies qualify him to serve on our board of directors.

Randal Scott, Ph.D. has served on our board of directors since February 2016. Dr. Scott is a co-founder and Chair of the board of directors of Genome Medical, Inc., a genomic medicine company founded in August 2016. Previously, Dr. Scott was a co-founder of Invitae Corporation, a publicly held genetic information company, where he served as Chair of the board of directors and Chief Executive Officer from August 2012 to January 2017 and Executive Chair from January 2017 to August 2019. Prior to Invitae, Dr. Scott co-founded Genomic Health, where he served as Chair of the board of directors and Chief Executive Officer from August 2000 to 2009 and Executive Chair from 2009 to August 2012. Dr. Scott has also served on the board of directors of BridgeBio Pharma, Inc., a

publicly held genetic disease-focused company, since June 2020 and Freenome Holdings, Inc., a private health technology company, since December 2017. Dr. Scott received a B.S. in Chemistry from Emporia State University and a Ph.D. in Biochemistry from the University of Kansas. Our board of directors believes Dr. Scott's extensive experience building and leading successful biopharmaceutical companies qualify him to serve on our board of directors.

Family Relationships

There are no family relationships among any of the directors or executive officers.

Board composition

Our business and affairs are organized under the direction of our board of directors, which currently consists of nine members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and on an ad hoc basis as required.

Our board of directors has determined that all of our directors other than Mr. Coe, Dr. Baker, Dr. Cheong and Dr. Ismagilov are independent directors, as defined by Rule 5605(a)(2) of the Nasdaq Stock Market (Nasdaq) Listing Rules.

In accordance with the terms of our amended and restated certificate of incorporation and amended and restated bylaws, we have divided our board of directors into three classes, as follows:

- Class I, which will consist of Dr. Baker, Dr. Gilliam and Mr. Posard, whose terms will expire at our 2022 annual meeting of stockholders;
- Class II, which will consist of Mr. Coe, Ms. Popovits and Dr. Scott, whose terms will expire at our 2023 annual meeting of stockholders; and
- Class III, which will consist of Dr. Cheong, Ms. Hilleman and Dr. Ismagilov, whose terms will expire at our 2024 annual meeting of stockholders.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our board of directors is currently nine members. The authorized number of directors may be changed only by resolution of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of our board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66 2/3% of our voting stock.

Nominating agreement

On November 1, 2019, we entered into a nominating agreement (Nominating Agreement), with Baker Brothers Life Sciences, L.P. and 667, L.P. (together, Baker Brothers). Pursuant to the Nominating Agreement, during the period beginning at the closing of this offering until when Baker Brothers no longer beneficially owns at least 5,317,097 shares (subject to adjustment for stock splits, combinations, recapitalizations and similar transactions) of our common stock (Initial Period), we will 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, two individuals designated by Baker Brothers (each, a Baker Designee) and during the period beginning at the closing of this offering until when Baker Brothers no longer beneficially owns at least 1,993,911 shares (subject to adjustment for stock splits, combinations, recapitalizations and similar transactions) of our common stock (together with the Initial Period, the Nominating Period), we will 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 Baker Designee, unless a majority of our disinterested directors reasonably and in good faith determines that such Baker Designee would not be qualified to serve as our director under law, rules of the stock exchange on which our shares

are listed, our amended and restated bylaws, or any of our company policies. In such case, we would notify Baker Brothers sufficiently in advance of the date on which the proxy materials related to such Baker Designee are to be mailed to enable Baker Brothers to propose a replacement Baker Designee. If a Baker Designee resigns his or her seat on our board of directors or is removed or does not become a director for any reason, the vacancy will be filled by the election or appointment of another Baker Designee as soon as reasonably practicable, subject to compliance with applicable laws, rules and regulations. Furthermore, during the Nominating Period, we will have the obligation to invite one board of directors observer designee of Baker Brothers, to attend all meetings of our board of directors and all meetings of the committees of our board of directors as a nonvoting observer. The Nominating Agreement automatically terminates upon the earlier of when Baker Brothers, together with its affiliates, no longer beneficially owns at least 1,329,274 shares (subject to adjustment for stock splits, combinations, recapitalizations and similar transactions) of our common stock or the consummation of our acquisition in a change of control transaction as such terms are defined in our amended and restated certificate of incorporation, or upon mutual consent of the parties.

Board leadership structure

Our board of directors is currently chaired by Dr. Baker, who has authority, among other things, to call and preside over board of directors meetings, to set meeting agendas and to determine materials to be distributed to the board of directors. Accordingly, the Chairman has substantial ability to shape the work of the board of directors. We believe that separation of the positions of Chairman and Chief Executive Officer reinforces the independence of the board of directors in its oversight of our business and affairs. In addition, we have a separate chair for each committee of our board of directors. The chair of each committee is expected to report annually to our board of directors on the activities of their committee in fulfilling their responsibilities as detailed in their respective charters or specify any shortcomings should that be the case.

Board committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee.

Audit committee

Our audit committee consists of Ms. Hilleman, Mr. Posard and Dr. Scott. Our board of directors has determined that each member of our audit committee satisfies the listing standards of Nasdaq and SEC independence requirements. Ms. Hilleman serves as the chair of our audit committee. The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent registered public accounting firm and determining whether to retain our existing independent registered public accounting firm or engage a new independent registered public accounting firm;
- reviewing and approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent registered public accounting firm on our engagement team as required by law;
- prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption “Management’s discussion and analysis of financial condition and results of operations,” and discussing the statements and reports with our independent registered public accounting firm and management;
- reviewing, with our independent registered public accounting firm and management, significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;

- reviewing with management and our independent registered public accounting firm any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-person transactions in accordance with our related person transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management are implemented;
- reviewing related person transactions;
- reviewing on a periodic basis our investment policy; and
- reviewing and evaluating on an annual basis the performance of the audit committee and the audit committee charter.

Our board of directors has determined that Ms. Hilleman qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Listing Rules. In making this determination, our board has considered Ms. Hilleman's prior experience, business acumen and independence. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

We believe that the composition and functioning of our audit committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation committee

Our compensation committee consists of Dr. Gilliam, Ms. Popovits and Mr. Posard. The chair of our compensation committee is Ms. Popovits. Our board of directors has determined that each of Dr. Gilliam, Ms. Popovits and Mr. Posard is independent under the listing standards of Nasdaq and a "non-employee director" as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934 (Exchange Act).

The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- reviewing and making recommendations to the full board of directors regarding the compensation and other terms of employment of our executive officers;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing and making recommendations to the full board of directors regarding the type and amount of compensation to be paid or awarded to our non-employee board members;

- establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation, to the extent required by law;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing and making recommendations to the full board of directors regarding the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
- reviewing with management and approving our disclosures under the caption "Compensation discussion and analysis" in our periodic reports or proxy statements to be filed with the SEC, to the extent such caption is included in any such report or proxy statement;
- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and assessing on an annual basis the performance of the compensation committee and the compensation committee charter.

We believe that the composition and functioning of our compensation committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Nominating and corporate governance committee

Our nominating and corporate governance committee consists of Dr. Gilliam, Ms. Popovits and Dr. Scott. Dr. Scott serves as the chair of our nominating and corporate governance committee. Our board of directors has determined that each of Dr. Gilliam, Ms. Popovits and Dr. Scott is "independent" as defined under the applicable Nasdaq listing standards and SEC rules and regulations.

The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- determining the minimum qualifications for service on our board of directors;
- evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;
- evaluating, nominating and recommending individuals for membership on our board of directors;
- evaluating nominations by stockholders of candidates for election to our board of directors;
- considering and assessing the independence of members of our board of directors;
- developing a set of corporate governance policies and principles, including a code of business conduct and ethics, periodically reviewing and assessing these policies and principles and their application and recommending to our board of directors any changes to such policies and principles;
- considering questions of possible conflicts of interest of directors as such questions arise; and
- reviewing and assessing on an annual basis the performance of the nominating and corporate governance committee and the nominating and corporate governance committee charter.

We believe that the composition and functioning of our nominating and corporate governance committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation committee interlocks and insider participation

None of our current or former executive officers serve as a member of the compensation committee. None of our officers serve, or have served during the last completed fiscal year, on the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee. Prior to establishing the compensation committee, our full board of directors made decisions relating to compensation of our officers.

Code of business conduct and ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions. A copy of the code is available on the Corporate Governance section of our website, http://talis.bio.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of our common stock, to file reports of ownership on Forms 3, 4 and 5 with the SEC. Officers, directors and greater than 10% stockholders are required to furnish us with copies of all Forms 3, 4 and 5 they file. We did not have a class of equity securities registered pursuant Section 12 of the Exchange Act during the fiscal year ended December 31, 2020, as our initial public offering was completed in February 2021. As a result, our executive officers and directors, and persons who own more than 10% of a registered class our common stock, were not subject to Section 16(a) during the fiscal year ended December 31, 2020.

Item 11. Executive and Director Compensation.

The following table summarizes information regarding the compensation awarded to, earned by, or paid to our principal executive officer and our two other most highly compensated executive officers during 2020, who we refer to in this Annual Report as our named executive officers. Brian Coe, our Chief Executive Officer, Robert Kelley, our Chief Commercial Officer, and Douglas Liu, our Senior Vice President, Operations, are our named executive officers for the year ended December 31, 2020.

Summary compensation table

The following table sets forth information regarding compensation earned by our named executive officers with respect to the fiscal year ended December 31, 2020 and, with respect to Mr. Coe, during the fiscal year ended December 31, 2019.

Name and principal position	Year	Salary ($)	Bonus ($)(1)	Option awards ($)(2)		All other compensation ($)(3)	Total ($)
Brian Coe *Chief Executive Officer*	2020	361,012	—	4,698,594	(4)	16,481	5,076,087
	2019	340,000	136,000	—		16,080	492,080
Robert Kelley. *Chief Commercial Officer(5)*	2020	101,136	—	1,261,103		3,701	1,365,940
Douglas Liu *Senior Vice President, Operations(6)*	2020	85,088	—	1,335,600		355	1,421,043

(1) The cash bonus amounts earned by each named executive officer for 2020 performance are expected to be determined in April 2021. For more information, see "—Bonus opportunity" below.

(2) In accordance with Securities and Exchange Commission rules, this column reflects the aggregate grant date fair value of the stock option awards granted during 2019 and 2020. These amounts have been computed in accordance with Financial Accounting Standards Board, Accounting Standards Codification Topic 718, *Compensation—Stock Compensation* (FASB ASC Topic 718). Assumptions used in the calculation of these amounts are described in Note 10 to our audited financial statements and notes appearing elsewhere in this Annual Report. These amounts do not reflect the actual economic value that will be realized by our named executive officers upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

(3) Amounts shown represent the following: (a) for Mr. Coe, $15,280 and $15,632 for 401(k) matching contributions in 2019 and 2020, respectively and $800 and $849 in life insurance premiums paid on behalf of Mr. Coe in 2019 and 2020, respectively, (b) for Mr. Kelley, $3,551 for 401(k) matching contributions in 2020 and $150 in life insurance premiums paid on behalf of Mr. Kelley in 2020, and (c) for Mr. Liu, $355 in life insurance premiums paid on behalf of Mr. Liu in 2020.

(4) This amount also reflects (i) the incremental fair value, computed in accordance with FASB ASC Topic 718 as of March 2020, when certain of Mr. Coe's options were amended to reduce the exercise price per share to $1.51, as described below under "—Equity-based incentive awards" and (ii) the grant date fair value for the performance-vesting option award granted to Mr. Coe in February 2020 of $293,962, based on the probable outcome of the performance condition as of the grant date, plus the incremental fair value of the modification of the option award in August 2020 of $1,074,607, computed as of the modification date, each in accordance with FASB ASC Topic 718. The maximum potential value of the performance vesting-option award (assuming the highest level of performance achievement) is $1,368,568, calculated under FASB ASC Topic 718.

(5) Mr. Kelley commenced employment as our Chief Commercial Officer in August 2020.

(6) Mr. Liu commenced employment as our Senior Vice President, Operations in September 2020.

Narrative to the summary compensation table

Annual base salary

The base salary of our named executive officers is generally determined and approved by our board of directors in connection with the commencement of employment of the named executive officer and may be adjusted

from time to time thereafter as the board of directors determines appropriate. The 2020 annual base salaries for our named executive officers are set forth in the table below.

Name	2020 Base Salary ($)(1)
Brian Coe *Chief Executive Officer*	375,000
Robert Kelley *Chief Commercial Officer*	300,000
Douglas Liu *Senior Vice President, Operations*	325,000

(1) Mr. Coe's base salary was increased from $340,000 to $375,000 effective May 2020. Mr. Kelley's and Mr. Liu's base salaries were determined in connection with their commencement of employment with us.

Bonus opportunity

In addition to base salaries, each of our named executive officers is eligible to receive annual cash bonuses, which are designed to provide appropriate incentives to our named executive officers to achieve defined annual corporate goals and to reward our named executive officers for their individual achievements. The annual bonus awarded to each named executive officer may be based in part on the extent to which we achieve corporate goals. At the end of the year, our board of directors reviews our performance against each corporate goal and considers the extent to which we achieved each of our corporate goals.

There is no minimum bonus percentage or amount established for our named executive officer and, as a result, the bonus amounts vary from year to year based on corporate and, when applicable, individual performance.

For 2020, each of Mr. Coe, Mr. Kelley and Mr. Liu was eligible for a target bonus equal to 40%, 30% and 40% of their base salary, respectively. Annual cash bonuses for 2020 performance have not yet been approved and are expected to be determined in March 2021.

Equity-based incentive awards

Our equity-based incentive awards are designed to align our named executive officers' interests with those of our stockholders and to retain and incentivize our named executive officers over the long-term. Our board of directors is responsible for approving equity grants. Vesting of equity awards is generally tied to continuous service with us and serves as an additional retention measure. Our named executive officers generally are awarded an initial new hire grant upon commencement of employment. Additional grants may occur periodically in order to specifically incentivize our named executive officers with respect to achieving certain corporate goals or to reward our named executive officers for exceptional performance.

Prior to the closing of our initial public offering, we have granted all equity awards pursuant to the 2013 Plan, the terms of which are described below under "—Equity benefit plans." All options are granted with a per share exercise price equal to no less than the fair market value of a share of our common stock on the date of the grant of such award. Generally, our option awards vest over a four-year period subject to the holder's continuous service to us, as further described under "—Outstanding equity awards at fiscal year-end" below. Following the closing of our initial public offering, we will grant equity awards under the 2021 Plan, the terms of which are described below under "—Equity benefit plans."

In February 2020, our board of directors granted options to purchase 817,482 shares to Mr. Coe with an exercise price per share of $1.51. The options vest monthly over four years beginning on November 1, 2019, subject to Mr. Coe's continued services to us. In addition, the options provide for "double trigger" vesting acceleration if upon or within 12 months following a change in control of the company Mr. Coe experiences an involuntary termination without cause (and not due to death or disability) or a voluntary termination with good reason. In February 2020, our board of directors also granted Mr. Coe an option to purchase 241,958 shares at an exercise price

per share of $1.51; the option was most recently amended in October 2020 and vests in full upon the first commercial sale of the company's first product, subject to Mr. Coe's continued services to us.

In addition, in March 2020, we amended certain outstanding options, including options held by Mr. Coe, which were "underwater," meaning the exercise price per share of these options was greater than the current fair market value of our common stock. The amendment reduced the exercise price per share of such options to $1.51, the fair market value of our common stock as determined by our board of directors on the date of the repricing. We believe that repricing these underwater options was important for the growth and development of our business in order to provide appropriate retention and motivation incentives for our employees holding these options. Mr. Coe's repriced options are further discussed below under "—Outstanding equity awards at fiscal year end."

In August 2020, our board of directors granted an option to purchase 587,627 shares to Mr. Coe with an exercise price per share of $6.25. The option vest as follows: 25% of the shares vest on August 4, 2021, and the balance vests in 36 equal monthly installments thereafter, subject to Mr. Coe's continued services to us. The option also provides for "double trigger" vesting acceleration, as described above.

In September 2020, our board of directors granted options to purchase 297,202 shares to Mr. Kelley and 314,685 shares to Mr. Liu, each with an exercise price per share of $6.25. The options vest as follows: 25% of the shares vest on August 31, 2021, for Mr. Kelley, and September 28, 2021, for Mr. Liu, and the balance vests in 36 equal monthly installments thereafter, subject to the named executive officer's continued services to us. In addition, the options provide for "double trigger" vesting acceleration, as described above.

Employment agreements with our named executive officers

We do not currently maintain a written employment agreement or offer letter agreement with Mr. Coe.

We entered into an offer letter with Mr. Kelley in August 2020 that provides for his initial base salary and annual target bonus and initial stock option grant, each as described above under "—Annual base salary," "—Bonus opportunity" and "—Equity-based incentive awards."

We entered into an offer letter with Mr. Liu in September 2020 that provides for his initial base salary and annual target bonus and initial stock option grant, each as described above under "—Annual base salary," "—Bonus opportunity" and "—Equity-based incentive awards."

Each of our current named executive officer's employment is "at will" and may be terminated by us at any time. For a discussion of the severance and other benefits to be provided in connection with a termination of employment and/or a change in control under the arrangements with our named executive officers please see "—Potential payments upon termination or change in control" below.

Potential payments upon termination or change in control

Regardless of the manner in which service terminates, each of our named executive officers is entitled to receive amounts earned during his or her term of service, including unpaid salary and unused vacation, as applicable.

Effective in connection with the closing of our initial public offering, each of our named executive officers became eligible to receive benefits under the terms of our Severance and Change in Control Plan adopted by the board of directors in February 2021 (Severance Plan). The Severance Plan provides for severance and/or change in control benefits to the named executive officers upon (i) a "change in control termination" or (ii) a "regular termination" (each as described below). Upon a change in control termination, each of our named executive officers is entitled to a lump sum payment equal to a portion of his base salary (18 months for Mr. Coe and 12 months for each of Mr. Kelley and Mr. Liu), a lump sum payment equal to 150% (for Mr. Coe) or 100% (for each of Mr. Kelley and Mr. Liu) of his annual target cash bonus, payment of COBRA premiums for a period of time (up to 18 months for Mr. Coe and 12 months for each of Mr. Kelley and Mr. Liu) and accelerated vesting of outstanding time-vesting equity awards. To the extent an equity award is not assumed, continued or substituted for in the event of certain

change in control transactions and the executive's employment is not terminated as of immediately prior to such change in control, the vesting of such equity award will also accelerate in full (and for equity awards subject to performance vesting, performance will be deemed to be achieved at target, unless otherwise provided in individual award documents). Upon a regular termination, each of our named executive officers is entitled to a lump sum payment equal to a portion of his base salary (12 months for Mr. Coe and 6 months for each of Mr. Kelley and Mr. Liu) and payment of COBRA premiums for a period of time (up to 12 months for Mr. Coe and 6 months for each of Mr. Kelley and Mr. Liu). All severance benefits under the Severance Plan are subject to the executive's execution of an effective release of claims against the company.

For purposes of the Severance Plan, a "regular termination" is an involuntary termination (i.e., a termination other than for cause (and not as a result of death or disability) or a resignation for good reason, as defined in the Severance Plan) that does not occur during the period of time beginning three months prior to, and ending 12 months following, a "change in control" (as defined in the 2021 Plan), or the "change in control period." A "change in control termination" is a regular termination that occurs during the change in control period.

Each of our named executive officers holds options that were granted subject to the terms of our 2013 Plan. A description of the termination and change in control provisions in our 2013 Plan and applicable to the options granted to our named executive officers is provided below under "—Equity benefit plans" and, with respect to our named executive officers, "—Outstanding equity awards at fiscal year-end" and above under "—Equity-based incentive awards." In addition, all of Mr. Coe's, Mr. Kelley's and Mr. Liu's time-vesting option grants (including the repriced awards) provide for "double trigger" acceleration as described above under "—Equity-based incentive awards."

Outstanding equity awards at fiscal year end

The following table sets forth certain information regarding equity awards granted to our named executive officers that remain outstanding as of December 31, 2020.

		Option awards(1)				
	Vesting commencement date	Number of securities underlying unexercised options exercisable (#)	Number of securities underlying unexercised options unexercisable (#)	Equity incentive plan awards: number of securities underlying unexercised unearned options (#)	Option exercise price ($)(2)(3)	Option expiration date
Brian Coe	7/1/2013	50,640	—	—	1.51	12/18/2023
	7/30/2015	33,274	—	—	1.51	7/29/2025
	8/1/2017	20,139	4,028	—	1.51	7/11/2027
	5/1/2018	4,588	2,517	—	1.51	5/20/2028
	10/1/2018	18,939	16,026	—	1.51	11/4/2028
	(4)	—	—	241,958	1.51	2/11/2030
	11/1/2019	221,401	596,081	—	1.51	2/11/2030
	8/4/2020	—	587,627	—	6.25	8/5/2030
Robert Kelley	8/31/2020	—	297,202	—	6.25	9/3/2030
Douglas Liu	9/28/2020	—	314,685	—	6.25	9/28/2030

(1) All of the option awards were granted under the 2013 Plan, the terms of which plan are described below under "—Equity benefit plans."

(2) Each option, other than as noted in footnote (4) below, vests as follows: 25% of the shares subject to the option vest on the 12-month anniversary of the vesting commencement date, and the balance of the shares vest in 36 equal monthly installments over the next three years, subject to the named executive officer's continued services to us, subject to full vesting acceleration, if a change in control occurs and the named executive officer's continuous service terminates due to an involuntary termination (not including death or disability) without cause or due to a voluntary termination with good reason as of or within 12 months after such change in control, then the vesting and exercisability of the option will be accelerated in full.

(3) Options held by Mr. Coe were amended in March 2020 to reduce the exercise price per share to $1.51, as described above under "—Equity-based incentive awards."

(4) This option vests in full upon the first commercial sale of the company's first product, subject to Mr. Coe's continued services to us.

Perquisites, health, welfare and retirement benefits

Each of our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, life, long term disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. We pay the premiums for the life, disability, accidental death and dismemberment insurance for all of our employees. In addition, we provide the opportunity to participate in a 401(k) plan to our employees, including each of our named executive officers, as discussed in the section below entitled "—401(k) plan."

401(k) plan

We maintain a defined contribution employee retirement plan (401(k) plan), for our employees. Our named executive officers are each eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Code. The 401(k) plan provides that each participant may contribute up to the lesser of 100% of his or her compensation or the statutory limit, which is $19,500 for calendar years 2020 and 2021. Participants that are 50 years or older can also make "catch-up" contributions, which in calendar years 2020 and 2021 may be up to an additional $6,500 above the statutory limit. Participant contributions are held and invested, pursuant to the participant's instructions, by the plan's trustee. 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%. We may also elect to provide for discretionary profit sharing contributions, but we did not provide any such contributions in 2020. In general, eligible compensation for purposes of the 401(k) plan includes an employee's earnings reportable on IRS Form W-2 subject to certain adjustments and exclusions as permitted and required under the Code. The 401(k) plan currently does not offer the ability to invest in our securities.

We do not provide perquisites or personal benefits to our executive officers, except in limited circumstances. We did not provide any such perquisites or personal benefits to our named executive officers in 2020.

Equity benefit plans

2021 Equity Incentive Plan

Our board of directors adopted our 2021 Equity Incentive Plan (2021 Plan), and our stockholders approved our 2021 Plan, in February 2021. Our 2021 Plan is a successor to and continuation of our 2013 Equity Incentive Plan (2013 Plan) (as described below). Our 2021 Plan became effective on the date of the underwriting agreement related to our initial public offering. The 2021 Plan came into existence upon its adoption by our board of directors and no grants were made under the 2021 Plan prior to its effectiveness. No further grants will be made under the 2013 Plan following the effectiveness of the 2021 Plan.

Awards. Our 2021 Plan provides for the grant of incentive stock options (ISOs) within the meaning of Section 422 of the Internal Revenue Code of 1984, as amended, to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants, including employees and consultants of our affiliates.

Authorized shares. Initially, the maximum number of shares of our common stock that may be issued under our 2021 Plan will not exceed 12,840,904 shares of our common stock, which is the sum of (1) 3,200,000 new shares, plus (2) any shares that remain available for the issuance of awards under our 2013 Plan as of immediately prior to the time our 2021 Plan becomes effective, plus (3) any shares subject to outstanding stock options or other stock awards granted under our 2013 Plan that, on or after the 2021 Plan becomes effective, terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, if any, as such shares become available from time to time. In addition, the number of shares of our common

stock reserved for issuance under our 2021 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2022 through January 1, 2031, in an amount equal to (i) 4% of the total number of shares of our common stock outstanding on December 31 of the preceding year, or (ii) a lesser number of shares determined by our board of directors prior to the applicable January 1. The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2021 Plan is 39,000,000 shares.

Shares subject to stock awards granted under our 2021 Plan that expire or terminate without being exercised in full or that are paid out in cash rather than in shares do not reduce the number of shares available for issuance under our 2021 Plan. Shares withheld under a stock award to satisfy the exercise, strike or purchase price of a stock award or to satisfy a tax withholding obligation do not reduce the number of shares available for issuance under our 2021 Plan. If any shares of our common stock issued pursuant to a stock award are forfeited back to or repurchased or reacquired by us (1) because of a failure to meet a contingency or condition required for the vesting of such shares, (2) to satisfy the exercise, strike or purchase price of an award or (3) to satisfy a tax withholding obligation in connection with an award, the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under the 2021 Plan. Any shares previously issued which are reacquired in satisfaction of tax withholding obligations or as consideration for the exercise or purchase price of a stock award will again become available for issuance under the 2021 Plan.

The maximum number of shares of common stock subject to stock awards granted under the 2021 Plan or otherwise during any period commencing on the date of the company's annual meeting of stockholders for a particular year and ending on the day immediately prior to the date of the company's annual meeting of stockholders for the next subsequent year to any non-employee director, taken together with any cash fees paid by us to such non-employee director during such period for service on the board of directors, will not exceed $750,000 in total value, or with respect to the period in which a non-employee director is first appointed or elected to our board of directors, $1,000,000 in total value, in each case calculating the value of any such stock awards based on the grant date fair value of such stock awards for financial reporting purposes.

Plan administration. Our board of directors, or a duly authorized committee of our board of directors, will administer our 2021 Plan and is referred to as the "plan administrator" herein. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees (other than officers) to receive specified stock awards and (2) determine the number of shares subject to such stock awards. Under our 2021 Plan, the plan administrator has the authority to determine award recipients, grant dates, the numbers and types of stock awards to be granted, the applicable fair market value, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award.

The plan administrator has the power to modify outstanding awards under our 2021 Plan. Subject to the terms of our 2021 Plan, the plan administrator has the authority to reprice any outstanding stock award, cancel and re-grant any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any materially impaired participant.

Stock options. ISOs and NSOs are granted under stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2021 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2021 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

The plan administrator determines the term of stock options granted under the 2021 Plan, up to a maximum of 10 years. Unless the terms of an optionholder's stock option agreement, or other written agreement between us and the recipient approved by the plan administrator, provide otherwise, if an optionholder's service relationship with us or any of our affiliates ceases for any reason other than disability, death, or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that either an exercise of the option or an immediate sale of shares acquired upon exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may

generally exercise any vested options for a period of 18 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, or (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options or stock appreciation rights generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the plan administrator or a duly authorized officer, an option may be transferred pursuant to a domestic relations order, official marital settlement agreement, or other divorce or separation instrument.

Tax limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

Restricted stock unit awards. Restricted stock unit awards are granted under restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, or other written agreement between us and the recipient approved by the plan administrator, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted stock awards. Restricted stock awards are granted under restricted stock award agreements adopted by the plan administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past or future services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The plan administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock appreciation rights. Stock appreciation rights are granted under stock appreciation right agreements adopted by the plan administrator. The plan administrator determines the purchase price or strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the 2021 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator. Stock appreciation rights may be settled in cash or shares of common stock or in any other form of payment as determined by the Board and specified in the stock appreciation right agreement.

The plan administrator determines the term of stock appreciation rights granted under the 2021 Plan, up to a maximum of 10 years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability, or death, the participant may generally exercise any vested stock appreciation right for a

period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance awards. The 2021 Plan permits the grant of performance awards that may be settled in stock, cash or other property. Performance awards may be structured so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the common stock.

The performance goals may be based on any measure of performance selected by the board of directors. The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates, or business segments, and may be either absolute or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the board of directors at the time the performance award is granted, the board will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (i) to exclude restructuring and/or other nonrecurring charges; (ii) to exclude exchange rate effects; (iii) to exclude the effects of changes to generally accepted accounting principles; (iv) to exclude the effects of any statutory adjustments to corporate tax rates; (v) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (vi) to exclude the dilutive effects of acquisitions or joint ventures; (vii) to assume that any portion of our business which is divested achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (viii) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (ix) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (x) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (xi) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.

Other stock awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award (or cash equivalent) and all other terms and conditions of such awards.

Changes to capital structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2021 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued on the exercise of ISOs, and (4) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate transactions. The following applies to stock awards under the 2021 Plan in the event of a corporate transaction, unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the plan administrator at the time of grant.

In the event of a corporate transaction, any stock awards outstanding under the 2021 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous

service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction), and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

In the event a stock award will terminate if not exercised prior to the effective time of a corporate transaction, the plan administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the per share amount payable to holders of common stock in connection with the corporate transaction, over (ii) any per share exercise price payable by such holder, if applicable. In addition, any escrow, holdback, earn out or similar provisions in the definitive agreement for the corporate transaction may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of common stock.

Under the 2021 Plan, a corporate transaction is generally defined as the consummation of: (i) a sale of all or substantially all of our assets, (ii) the sale or disposition of at least 50% of our outstanding securities, (iii) a merger or consolidation where we do not survive the transaction, or (iv) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

Change in control. Awards granted under the 2021 Plan may be subject to acceleration of vesting and exercisability upon or after a change in control (as defined in the 2021 Plan) as may be provided in the applicable stock award agreement or in any other written agreement between us or any affiliate and the participant, but in the absence of such provision, no such acceleration will automatically occur.

Under the 2021 Plan, a change in control is generally defined as: (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (ii) a consummated merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity) in substantially the same proportions as their ownership immediately prior to such transaction; (iii) a consummated sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction; or (iv) when a majority of our board of directors becomes comprised of individuals who were not serving on our board of directors on the date the 2021 Plan was adopted by the board of directors, or the incumbent board, or whose nomination, appointment, or election was not approved by a majority of the incumbent board still in office.

Plan amendment or termination. Our board of directors has the authority to amend, suspend, or terminate our 2021 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopts our 2021 Plan. No stock awards may be granted under our 2021 Plan while it is suspended or after it is terminated.

2013 Equity incentive plan

Our board of directors and stockholders adopted our 2013 Plan in June 2013. The 2013 Plan was most recently amended by our board of directors and stockholders in October 2020. As of December 31, 2020, there were no shares remaining available for the future grant of stock awards under our 2013 Plan. As of December 31, 2020, there were outstanding stock options covering a total of 7,737,095 shares of our common stock that were granted under our 2013 Plan. Any shares of common stock remaining available for issuance under the 2013 Plan upon the

2021 Plan's effectiveness in connection with the closing of our initial public offering have become available for issuance under the 2021 Plan.

Stock awards. Our 2013 Plan provides for the grant of ISOs within the meaning of Section 422 of the Code to employees, including employees of any parent or subsidiary, and for the grant of NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards and other forms of stock awards to employees, directors and consultants, including employees and consultants of our affiliates. To date, we have only granted options under the 2013 Plan.

Authorized shares. Subject to certain capitalization adjustments, the aggregate number of shares of common stock that may be issued pursuant to stock awards under the 2013 Plan will not exceed 9,665,351 shares. The maximum number of shares of our common stock that may be issued pursuant to the exercise of ISOs under our 2013 Plan is 9,665,351 shares.

Shares subject to stock awards granted under our 2013 Plan that expire or otherwise terminate without being exercised in full or that are settled in cash rather than in shares do not reduce or otherwise offset the number of shares available for issuance of awards under our 2013 Plan. Additionally, if any shares issued pursuant to a stock award are forfeited back to or repurchased because of the failure to meet a contingency or condition required to vest or are reacquired in satisfaction of a tax withholding obligation or as consideration for the exercise price of a stock award, then the shares that are forfeited, repurchased or reacquired will revert to and again become available for issuance of awards under the 2013 Plan.

Plan administration. Our board of directors, or a duly authorized committee of our board of directors to which the board delegates its administrative authority, will administer our 2013 Plan and is referred to as the "plan administrator" herein. The plan administrator may also delegate to one or more of our officers the authority to (1) designate employees (other than officers) to receive specified options and stock appreciation rights (and to the extent permitted by applicable law, other stock awards) and (2) determine the number of shares subject to such stock awards; provided, however, that the board resolutions regarding such delegation must specify the total number of shares that may be subject to awards granted by such officer, and provided further, that no officer may grant an award under the 2013 Plan to himself or herself. Under our 2013 Plan, the plan administrator has the authority to, among other things, determine award recipients, dates of grant, the numbers and types of stock awards to be granted, the applicable fair market value and the provisions of each stock award, including the period of their exercisability and the vesting schedule applicable to a stock award, to construe and interpret the 2013 Plan and awards granted thereunder (and to establish, amend and revoke any rules and regulations for the administration of the 2013 Plan and any such awards), or to accelerate the vesting of awards.

Under the 2013 Plan, the plan administrator also generally has the authority to effect, with the consent of any adversely affected participant, (A) the reduction of the exercise, purchase, or strike price of any outstanding award; (B) the cancellation of any outstanding award and the grant in substitution therefor of other awards, cash, or other consideration; or (C) any other action that is treated as a repricing under generally accepted accounting principles.

Stock options. ISOs and NSOs are granted under stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2013 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant (or 110% of the fair market value for certain major stockholders). Options granted under the 2013 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

The plan administrator determines the term of stock options granted under the 2013 Plan, up to a maximum of 10 years (or five years, for certain major stockholders). If an optionholder's service relationship with us or any of our affiliates ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of up to three months following the cessation of service. This period may be extended in the event that either an exercise of the option or an immediate sale of shares acquired upon exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested

options for a period of up to 18 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of up to 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order payable to us, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, (5) a deferred payment arrangement, or (6) other legal consideration approved by the plan administrator and specified in the stock award agreement.

Unless the plan administrator provides otherwise, options generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the plan administrator or a duly authorized officer in each case, (i) an option may be transferred pursuant to a domestic relations order, official marital settlement agreement, or other divorce or separation instrument and (ii) an optionholder may designate a beneficiary who may exercise the option following the optionholder's death.

Tax limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

Changes to capital structure. In the event of a capitalization adjustment, the plan administrator will make appropriate and proportionate adjustments to (1) the class and maximum number of shares reserved for issuance under the 2013 Plan, (2) the class and maximum number of shares that may be issued on the exercise of ISOs, and (3) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate transactions. Our 2013 Plan provides that in the event of a corporate transaction, unless otherwise provided in an award agreement or other written agreement between us and the award holder, the plan administrator may take one or more of the following actions with respect to such stock awards:

- arrange for the assumption, continuation, or substitution of a stock award by a surviving or acquiring corporation;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring corporation;
- accelerate the vesting, in whole or in part, of the stock award and provide for its termination if not exercised (if applicable) at or before the effective time of the transaction;
- arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us;
- cancel or arrange for the cancellation of the stock award, to the extent not vested or not exercised before the effective time of the transaction, in exchange for such cash consideration, if any, as our board of directors, in its sole discretion, may consider appropriate; and
- make a payment equal to the excess, if any, of (A) the value of the property the participant would have received on exercise of the award immediately before the effective time of the transaction, over (B) any exercise price payable by the participant in connection with the exercise.

The plan administrator is not obligated to treat all stock awards or portions of stock awards in the same manner and is not obligated to treat all participants in the same manner.

Under the 2013 Plan, a corporate transaction is generally defined as the consummation of: (i) a sale or other disposition of all or substantially all of our assets, (ii) the sale or disposition of at least 50% of our outstanding securities, (iii) a merger or consolidation where we do not survive the transaction, or (iv) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

Change in control. A stock award may be subject to additional acceleration of vesting and exercisability upon or after a change in control as may be provided in an applicable award agreement or other written agreement, but in the absence of such provision, no such acceleration will occur.

Under the 2013 Plan, a change in control is generally defined as: (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (ii) a consummated merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity) in substantially the same proportions as their ownership immediately prior to such transaction; or (iii) a consummated sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction.

Plan amendment or termination. Our board of directors has the authority to amend, suspend, or terminate our 2013 Plan, provided that such action does not impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. Unless terminated sooner, the 2013 Plan will automatically terminate on June 25, 2023. No stock awards may be granted under our 2013 Plan while it is suspended or after it is terminated. No further grants will be made under the 2013 Plan.

2021 Employee Stock Purchase Plan

Our board of directors adopted our 2021 Employee Stock Purchase Plan (ESPP), and our stockholders approved our ESPP, in February 2021. The ESPP became effective immediately prior to and contingent upon the execution of the underwriting agreement related to our initial public offering. The purpose of the ESPP is to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. The ESPP includes two components. One component is designed to allow eligible U.S. employees to purchase our common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. In addition, purchase rights may be granted under a component that does not qualify for such favorable tax treatment because of deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the United States while complying with applicable foreign laws.

Share reserve. Following the closing of our initial public offering, the ESPP authorizes the issuance of 550,000 shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2022, through January 1, 2031, by the lesser of (1) 1% of the total number of shares of our common stock outstanding on December 31st of the preceding year and (2) 1,550,000 shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (1) and (2). As of the date hereof, no shares of our common stock have been purchased under the ESPP.

Administration. Our board of directors administers the ESPP and may delegate its authority to administer the ESPP to our compensation committee. The ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares

of our common stock will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

Payroll deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings (as defined in the ESPP) for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share that is at least the lesser of (1) 85% of the fair market value of a share of our common stock on the first date of an offering, or (2) 85% of the fair market value of a share of our common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors, including: (1) being customarily employed for more than 20 hours per week, (2) being customarily employed for more than five months per calendar year, or (3) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of $25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each calendar year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

Changes to capital structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, the board of directors will make appropriate adjustments to: (1) the class(es) and maximum number of shares reserved under the ESPP, (2) the class(es) and maximum number of shares by which the share reserve may increase automatically each year, (3) the class(es) and number of shares subject to and purchase price applicable to outstanding offerings and purchase rights, and (4) the class(es) and number of shares that are subject to purchase limits under ongoing offerings.

Corporate transactions. In the event of certain significant corporate transactions, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued, or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within 10 business days before such corporate transaction, and such purchase rights will terminate immediately after such purchase.

Under the ESPP, a corporate transaction is generally the consummation of: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 50% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction, and (4) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

ESPP amendment or termination. Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

Limitation of liability and indemnification

Our amended and restated certificate of incorporation limits the liability of directors to the maximum extent permitted by Delaware law.

Delaware law allows a corporation to eliminate the personal liability of directors of a corporation to the corporation and its stockholders for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- breach of his or her duty of loyalty to the corporation or its stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation does not eliminate a director's duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, will remain available under Delaware law. These limitations also do not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Our amended and restated bylaws provide that we will indemnify our directors and executive officers and may indemnify other officers, employees and other agents, to the fullest extent permitted by law. Our amended and restated bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding and also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our amended and restated bylaws permit such indemnification. We have obtained a policy of directors' and officers' liability insurance.

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated bylaws. These agreements, among other things, will require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Director compensation

The following table sets forth in summary form information concerning the compensation that we paid or awarded during the year ended December 31, 2020 to each of our non-employee directors.

Name(1)	Fees earned or paid in cash ($)		Option awards ($)(2)(3)		Total ($)
Felix Baker, Ph.D.	—		—		—
Raymond Cheong, M.D., Ph.D.	—		—		—
Melissa Gilliam, M.D., M.P.H.	—		371,349		371,349
Rustem F. Ismagilov, Ph.D.	75,000	(4)	1,212,237	(5)	1,287,237
Kimberly J. Popovits	12,818		260,448		273,266
Matthew L. Posard	24,000		293,643		317,643
Randal Scott, Ph.D.	24,000		293,643		317,643

(1) Dr. Cheong, Dr. Gilliam and Ms. Popovits joined our board of directors in June 2020, December 2020 and March 2020, respectively.

(2) As of December 31, 2020, the aggregate number of shares underlying outstanding options to purchase our common stock held by our non-employee directors were: Dr. Gilliam, 62,937; Dr. Ismagilov, 511,301; Ms. Popovits, 125,721; Mr. Posard, 143,779, and Dr. Scott, 143,779. None of our other non-employee directors held options to purchase our common stock as of December 31, 2020. None of our non-employee directors held other unvested stock awards as of December 31, 2020.

(3) In accordance with Securities and Exchange Commission rules, this column reflects the aggregate grant date fair value of the stock option awards granted during 2020. These amounts have been computed in accordance with Financial Accounting Standards Board, Accounting Standards Codification Topic 718, *Compensation—Stock Compensation*. Assumptions used in the calculation of these amounts are described in Note 10 to our audited financial statements and notes appearing elsewhere in this prospectus. These amounts do not reflect the actual economic value that will be realized by our non-employee directors upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options. In addition, with respect to Mr. Posard and Dr. Scott only, the amounts shown in this column also reflects the incremental fair value, computed in accordance with Financial Accounting Standards Board, Accounting Standards Codification Topic 718, *Compensation—Stock Compensation* as of March 2020, when Mr. Posard's and Dr. Scott's options were amended to reduce the exercise price per share to $1.51, as described above under "—Equity-based incentive awards."

(4) Consists of consulting fees paid pursuant to a consulting agreement with Dr. Ismagilov for his service as a member of our scientific advisory board, as described under "Certain relationships and related person transactions—Consulting arrangements."

(5) This amount includes the grant date fair value of $316,595 for a stock option award granted to Dr. Ismagilov pursuant to the consulting agreement described in footnote (4) above.

In February 2016, we entered into letter agreements with each of Mr. Posard and Dr. Scott confirming their appointment to the board of directors, pursuant to which each is entitled to a stipend of $24,000 per year, which was paid on a quarterly basis. Pursuant to the letters, Mr. Posard and Dr. Scott were each entitled to an option to purchase 8,636 shares of our common stock, which were granted in February 2016 and have fully vested.

In February 2020, our board of directors granted options to purchase 290,306 shares to Dr. Ismagilov, 82,788 shares to Mr. Posard and 82,788 shares to Mr. Scott, each with an exercise price per share of $1.51. The options vest monthly over four years beginning on November 1, 2019, subject to the director's continued services to us. In addition, the options provide for "single trigger" vesting acceleration if a change in control occurs and the director remains in service immediately prior to the change in control.

In addition, in March 2020, we amended certain outstanding underwater options held by Mr. Posard and Dr. Scott. The amendment reduced the exercise price per share of such options to $1.51, the fair market value of our common stock as determined by our board of directors on the date of the repricing. The repricing is further described above under "—Equity-based incentive awards."

In March 2020, we entered into a letter agreement with Ms. Popovits confirming her appointment to the board of directors, pursuant to which Ms. Popovits is entitled to a stipend of $24,000 per year, to be paid on a quarterly basis, and an option to purchase shares of our common stock equal to 0.35% of the company on a fully diluted basis. In May 2020, our board of directors granted an option to purchase 84,615 shares to Ms. Popovits in connection with her commencement of services with us at an exercise price per share of $1.51. The option vests as follows: 25% of the shares vest on March 19, 2021, and the balance vests in 36 equal monthly installments thereafter, subject to Ms. Popovits' continued services to us. The option also provides for "single trigger" vesting acceleration, as described above.

In August 2020, our board of directors granted options to purchase 47,011 shares to Mr. Posard, 47,011 shares to Dr. Scott, 41,106 shares to Ms. Popovits and 141,032 shares to Dr. Ismagilov, each at an exercise price per share of $6.25. The options vest as follows: 25% of the shares vest on August 4, 2021, and the balance vests in 36 equal monthly installments thereafter, subject to the director's continued services to us. The option also provides for "single trigger" vesting acceleration, as described above.

In September 2020, our board of directors granted an option to purchase 79,963 shares to Dr. Ismagilov at an exercise price per share of $6.25. The option vests as follows: one-sixth of the shares vest on September 1, 2020, and the balance vests in five equal monthly installments thereafter, subject to Dr. Ismagilov's continued services to us.

In December 2020, we entered into a letter agreement with Dr. Gilliam confirming her appointment to the board of directors, pursuant to which Dr. Gilliam is entitled to a stipend of $40,000 per year, to be paid on a quarterly basis, and an option to purchase 62,937 shares of our common stock. In December 2020, our board of directors granted an option to purchase 62,937 shares to Dr. Gilliam at an exercise price per share of $8.67. The option vests as follows: 25% of the shares vest on December 15, 2021, and the balance vests in 36 equal monthly installments thereafter, subject to Dr. Gilliam's continued services to us. In addition, the option provides for "single trigger" vesting acceleration, as described above.

Outstanding equity awards held by our non-employee directors are subject to the terms of our 2013 Plan, as described above under "—Equity benefit plans—2013 Equity Incentive Plan."

We have reimbursed and will continue to reimburse all of our non-employee directors for their travel, lodging and other reasonable expenses incurred in attending meetings of our board of directors and committees of our board of directors.

Non-employee director compensation policy

Our board of directors adopted a non-employee director compensation policy in February 2021 that became effective upon the execution and delivery of the underwriting agreement related to our initial public offering and will be applicable to all of our non-employee directors. This compensation policy provides that each such non-employee director will receive the following compensation for service on our board of directors:

- an annual cash retainer of $40,000;
- an additional annual cash retainer of $40,000 for service as non-employee chairman of the board of directors;
- an additional annual cash retainer of $22,500 for service as lead independent director;
- an additional annual cash retainer of $10,000, $7,000 and $5,000 for service as a member of the audit committee, compensation committee and the nominating and corporate governance committee, respectively;
- an additional annual cash retainer of $20,000, $14,000 and $10,000 for service as chair of the audit committee, chair of the compensation committee and chair of the nominating and corporate governance committee, respectively (in lieu of the committee member retainer above);
- an initial option grant to purchase shares of our common stock with an aggregate Black-Scholes option value of $340,000, vesting in 36 equal monthly installments; and
- an annual option grant to purchase shares of our common stock with an aggregate Black-Scholes option value of $170,000, vesting in 12 equal monthly installments.

Each of the option grants described above will be granted under our 2021 Plan, the terms of which are described in more detail above under "Executive and director compensation—Equity benefit plans—2021 Equity Incentive Plan." Each such option grant will vest and become exercisable subject to the director's continuous service with us, provided that each option will vest in full upon a change in control of the company. The term of each option

will be 10 years, subject to earlier termination as provided in the 2021 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).

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

The following table sets forth information with respect to the beneficial ownership of our capital stock by:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock or our Series 1 convertible preferred stock;
- each of our named executive officers;
- each of our directors; and
- all of our directors and executive officers as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership below is based on 25,636,179 shares of our common stock and 29,863,674 shares of our Series 1 convertible preferred stock outstanding as of February 17, 2021. In computing the number of shares beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares subject to options held by the person that are currently exercisable, or exercisable within 60 days of February 17, 2021. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o Talis Biomedical Corporation, 230 Constitution Drive, Menlo Park, California 94025.

	Common Stock		Series 1 Convertible Preferred Stock		Total Outstanding Capital Stock
	Shares	%	Shares	%	%
5% or Greater Stockholders					
Entities affiliated with Baker Brothers Advisors, L.P. (1)	7,575,536	29.6%	29,863,674	100%	67.5%
Entities affiliated with ArrowMark Fundamental Opportunity Fund, LP (2)	6,025,182	23.5%	—	—	10.9%
Named Executive Officers and Directors					
Brian Coe (3)	522,824	2.0%	—	—	*
Robert Kelley	—	—	—	—	—
Douglas Liu (4)	4,000	*	—	—	*
Felix Baker, Ph.D.	7,575,536	29.6%	29,863,674	100%	67.5%
Raymond Cheong, M.D., Ph.D.	—	—	—	—	*
Melissa Gilliam	—	—	—	—	*
Jeryl L. Hilleman (5)	975	*	—	—	*
Rustem F. Ismagilov (6)	448,441	1.8%	—	—	*
Kim Popovits (7)	228,955	*	—	—	*
Matt Posard (8)	103,796	*	—	—	*
Randy Scott (9)	1,743,861	6.8%	—	—	3.1%
All directors and executive officers as a group (14 persons) (10)	10,746,038	42.0%	29,863,674	100%	72.6%

*Represents beneficial ownership of less than 1%.

(1) Consists of (i) 571,659 shares of common stock and 2,345,481 shares of Series 1 convertible preferred stock held by 667, L.P. (667), (ii) 7,003,176 shares of common stock and 27,511,741 shares of Series 1 convertible preferred stock held by Baker Brothers Life Sciences, L.P. (Baker Life Sciences), (iii) 590 shares of common stock and 5,420 shares of Series 1 convertible preferred stock held by FBB Associates, and (iv) 111 shares of common stock and 1,032 shares of Series 1 convertible preferred stock held by FBB3 LLC. Baker Bros., is the management company and investment adviser to 667 and Baker Life Sciences and has sole voting and investment power with respect to the shares held by 667 and Baker Life Sciences. Baker Bros. Advisors (GP) LLC (BBA-GP) is the sole general partner of Baker Bros. Julian C. Baker and Felix J. Baker are managing members of BBA-GP. BBA-GP, Felix J. Baker, Julian C. Baker and Baker Bros. may be deemed to be beneficial owners of the securities directly held by Baker Bros. Julian C. Baker, Felix J. Baker, BBA-GP and Baker Bros. The address for the above referenced entities is 860 Washington Street, 3rd Floor, New York, NY 10014.

(2) Consists of (i) 3,116,925 shares of common stock purchased pursuant to the Company's initial public offering held by ArrowMark Fundamental Opportunity Fund, LP and affiliated entities, (ii) 334,159 shares of common stock held by ArrowMark Fundamental Opportunity Fund, LP, (iii) 312,233 shares of common stock held by ArrowMark Life Science Fund, LP, (iv) 199,226 shares of common stock held by Iron Horse Investments, LLC (Iron Horse), (v) 47,260 shares of common stock held by Lookfar Investments, LLC (Lookfar), (vi) 725,165 held by Meridian Growth Fund, (vii) 705,537 shares of common stock held by Meridian Small Cap Growth Fund (together with Meridian Growth Fund, Meridian), (viii) 417,513 shares of common stock held by THB Iron Rose LLC, (ix) 1,764 shares of common stock held by THB Iron Rose, LLC Life Science Portfolio (together with THB Iron Rose LLC, THB), (x) 163,579 shares of common stock held by AP Investment Series - Series I (AP Investment), and (xi) 1,764 shares of common stock held by Tony Yao. ArrowMark Partners GP, LLC (Arrow GP), is the general partner of ArrowMark Fundamental Opportunity Fund, LP and David Corkins is the managing member of Arrow GP. ArrowMark Colorado Holdings LLC (Arrow Colorado) is investment advisor to Meridian, Lookfar, Iron Horse, THB and AP Investment. Mr. Corkins is a managing member of Arrow Colorado and Mr. Yao is a portfolio manager of Arrow Colorado. The address of the Arrow Funds is c/o ArrowMark Partners, 100 Fillmore St, Suite 325, Denver, CO 80206.

(3) Consists of (i) 58,881 shares of common stock held by Mr. Coe and 422,624 shares of common stock issuable to Mr. Coe pursuant to options exercisable within 60 days of February 17, 2021, (ii) 7,832 shares of common stock held by trusts in which Mr. Coe's children are sole beneficiaries, respectively, and (iii) 33,487 shares of common stock held by a trust in which Mr. Coe's spouse and children are beneficiaries. Mr. Coe disclaims beneficial ownership of the securities in clauses (ii) and (iii) except to the extent of his pecuniary interest therein.

(4) Consists of 4,000 shares of common stock held by Mr. Liu.

(5) Consists of 975 shares of common stock issuable to Ms. Hilleman pursuant to options exercisable within 60 days of February 17, 2021.

(6) Consists of (i) 119,440 shares of common stock held by Dr. Ismagilov and 182,779 shares of common stock issuable to Dr. Ismagilov pursuant to options exercisable within 60 days of February 17, 2021 and (ii) 146,222 shares of common stock held by Dr. Ismagilov's spouse.

(7) Consists of (i) 25,776 shares of common stock held by Ms. Popovits, (ii) 21,153 shares of common stock issuable to Ms. Popovits pursuant to options exercisable within 60 days of February 17, 2021 and, (iii) 182,026 shares of common stock held by MSL FBO Kimberly J. Popovits Patrick J. Popovits TTEE U/AD 05-17-2020 FBO Popovits 2010 Trust (Popovits Trust). Ms. Popovits and her spouse are trustees of the Popovits Trust and share voting and dispositive power.

(8) Consists of (i) 41,296 shares of common stock issuable to Mr. Posard pursuant to options exercisable within 60 days of February 17, 2021 and (ii) 62,500 shares of common stock held by Mr. Posard.

(9) Consists of (i) 41,296 shares of common stock issuable to Dr. Scott pursuant to options exercisable within 60 days of February 17, 2021, (ii) 1,390,065 shares of common stock held by the Thinking Bench Capital, LLC, and (iii) 312,500 shares of common stock held by the OG Family Trust, u/d/t May 30, 2014 (OG Trust). Dr. Scott and his spouse are trustees of the OG Trust and share voting and dispositive power.

(10) Consists of (i) the shares described in footnote (1) and footnote (3) through (9) above, and 130,950 shares of common stock issuable pursuant to options exercisable within 60 days of February 17, 2021 held by executive officers not named in the table above and (ii) 4,700 shares of common stock held by executive officers not named in the table above.

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

The following includes a summary of transactions since January 1, 2019 to which we have been a party, in which the amount involved in the transaction exceeded $120,000 or, if less, 1% of the average of our total assets as of December 31, 2019 and 2020, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described in "Item 11. Executive and director compensation."

Convertible note financing

From March 2019 through August 2019, we issued and sold convertible promissory notes (Convertible Notes) in the aggregate principal amount of $15.0 million. The Convertible Notes accrued interest at a rate of 6.5% per annum and were subject to installment adjustments whereby upon the issuance of each Convertible Note, the principal owed increased by 10.0% of the face value of such Convertible Note. An additional 5.0% installment adjustment was applied based on the outstanding principal and accrued interest owed on each Convertible Note issued in March 2019 (Initial Closing Date) on each of the 150th, 180th and 210th day after the Initial Closing Date. In November 2019, the aggregate contractually calculated principal amount of the Convertible Notes and accrued interest totaling approximately $19.0 million were converted into 6,937,252 shares of our Series D-2 convertible preferred stock at a conversion price of $2.74 per share. The participants in the convertible note financing included entities affiliated with members of our board of directors and holders of more than 5% of our capital stock. The following table sets forth the principal amount of Convertible Notes issued to these related persons.

Name of stockholder	Principal amount of notes
Entities affiliated with Baker Bros. Advisors LP(1)	$ 15,000,000

(1) Consists of (i) $1,236,150 in Convertible Notes issued to 667, L.P. and (ii) $13,763,850 in Convertible Notes issued to Baker Brothers Life Sciences, L.P. Dr. Baker, a managing member of Baker Bros. Advisors (GP) LLC, the sole general partner of Baker Bros., and Dr. Cheong, an employee of Baker Bros., are both members of our board of directors.

Convertible preferred stock financings

From November 2019 to December 2019, pursuant to a Series C-1 preferred stock and Series D-1 preferred stock purchase agreement, we issued and sold shares of our Series C-1 convertible preferred stock, Series D-1 convertible preferred stock, and Series D-2 convertible preferred stock. The purchase price for this financing was to be funded in three separate tranches, with a proportional number of shares subject to forfeiture should any tranche not be called or funded. The first and second tranches were funded and the timeline to call the third tranche expired and the corresponding shares were forfeited. Taking into account such forfeitures, we issued and sold an aggregate of 13,404,197 shares of our Series C-1 convertible preferred stock, 1,437,178 shares of our Series D-1 convertible preferred stock, and 10,372,452 shares of our Series D-2 convertible preferred stock, each at a purchase price of approximately $2.74 per share, and received gross proceeds of approximately $65.2 million, including the conversion of the Convertible Notes.

From June 2020 to July 2020, pursuant to a Series E preferred stock purchase agreement, we issued and sold an aggregate of 2,289,899 shares of our Series E-1 convertible preferred stock and 11,187,189 shares of our Series E-2 convertible preferred stock, each at a purchase price of $7.42 per share, and received gross proceeds of approximately $100.0 million.

During the fourth quarter of 2020, pursuant to a Series F preferred stock purchase agreement, we issued and sold an aggregate of 4,859,897 shares of our Series F-1 convertible preferred stock and 9,958,539 shares of our Series F-2 convertible preferred stock, each at a purchase price of $8.55 per share, and received gross proceeds of approximately $126.7 million.

The participants in our convertible preferred stock financing included entities affiliated with members of our board of directors and holders of more than 5% of our capital stock. The following table sets forth the aggregate number of shares of convertible preferred stock issued to these related persons.

Name of stockholder	Series C-1 preferred	Series D-1 preferred	Series D-2 preferred	Series E-1 preferred	Series E-2 preferred	Series F-1 preferred	Series F-2 preferred	Aggregate consideration	
Entities affiliated with Baker Bros. Advisors LP(1)	11,183,572	—	10,372,452	3,304	11,187,189	—	9,958,539	$ 208,234,402	(2)
Entities affiliated with ArrowMark Fundamental Opportunity Fund, LP(3)	1,833,240	—	—	1,020,631	—	994,150	—	$ 21,096,142	
Randal Scott, Ph.D.(4)	—	1,076,643	—	534,402	—	432,749	—	$ 10,615,369	
Kimberly J. Popovits(5)	—	—	—	431,642	—	128,655	—	$ 4,302,784	

(1) Consists of shares purchased by 667, L.P., Baker Brothers Life Sciences, L.P., FBB Associates and FBB3 LLC. Dr. Baker, a managing member of Baker Bros. Advisors (GP) LLC, the sole general partner of Baker Bros., and Dr. Cheong, an employee of Baker Bros., are both members of our board of directors.

(2) Excludes the aggregate contractually calculated principal amount of the convertible notes and accrued interest of $19.0 million that were converted into an aggregate of 6,937,252 shares of our Series D-2 convertible preferred stock.

(3) Consists of shares purchased by AP Investment Series - Series I, ArrowMark Fundamental Opportunity Fund, LP, ArrowMark Life Science Fund, LP, Iron Horse Investments, LLC, Lookfar Investments, LLC, Meridian Growth Fund, Meridian Small Cap Growth Fund, THB Iron Rose LLC, THB Iron Rose, LLC Life Science Portfolio and Tony Yao.

(4) Consists of shares purchased by Randal W. Scott and Eileen M. Scott, Trustees of the OG Trust. Dr. Scott, a member of our board of directors, is a trustee of the OG Trust and has a financial interest in the OG Trust.

(5) Consists of shares purchased by the Popovits Trust. Ms. Popovits, a member of our board of directors, is a trustee of the Popovits Trust and has a financial interest in the Popovits Trust.

Investor agreements

In connection with our Series F convertible preferred stock financing, we entered into an investors' rights agreement, voting agreement and right of first refusal and co-sale agreement containing registration rights, information rights, voting rights and rights of first refusal and co-sale, among other things, with certain of our stockholders. The foregoing agreements will terminated upon the closing of our initial public offering, except for the registration rights set forth in the investors' rights agreements.

Consulting arrangements

In January 2019, we entered into a consulting agreement, as amended in December 2020, with Rustem F. Ismagilov, one of our co-founders and a member of our board of directors, pursuant to which Dr. Ismagilov provides general scientific, and strategic consulting regarding our development and commercialization efforts and serves as chair of our Scientific Advisory Board (SAB). Pursuant to his amended consulting agreement, Dr. Ismagilov receives a consulting fee of $75,000 per year for services rendered, as requested from time to time and for his service on the SAB. Further, pursuant to his amended consulting agreement, Dr. Ismagilov, during a partial sabbatical from Caltech from August 2020 through December 2020, devoted three days per week to support our efforts to complete development of our Talis One system and is entitled to an option to purchase shares of our common stock with a value of $300,000, which option was granted in September 2020. Unless terminated earlier, the amended consulting agreement will expire on December 31, 2022.

Equity grants

We have granted stock options to our executive officers and certain members of our board of directors. For a description of these options, see "Item 11. Executive and director compensation."

Nominating agreement

In November 2019, we entered into the Nominating Agreement with the Baker Brothers pursuant to which 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, individuals designated by the Baker Brothers. The Nominating Agreement also provides the Baker Brothers the right to designate a nonvoting observer to attend all meetings of our board of directors and all meetings of the committees of our board of directors subject to certain conditions and exceptions. For more information regarding this agreement, see the section entitled "Board composition—Nominating agreement" in Item 10 above.

Indemnification agreements

Our amended and restated certificate of incorporation contains provisions limiting the liability of directors, and our amended and restated bylaws provides that we will indemnify each of our directors to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our officers and employees when determined appropriate by our board of directors.

We have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, as described above in Item 11 under the section entitled "Limitation of liability and indemnification." The indemnification agreements will provide that we will indemnify each of our directors, executive officers and such other employees against any and all expenses incurred by that director, executive officer or other employee because of his or her status as one of our directors, executive officers or other employees, to the fullest extent permitted by Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws. In addition, the indemnification agreements will provide that, to the fullest extent permitted by Delaware law, we will advance all expenses incurred by our directors, executive officers and other employees in connection with a legal proceeding involving his or her status as a director, executive officer or employee.

Policies and procedures for transactions with related persons

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of "related-person transactions." For purposes of our policy only, a "related-person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any "related person" are participants involving an amount that exceeds $120,000 or, if less, 1% of the average of our total assets at year end for the prior two completed fiscal years. Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A related person is any executive officer, director, nominee to become a director or a holder of more than five percent of our common stock, including any of their immediate family members and affiliates, including entities owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors) for review. The presentation must include a description of, among other things, all of the parties thereto, the direct and indirect interests of the related persons, the purpose of the transaction, the material facts, the benefits of the transaction to us and whether any alternative transactions are available, an assessment of whether the terms are comparable to the terms available from unrelated third parties and management's recommendation. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our audit committee or another independent body of our board of directors takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval. All of the transactions described in this section occurred prior to the adoption of this policy.

Item 14. Principal Accounting Fees and Services.

The following table represents aggregate fees billed to or to be billed us by Ernst & Young LLP for the periods set forth below.

	Fiscal Year Ended	
	2020	2019
	(in thousands)	
Audit Fees (1)	$ 1,740,000	$ 235,000
Audit-related Fees	-	-
Tax Fees	-	-
All Other Fees	-	-
Total Fees	$ 1,740,000	$ 235,000

(1) Audit fees of Ernst & Young for the years ending December 31, 2020 and 2019 were for professional services rendered for the audits of our financial statements, including accounting consultation, reviews of quarterly financial statements and professional services rendered in connection with our registration statements. Fees for 2020 include services associated with our initial public offering, which was completed in February 2021.

All fees described above were approved by the Board of Directors.

Pre-Approval Policies and Procedures

The audit committee has adopted a policy (the "Pre-Approval Policy") that sets forth the procedures and conditions pursuant to which audit and non-audit services proposed to be performed by the independent auditor may be pre-approved. The Pre-Approval Policy generally provides that we will not engage Ernst & Young to render any audit, review, attest, tax or other non-audit services unless the service is either (i) explicitly approved by the Audit Committee (specific pre-approval) or (ii) entered into pursuant to the pre-approval policies and procedures described in the Pre-Approval Policy. With respect to each service proposed to be pre-approved, the independent auditor must provide timely and sufficient detail to enable the audit committee's assessment of the permissibility of the service to be provided, fee arrangements and the effect of the service on the independent registered public accounting firm's independence.

PART IV

Item 15. Exhibits, 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 178 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.
4.5	Registration Rights Agreement, dated March 26, 2021, by and among the Registrant, Baker Brothers Life Sciences L.P. and 667, L.P.
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 92.2 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+	Talis Biomedical Corporation Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on February 8, 2021).
10.6+	Talis Biomedical Corporation Severance and Change in Control Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on February 8, 2021).

10.7+	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).
10.8+	Offer Letter, dated December 1, 2014, by and between the Registrant and Karen E. Flick (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021).
10.9+	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).
10.10+	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).
10.11+	Offer Letter, dated April 23, 2019, by and between the Registrant and Ramesh Ramakrishnan (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021).
10.12	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).
10.13*	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).
10.14*	Contract, dated July 30, 2020, by and between the Registrant and the National Institutes of Health (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021).
10.15	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).
10.16	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).
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.

+ Indicates management contract or compensatory plan.

* Certain portions of this exhibit (indicated by "[***]") have been omitted as the Registrant determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Registrant if publicly disclosed.

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

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 30, 2021

By: /s/ Brian Coe
Brian Coe
Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Brian Coe 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/ Brian Coe **Brian Coe**	Chief Executive Officer and Member of the Board of Directors (*Principal Executive Officer)*	March 30, 2021
/s/ J. Roger Moody, Jr. **J. Roger Moody, Jr.**	Chief Financial Officer (*Principal Financial and Accounting Officer*)	March 30, 2021
/s/ Felix Baker, Ph.D. **Felix Baker, Ph.D.**	Member of the Board of Directors	March 30, 2021
/s/ Raymond Cheong, M.D., Ph.D. **Raymond Cheong, M.D., Ph.D.**	Member of the Board of Directors	March 30, 2021
/s/ Melissa Gilliam M.D., M.P.H **Melissa Gilliam M.D., M.P.H.**	Member of the Board of Directors	March 30, 2021
/s/ Jeryl L. Hilleman **Jeryl L. Hilleman**	Member of the Board of Directors	March 30, 2021
/s/ Rustem F. Ismagilov, Ph.D. **Rustem F. Ismagilov, Ph.D.**	Member of the Board of Directors	March 30, 2021
/s/ Kimberly J. Popovits **Kimberly J. Popovits**	Member of the Board of Directors	March 30, 2021
/s/ Matthew L. Posard **Matthew L. Posard**	Member of the Board of Directors	March 30, 2021
/s/ Randal Scott, Ph.D. **Randal Scott, Ph.D.**	Member of the Board of Directors	March 30, 2021

Exhibit 4.4

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF
THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

Talis Biomedical Corporation (we, our or us) has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended. The following summary does not purport to be complete and is based on the provisions of our amended and restated certificate of incorporation (Restated Certificate) and amended and restated bylaws (Restated Bylaws) and the applicable provisions of the Delaware General Corporation Law. This information is qualified entirely by reference to the applicable provisions of our Restated Certificate, Restated Bylaws, and the Delaware General Corporation Law. Our Restated Certificate and Restated Bylaws have previously been filed as exhibits with the Securities and Exchange Commission.

General

Our authorized capital stock consists of 200,000,000 shares of common stock, par value $0.0001 per share, and 170,000,000 shares of preferred stock, par value $0.0001 per share. Our board of directors has the authority, without stockholder approval, except as required by the listing standards of The Nasdaq Stock Market LLC, to issue additional shares of our capital stock.

Common stock

Voting

Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding-up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Series 1 convertible preferred stock

Voting

Except as otherwise expressly provided in our Restated Certificate or required by applicable law, or as described under the section below entitled “Series 1 convertible preferred stock—Protective provisions,” on any matter that is submitted to a vote of our stockholders, 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 vote together as a single class on all matters (including the election of directors) submitted to a vote of stockholders. The Series 1 convertible preferred stock does not have cumulative voting rights.

Conversion

The Series 1 convertible preferred stock is convertible, at the election of the holder, into Series 2 convertible preferred stock on a one-for-one basis at any time following February 17, 2024. Shares of Series 1 convertible preferred stock automatically convert to common stock on a one-for-one basis upon any sale or transfer of such shares of Series 1 convertible preferred stock.

Dividends

The Series 1 convertible preferred stock has the right to receive dividends first or simultaneously with payment of dividends on common stock.

Liquidation preference

In the event of any liquidation or dissolution of the company, holders of the Series 1 convertible preferred stock 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 thereafter shall participate pari passu with the holders of our common stock (on an as-if-converted-to-common-stock basis).

Protective provisions

Consent of the holders of a majority of the voting rights of the outstanding Series 1 convertible preferred stock 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.

Series 2 convertible preferred stock

Voting

The Series 2 convertible preferred stock has no voting rights except as required by law or as set forth in our Restated Certificate, or as described under the section below entitled “Series 2 convertible preferred stock—Protective provisions.”

Conversion

Conversion of the Series 2 convertible preferred stock is prohibited if the holder exceeds a specified threshold of voting security ownership. The Series 2 convertible preferred stock is convertible into common stock on a one-for-one basis, subject to adjustment for events such as stock splits, combinations and the like; provided that such holder shall not be entitled to convert the Series 2 convertible preferred in excess of that number of convertible preferred shares which upon giving effect or immediately prior to

such conversion would cause (i) the aggregate number of shares of common stock beneficially owned by the holder, its affiliates and any persons who are members of a Section 13(d) “group” with such holder or its affiliates to exceed 4.99% (Maximum Percentage) of the total number of issued and outstanding shares of our common stock following such conversion, or (ii) the combined voting power of our securities beneficially owned by such holder and its affiliates and any other persons who are members of a Section 13(d) “group” with such holder or its affiliates to exceed the Maximum Percentage of the combined voting power of all of the securities of our then outstanding following such conversion. For purposes of this paragraph, beneficial ownership and whether a holder is a member of a Section 13(d) “group” shall be calculated and determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended and the rules promulgated thereunder (Exchange Act). The Maximum Percentage may be increased or decreased to any other percentage not in excess of 19.99% designated by such holder of Series 2 convertible preferred stock upon 61 days’ notice to us. Shares of Series 2 convertible preferred stock automatically convert to common stock on a one-for-one basis upon any sale or transfer of such shares of Series 2 convertible preferred stock.

Dividends

The Series 2 convertible preferred stock has the right to receive dividends first or simultaneously with payment of dividends on common stock.

Liquidation preference

In the event of any liquidation or dissolution of the company, holders of the Series 2 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 2 convertible preferred stock and thereafter shall participate pari passu with the holders of our common stock (on an as-if-converted-to-common-stock basis).

Protective provisions

Consent of the holders of a majority of the voting rights of the outstanding Series 2 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 2 convertible preferred stock.

Anti-takeover effects of certain provisions

Delaware anti-takeover law

We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years following the time that such stockholder became an interested stockholder, unless:

- prior to such time the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (1) by persons who are directors and also officers and (2)

employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- at or subsequent to such time, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

A Delaware corporation may “opt out” of these provisions with an express provision in its original certificate of incorporation or an express provision in its amended and restated certificate of incorporation or amended and restated bylaws resulting from a stockholders’ amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Restated Certificate and Restated Bylaws

Provisions of our Restated Certificate 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 Restated Certificate and Restated Bylaws:

- permit our board of directors to issue any or all of the unissued and undesignated 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);
- 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; and
- provide that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) is be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) 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 provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; (v) 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 (vi) any action asserting a claim against us or any of our directors, officers or other employees 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; provided, that, this Delaware forum provision set forth in our Restated Certificate and Restated Bylaws does not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended (Securities Act), or the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction.

Further, our Restated Certificate provides that unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States is be the exclusive forum for resolution of any complaint asserting a cause of action arising under the Securities Act.

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 the voting power of all of our then outstanding capital stock.

Nasdaq Global Market listing

Our common stock has been approved for listing on The Nasdaq Global Market under the symbol “TLIS.”

Transfer agent and registrar

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, Inc.

Exhibit 4.5

REGISTRATION RIGHTS AGREEMENT

This Registration Rights Agreement (this "Agreement") is made as of March 26, 2021 by and between Talis Biomedical Corporation, a Delaware corporation (the "Company"), and the persons listed on the attached Schedule A who are signatories to this Agreement (collectively, the "Investors"). Unless otherwise defined herein, capitalized terms used in this Agreement have the respective meanings ascribed to them in Section 1.

RECITALS

WHEREAS, the Company and the Investors wish to provide for certain arrangements with respect to the registration of the Registrable Securities (as defined below) by the Company under the Securities Act (as defined below).

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth herein, and other consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereto agree as follows:

Section 1.
Definitions

1.1. Certain Definitions. In addition to the terms defined elsewhere in this Agreement, as used in this Agreement, the following terms have the respective meanings set forth below:

(a) "Block Trade" shall mean an offering of Registrable Securities which requires both the Investors and the Company to enter into a sale agreement and is limited in scope of selling efforts as compared to an Underwritten Offering.

(b) "Board" shall mean the Board of Directors of the Company.

(c) "Commission" shall mean the Securities and Exchange Commission or any other federal agency at the time administering the Securities Act.

(d) "Common Stock" shall mean the Company's Common Stock.

(e) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended, or any similar successor federal statute and the rules and regulations thereunder, all as the same shall be in effect from time to time.

(f) "Investor Rights Agreement" shall mean the Amended and Restated Investor Rights Agreement entered into as of October 30, 2020 by and among the Company and the investors listed on Exhibit A thereto.

(g) "Governmental Entity" shall mean any federal, state, local or foreign government, or any department, agency, or instrumentality of any government; any public international organization, any transnational governmental organization; any court of competent jurisdiction, arbitral, administrative agency, commission, or other governmental regulatory authority or quasi-

governmental authority, any political party; and any national securities exchange or national quotation system.

(h) "Other Securities" shall mean securities of the Company, other than Registrable Securities (as defined below).

(i) "Person" shall mean any individual, partnership, corporation, company, association, trust, joint venture, limited liability company, unincorporated organization, entity or division, or any government, governmental department or agency or political subdivision thereof.

(j) "Registrable Securities" shall mean the shares of Common Stock and any Common Stock issued or issuable upon the exercise or conversion of any other securities (whether equity, debt or otherwise) of the Company now owned or hereafter acquired by any of the Investors. Registrable Securities shall cease to be Registrable Securities upon the earliest to occur of the following events: (i) such Registrable Securities have been sold pursuant to an effective Registration Statement; (ii) such Registrable Securities have been sold by the Investors pursuant to Rule 144 (or other similar rule), (iii) at any time after any of the Investors become an affiliate of the Company, such Registrable Securities may be resold by the Investor holding such Registrable Securities without limitations as to volume or manner of sale pursuant to Rule 144; or (iv) ten (10) years after the date of this Agreement. For purposes of this definition, in order to determine whether an Investor is an "affiliate" (as such term is defined and used in Rule 144, and including for determining whether volume or manner of sale limitations of Rule 144 apply) the parties will assume that all convertible securities (whether equity, debt or otherwise) have been converted into Common Stock.

(k) The terms "register," "registered" and "registration" shall refer to a registration effected by preparing and filing a Registration Statement in compliance with the Securities Act, and such Registration Statement becoming effective under the Securities Act.

(l) "Registration Expenses" shall mean all expenses incurred by the Company in effecting any registration pursuant to this Agreement, including, without limitation, all registration, qualification, and filing fees, printing expenses, escrow fees, fees and disbursements of counsel for the Company, up to $50,000 of reasonable legal expenses of one special counsel for Investors (if different from the Company's counsel and if such counsel is reasonably approved by the Company) in connection with the preparation and filing of the Resale Registration Shelf (as defined below), and up to $50,000 of reasonable legal expenses of one special counsel for the Investors (if different from the Company's counsel and if such counsel is reasonably approved by the Company) per Underwritten Offering, blue sky fees and expenses, and expenses of any regular or special audits incident to or required by any such registration, but shall not include Selling Expenses.

(m) "Registration Statement" means any registration statement of the Company filed with, or to be filed with, the Commission under the Securities Act, including the related prospectus, amendments and supplements to such registration statement, including pre- and post-effective amendments, and all exhibits and all material incorporated by reference in such registration statement as may be necessary to comply with applicable securities laws other than a registration statement (and related prospectus) filed on Form S-4 or Form S-8 or any successor forms thereto.

(n) "Rule 144" shall mean Rule 144 as promulgated by the Commission under the Securities Act, as such rule may be amended from time to time, or any similar successor rule that may be promulgated by the Commission.

(o) "Securities Act" shall mean the Securities Act of 1933, as amended, or any similar successor federal statute and the rules and regulations thereunder, all as the same shall be in effect from time to time.

(p) "Selling Expenses" shall mean all underwriting discounts and selling commissions applicable to the sale of Registrable Securities, the fees and expenses of any legal counsel (except as provided in the definition of "Registration Expenses") and any other advisors any of the Investors engage and all similar fees and commissions relating to the Investors' disposition of the Registrable Securities.

(q) "Underwritten Offering" shall mean a public offering of Registrable Securities pursuant to an effective registration statement under the Securities Act (other than pursuant to a registration statement on Form S-4 or S-8 or any similar or successor form) which requires the Investors and the Company to enter into an underwriting agreement.

Section 2.
Resale Registration Rights

2.1. Resale Registration Rights.

(a) Following demand by any Investor the Company shall file with the Commission a Registration Statement on Form S-3 (except if the Company is not then eligible to register for resale the Registrable Securities on Form S-3, in which case such registration shall be on another appropriate form in accordance with the Securities Act) covering the resale of the Registrable Securities by the Investors (the "Resale Registration Shelf"), and the Company shall file such Resale Registration Shelf as promptly as reasonably practicable following such demand, and in any event within sixty (60) days of such demand; *provided that* no such demand shall be made prior to February 1, 2022. Such Resale Registration Shelf shall include a "final" prospectus, including the information required by Item 507 of Regulation S-K of the Securities Act, as provided by the Investors in accordance with Section 2.7. Notwithstanding the foregoing, before filing the Resale Registration Shelf, the Company shall furnish to the Investors a copy of the Resale Registration Shelf and afford the Investors an opportunity to review and comment on the Resale Registration Shelf. The Company's obligation pursuant to this Section 2.1(a) is conditioned upon the Investors providing the information contemplated in Section 2.7. Notwithstanding anything contained herein to the contrary, any demand made by an Investor pursuant to this Agreement that the Company file with the Commission a Registration Statement shall be deemed to be a demand for registration of the same nature (i.e., Form S-3 or Form S-1, underwritten or not) pursuant to the Investor Rights Agreement to the extent such rights are, at the relative time, available pursuant to the Investor Rights Agreement.

(b) The Company shall use its reasonable best efforts to cause the Resale Registration Shelf and related prospectuses to become effective as promptly as practicable after filing. The

Company shall use its reasonable best efforts to cause such Registration Statement to remain effective under the Securities Act until the earlier of the date (i) all Registrable Securities covered by the Resale Registration Shelf have been sold or may be sold freely without limitations or restrictions as to volume or manner of sale pursuant to Rule 144 or (ii) all Registrable Securities covered by the Resale Registration Shelf otherwise cease to be Registrable Securities pursuant to the definition of Registrable Securities. The Company shall promptly, and within two (2) business days after the Company confirms effectiveness of the Resale Registration Shelf with the Commission, notify the Investors of the effectiveness of the Resale Registration Shelf.

(c) Notwithstanding anything contained herein to the contrary, the Company shall not be obligated to effect, or to take any action to effect, a registration pursuant to Section 2.1(a):

(i) if the Company has and maintains an effective Registration Statement on Form S-3ASR that provides for the resale of an unlimited number of securities by selling stockholders (a "Company Registration Shelf");

(ii) during the period forty-five (45) days prior to the Company's good faith estimate of the date of filing of a Company Registration Shelf; or

(iii) if the Company has caused a Registration Statement to become effective pursuant to this Section 2.1 or pursuant to Section 2.2 of the Investor Rights Agreement during the prior twelve (12) month period.

(d) If the Company has a Company Registration Shelf in place at any time in which the Investors make a demand pursuant to Section 2.1(a), the Company shall file with the Commission, as promptly as practicable, and in any event within fifteen (15) business days after such demand, a "final" prospectus supplement to its Company Registration Shelf covering the resale of the Registrable Securities by the Investors (the "Prospectus"); provided, however, that the Company shall not be obligated to file more than one Prospectus pursuant to this Section 2.1(d) in any six month period to add additional Registrable Securities to the Company Registration Shelf that were acquired by the Investors other than directly from the Company or in an underwritten public offering by the Company. The Prospectus shall include the information required under Item 507 of Regulation S-K of the Securities Act, which information shall be provided by the Investors in accordance with Section 2.7. Notwithstanding the foregoing, before filing the Prospectus, the Company shall furnish to the Investors a copy of the Prospectus and afford the Investors an opportunity to review and comment on the Prospectus.

(e) Deferral and Suspension. At any time after being obligated pursuant to this Agreement to file a Resale Registration Shelf or Prospectus, or after any Resale Registration Shelf has become effective or a Prospectus is filed with the Commission, the Company may defer the filing of or suspend the use of any such Resale Registration Shelf or Prospectus, upon giving written notice of such action to the Investors with a certificate signed by the Chief Executive Officer of the Company stating that in the good faith judgment of the Board, the filing or use of any such Resale Registration Shelf or Prospectus covering the Registrable Securities would be seriously detrimental to the Company or its stockholders at such time and that the Board concludes, as a result, that it is in the best interests of the Company and its stockholders to defer the filing or

suspend the use of such Resale Registration Shelf or Prospectus at such time. The Company shall have the right to defer the filing of or suspend the use of such Resale Registration Shelf or Prospectus for a period of not more than one hundred twenty (120) days from the date the Company notifies the Investors of such deferral or suspension; provided that the Company shall not exercise the right contained in this Section 2.1(e) more than once in any twelve month period. In the case of the suspension of use of any effective Resale Registration Shelf or Prospectus, the Investors, immediately upon receipt of notice thereof from the Company, shall discontinue any offers or sales of Registrable Securities pursuant to such Resale Registration Shelf or Prospectus until advised in writing by the Company that the use of such Resale Registration Shelf or Prospectus may be resumed. In the case of a deferred Prospectus or Resale Registration Shelf filing, the Company shall provide prompt written notice to the Investors of (i) the Company's decision to file or seek effectiveness of the Prospectus or Resale Registration Shelf, as the case may be, following such deferral and (ii) in the case of a Resale Registration Shelf, the effectiveness of such Resale Registration Shelf. In the case of either a suspension of use of, or deferred filing of, any Resale Registration Shelf or Prospectus, the Company shall not, during the pendency of such suspension or deferral, be required to take any action hereunder (including any action pursuant to Section 2.2 hereof) with respect to the registration or sale of any Registrable Securities pursuant to any such Resale Registration Shelf, Company Registration Shelf or Prospectus.

(f) Other Securities. Subject to Section 2.2(e) below, any Resale Registration Shelf or Prospectus may include Other Securities, and may include securities of the Company being sold for the account of the Company; provided such Other Securities are excluded first from such Registration Statement in order to comply with any applicable laws or request from any Government Entity, Nasdaq or any applicable listing agency. For the avoidance of doubt, no Other Securities may be included in an Underwritten Offering pursuant to Section 2.2 without the consent of the Investors, except as may be required pursuant to the Investor Rights Agreement.

2.2. Sales and Underwritten Offerings of the Registrable Securities.

(a) Notwithstanding any provision contained herein to the contrary, the Investors, collectively, shall and subject to the limitations set forth in this Section 2.2, be permitted (i) one Underwritten Offering per calendar year, but no more than three Underwritten Offerings in total, and (ii) no more than two Underwritten Offerings or Block Trades in any twelve month period, to effect the sale or distribution of Registrable Securities.

(b) If the Investors intend to effect an Underwritten Offering or Block Trade pursuant to a Resale Registration Shelf or Company Registration Shelf to sell or otherwise distribute Registrable Securities, they shall so advise the Company and provide as much notice to the Company as reasonably practicable (and, in either case, not less than fifteen (15) business days prior to the Investors' request that the Company file a prospectus supplement to a Resale Registration Shelf or Company Registration Shelf).

(c) In connection with any offering initiated by the Investors pursuant to this Section 2.2 involving an underwriting of shares of Registrable Securities, the Investors shall be entitled to

select the underwriter or underwriters for such offering, subject to the consent of the Company, such consent not to be unreasonably withheld, conditioned or delayed.

(d) In connection with any offering initiated by the Investors pursuant to this Section 2.2 involving an Underwritten Offering of Registrable Securities, the Company shall not be required to include any of the Registrable Securities in such underwriting unless the Investors (i) enter into an underwriting agreement in customary form with the underwriter or underwriters, (ii) accept customary terms in such underwriting agreement with regard to representations and warranties relating to ownership of the Registrable Securities and authority and power to enter into such underwriting agreement and (iii) complete and execute all questionnaires, powers of attorney, custody agreements, indemnities and other documents as may be requested by such underwriter or underwriters. Further, the Company shall not be required to include any of the Registrable Securities in such underwriting if (Y) the underwriting agreement proposed by the underwriter or underwriters contains representations, warranties or conditions that are not reasonable in light of the Company's then-current business or (Z) the underwriter, underwriters or the Investors require the Company to participate in any marketing, road show or comparable activity that may be required to complete the orderly sale of shares by the underwriter or underwriters.

(e) If the total amount of securities to be sold in any offering initiated by the Investors pursuant to this Section 2.2 involving an underwriting of shares of Registrable Securities exceeds the amount that the underwriters determine in their sole discretion is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities (subject in each case to the cutback provisions set forth in this Section 2.2(e)), that the underwriters and the Company determine in their sole discretion shall not jeopardize the success of the offering. If the Underwritten Offering has been requested pursuant to Section 2.2(a) hereof, the number of shares that are entitled to be included in the registration and underwriting shall be allocated in the following manner: (a) first, shares of Company equity securities that the Company desires to include in such registration shall be excluded and (b) second, Registrable Securities requested to be included in such registration by the Investors shall be excluded. For the avoidance of doubt, no other person besides the Investors shall be entitled to participate in any Block Trade. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round down the number of shares allocated to any of the Investors to the nearest 100 shares.

2.3. Fees and Expenses. All Registration Expenses incurred in connection with registrations pursuant to this Agreement shall be borne by the Company. All Selling Expenses relating to securities registered on behalf of the Investors shall be borne by the Investors.

2.4. Registration Procedures. In the case of each registration of Registrable Securities effected by the Company pursuant to Section 2.1 hereof, the Company shall keep the Investors advised as to the initiation of each such registration and as to the status thereof. The Company shall use its reasonable best efforts, within the limits set forth in this Section 2.4, to:

(a) prepare and file with the Commission such amendments and supplements to such Registration Statement and the prospectuses used in connection with such Registration Statement as may be necessary to keep such Registration Statement effective and current and comply with

the provisions of the Securities Act with respect to the disposition of all securities covered by such Registration Statement;

(b) furnish to the Investors such numbers of copies of a prospectus, including preliminary prospectuses, in conformity with the requirements of the Securities Act, and such other documents as the Investors may reasonably request in order to facilitate the disposition of Registrable Securities;

(c) use its reasonable best efforts to register and qualify the Registrable Securities covered by such Registration Statement under such other securities or blue sky laws of such jurisdictions in the United States as shall be reasonably requested by the Investors, provided that the Company shall not be required in connection therewith or as a condition thereto to qualify to do business or to file a general consent to service of process in any such states or jurisdictions;

(d) in the event of an Underwritten Offering or Block Trade, and subject to Section 2.2(d), enter into and perform its obligations under an underwriting agreement or Block Trade sale agreement, in usual and customary form (including any "lock-ups" on behalf of the Company and its directors and officers), with the managing underwriter of such offering and take such other usual and customary action as the Investors may reasonably request in order to facilitate the disposition of such Registrable Securities;

(e) notify the Investors at any time when a prospectus relating to a Registration Statement covering any Registrable Securities is required to be delivered under the Securities Act of the happening of any event as a result of which the prospectus included in such Registration Statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing. The Company shall use its reasonable best efforts to amend or supplement such prospectus in order to cause such prospectus not to include any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing;

(f) provide a transfer agent and registrar for all Registrable Securities registered pursuant to such Registration Statement and, if required, a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

(g) if requested by an Investor, use reasonable best efforts to cause the Company's transfer agent to remove any restrictive legend from any Registrable Securities, within two business days following such request;

(h) cause to be furnished, at the request of the Investors, on the date that Registrable Securities are delivered to underwriters for sale in connection with an Underwritten Offering or Block Trade, (i) an opinion, dated such date, of the counsel representing the Company for the purposes of such registration, in form and substance as is customarily given to underwriters in an underwritten public offering, addressed to the underwriters, and (ii) a letter or letters from the independent certified public accountants of the Company, in form and substance as is

customarily given by independent certified public accountants to underwriters in an underwritten public offering, addressed to the underwriters; and

(i) cause all such Registrable Securities included in a Registration Statement pursuant to this Agreement to be listed on each securities exchange or other securities trading markets on which Common Stock is then listed.

2.5. The Investors Obligations.

(a) Discontinuance of Distribution. The Investors agree that, upon receipt of any notice from the Company of the occurrence of any event of the kind described in Section 2.4(e) hereof, the Investors shall immediately discontinue disposition of Registrable Securities pursuant to any Registration Statement covering such Registrable Securities until the Investors' receipt of the copies of the supplemented or amended prospectus contemplated by Section 2.4(e) hereof or receipt of notice that no supplement or amendment is required and that the Investors' disposition of the Registrable Securities may be resumed. The Company may provide appropriate stop orders to enforce the provisions of this Section 2.5(a).

(b) Compliance with Prospectus Delivery Requirements. The Investors covenant and agree that they shall comply with the prospectus delivery requirements of the Securities Act as applicable to them or an exemption therefrom in connection with sales of Registrable Securities pursuant to any Registration Statement filed by the Company pursuant to this Agreement.

(c) Notification of Sale of Registrable Securities. The Investors covenant and agree that they shall notify the Company following the sale of Registrable Securities to a third party as promptly as reasonably practicable, and in any event within thirty (30) days, following the sale of such Registrable Securities.

2.6. Indemnification.

(a) To the extent permitted by law, the Company shall indemnify the Investors, and, as applicable, their officers, directors, and constituent partners, legal counsel for each Investor and each Person controlling the Investors, with respect to which registration, related qualification, or related compliance of Registrable Securities has been effected pursuant to this Agreement, and each underwriter, if any, and each Person who controls any underwriter within the meaning of the Securities Act against all claims, losses, damages, or liabilities (or actions in respect thereof) to the extent such claims, losses, damages, or liabilities arise out of or are based upon (i) any untrue statement (or alleged untrue statement) of a material fact contained in any prospectus or other document (including any related Registration Statement) incident to any such registration, qualification, or compliance, or (ii) any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, or (iii) any violation or alleged violation by the Company of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities law applicable to the Company and relating to action or inaction required of the Company in connection with any such registration, qualification, or compliance; and the Company shall pay as incurred to the Investors, each such underwriter, and each Person who controls the Investors or underwriter, any legal and any other expenses

reasonably incurred in connection with investigating or defending any such claim, loss, damage, liability, or action; provided, however, that the indemnity contained in this Section 2.6(a) shall not apply to amounts paid in settlement of any such claim, loss, damage, liability, or action if settlement is effected without the consent of the Company (which consent shall not unreasonably be withheld); and provided, further, that the Company shall not be liable in any such case to the extent that any such claim, loss, damage, liability, or expense arises out of or is based upon any violation by such Investor of the obligations set forth in Section 2.5 hereof or any untrue statement or omission contained in such prospectus or other document based upon written information furnished to the Company by the Investors, such underwriter, or such controlling Person and stated to be for use therein.

(b) To the extent permitted by law, each Investor (severally and not jointly) shall, if Registrable Securities held by such Investor are included for sale in the registration and related qualification and compliance effected pursuant to this Agreement, indemnify the Company, each of its directors, each officer of the Company who signs the applicable Registration Statement, each legal counsel and each underwriter of the Company's securities covered by such a Registration Statement, each Person who controls the Company or such underwriter within the meaning of the Securities Act against all claims, losses, damages, and liabilities (or actions in respect thereof) arising out of or based upon (i) any untrue statement (or alleged untrue statement) of a material fact contained in any such Registration Statement, or related document, or (ii) any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, or (iii) any violation or alleged violation by such Investor of Section 2.5 hereof, the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities law applicable to such Investor and relating to action or inaction required of such Investor in connection with any such registration and related qualification and compliance, and shall pay as incurred to such persons, any legal and any other expenses reasonably incurred in connection with investigating or defending any such claim, loss, damage, liability, or action, in each case only to the extent that such untrue statement (or alleged untrue statement) or omission (or alleged omission) is made in (and such violation pertains to) such Registration Statement or related document in reliance upon and in conformity with written information furnished to the Company by such Investor and stated to be specifically for use therein; provided, however, that the indemnity contained in this Section 2.6(b) shall not apply to amounts paid in settlement of any such claim, loss, damage, liability, or action if settlement is effected without the consent of such Investor (which consent shall not unreasonably be withheld); provided, further, that such Investor's liability under this Section 2.6(b) (when combined with any amounts such Investor is liable for under Section 2.6(d)) shall not exceed such Investor's net proceeds from the offering of securities made in connection with such registration.

(c) Promptly after receipt by an indemnified party under this Section 2.6 of notice of the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against an indemnifying party under this Section 2.6, notify the indemnifying party in writing of the commencement thereof and generally summarize such action. The indemnifying party shall have the right to participate in and to assume the defense of such claim; provided, however, that the indemnifying party shall be entitled to select counsel for the defense of such claim with the approval of any parties entitled to indemnification, which approval shall not be

unreasonably withheld; provided further, however, that if either party reasonably determines that there may be a conflict between the position of the Company and the Investors in conducting the defense of such action, suit, or proceeding by reason of recognized claims for indemnity under this Section 2.6, then counsel for such party shall be entitled to conduct the defense to the extent reasonably determined by such counsel to be necessary to protect the interest of such party. The failure to notify an indemnifying party promptly of the commencement of any such action, if prejudicial to the ability of the indemnifying party to defend such action, shall relieve such indemnifying party, to the extent so prejudiced, of any liability to the indemnified party under this Section 2.6, but the omission so to notify the indemnifying party shall not relieve such party of any liability that such party may have to any indemnified party otherwise than under this Section 2.6.

(d) If the indemnification provided for in this Section 2.6 is held by a court of competent jurisdiction to be unavailable to an indemnified party with respect to any loss, liability, claim, damage, or expense referred to therein, then the indemnifying party, in lieu of indemnifying such indemnified party hereunder, shall contribute to the amount paid or payable by such indemnified party as a result of such loss, liability, claim, damage, or expense in such proportion as is appropriate to reflect the relative fault of the indemnifying party on the one hand and of the indemnified party on the other in connection with the statements or omissions that resulted in such loss, liability, claim, damage, or expense as well as any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission. In no event, however, shall (i) any amount due for contribution hereunder be in excess of the amount that would otherwise be due under Section 2.6(a) or Section 2.6(b), as applicable, based on the limitations of such provisions and (ii) a Person guilty of fraudulent misrepresentation (within the meaning of the Securities Act) be entitled to contribution from a Person who was not guilty of such fraudulent misrepresentation.

(e) Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with an Underwritten Offering, or the Block Trade sale agreement, are in conflict with the foregoing provisions, the provisions in the underwriting agreement or Block Trade sale agreement shall control; provided, however, that the failure of the underwriting agreement to provide for or address a matter provided for or addressed by the foregoing provisions shall not be a conflict between the underwriting agreement or the Block Trade sale agreement and the foregoing provisions.

(f) The obligations of the Company and the Investors under this Section 2.6 shall survive the completion of any offering of Registrable Securities in a Registration Statement under this Agreement or otherwise.

2.7. Information. The Investors shall furnish to the Company such information regarding the Investors and the distribution proposed by the Investors as the Company may reasonably request and as shall be reasonably required in connection with any registration referred to in this

Agreement. The Investors agree to, as promptly as practicable (and in any event prior to any sales made pursuant to a prospectus), furnish to the Company all information required to be disclosed in order to make the information previously furnished to the Company by the Investors not misleading. The Investors agree to keep confidential the receipt of any notice received pursuant to Section 2.4(e) and the contents thereof, except as required pursuant to applicable law. Notwithstanding anything to the contrary herein, the Company shall be under no obligation to name the Investors in any Registration Statement if the Investors have not provided the information required by this Section 2.7 with respect to the Investors as a selling securityholder in such Registration Statement or any related prospectus.

2.8. Rule 144 Requirements. With a view to making available to the Investors the benefits of Rule 144 and any other rule or regulation of the Commission that may at any time permit the Investors to sell Registrable Securities to the public without registration, the Company agrees to use its reasonable best efforts to:

(a) make and keep public information available, as those terms are understood and defined in Rule 144 at all times after the date hereof;

(b) file with the Commission in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act;

(c) prior to the filing of the Registration Statement or any amendment thereto (whether pre-effective or post-effective), and prior to the filing of any prospectus or prospectus supplement related thereto, to provide the Investors with copies of all of the pages thereof (if any) that reference the Investors; and

(d) furnish to any Investor, so long as the Investor owns any Registrable Securities, forthwith upon request (i) a written statement by the Company that it has complied with the reporting requirements of Rule 144, (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company, and (iii) such other information as may be reasonably requested by an Investor in availing itself of any rule or regulation of the Commission which permits an Investor to sell any such securities without registration.

2.9. Limitations on Subsequent Registration Rights. From and after the date of this Agreement, the Company shall not enter into any agreement with any holder or prospective holder of any securities of the Company which would provide to such holder rights with respect to the registration of such securities under the Securities Act or the Exchange Act that would conflict with or adversely affect any of the rights provided to the Investors in this Section 2; it being understood and agreed that any subsequent agreement of the Company with any holder or prospective holder of any securities of the Company of the same class (or convertible into or exchange for securities of the same class) as the Registrable Securities granting such Person rights under this Section 2 equivalent to the rights of the Investors under this Section 2 will not be prohibited by the terms of this Section 2.9.

Section 3.
Miscellaneous

3.1. Amendment. No amendment, alteration or modification of any of the provisions of this Agreement shall be binding unless made in writing and signed by each of the Company and the Investors.

3.2. Injunctive Relief. It is hereby agreed and acknowledged that it shall be impossible to measure in money the damages that would be suffered if the parties fail to comply with any of the obligations herein imposed on them and that in the event of any such failure, an aggrieved Person shall be irreparably damaged and shall not have an adequate remedy at law. Any such Person shall, therefore, be entitled (in addition to any other remedy to which it may be entitled in law or in equity) to injunctive relief, including, without limitation, specific performance, to enforce such obligations, and if any action should be brought in equity to enforce any of the provisions of this Agreement, none of the parties hereto shall raise the defense that there is an adequate remedy at law.

3.3. Notices. All notices required or permitted under this Agreement must be in writing and sent to the address or facsimile number identified below. Notices must be given: (a) by personal delivery, with receipt acknowledged; (b) by email followed by hard copy delivered by the methods under clause (c) or (d); (c) by prepaid certified or registered mail, return receipt requested; or (d) by prepaid reputable overnight delivery service. Notices shall be effective upon receipt. Either party may change its notice address by providing the other party written notice of such change. Notices shall be delivered as follows:

If to the Investors: At such Investor's address as set forth on Schedule A hereto

If to the Company:
Talis Biomedical Corporation
Attention: Chief of Staff, Senior Vice President, Legal
E-mail: info@talisbio.com
230 Constitution Drive
Menlo Park, California 94025

with a copy to:
Cooley LLP
Attention: Karen. E. Deschaine, Esq.
E-mail: kdeschaine@cooley.com

3.4. Governing Law; Jurisdiction; Venue; Jury Trial.

(a) This Agreement shall be governed by, and construed in accordance with, the law of the State of New York without giving effect to any choice or conflict of law provision or rule (whether of the State of New York or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of New York.

(b) Each of the Company and the Investors irrevocably and unconditionally submits, for itself and its property, to the nonexclusive jurisdiction of the courts of the State of New York sitting in the Borough of Manhattan, New York and of the United States District Court of the Southern District of New York, and any appellate court from any thereof, in any action or proceeding arising out of or relating to this Agreement and the transactions contemplated herein, or for recognition or enforcement of any judgment, and each of the Company and the Investors irrevocably and unconditionally agrees that all claims in respect of any such action or proceeding may be heard and determined in such New York state court or, to the fullest extent permitted by applicable law, in such federal court. Each of the Company and the Investors hereto agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

(c) Each of the Company and the Investors irrevocably and unconditionally waives, to the fullest extent permitted by applicable law, any objection that it may now or hereafter have to the laying of venue of any action or proceeding arising out of or relating to this Agreement and the transactions contemplated herein in any court referred to in Section 3.4(b) hereof. Each of the Company and the Investors hereby irrevocably waives, to the fullest extent permitted by applicable law, the defense of an inconvenient forum to the maintenance of such action or proceeding in any such court.

(d) EACH OF THE COMPANY AND THE INVESTORS HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH OF THE COMPANY AND THE INVESTORS (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PERSON HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PERSON WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT EACH OF THE COMPANY AND THE INVESTORS HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION.

3.5. Successors, Assigns and Transferees. Any and all rights, duties and obligations hereunder shall not be assigned, transferred, delegated or sublicensed by any party hereto without the prior written consent of the other party; provided, however, that the Investors shall be entitled to transfer Registrable Securities to one or more of their affiliates and, solely in connection therewith, may assign their rights hereunder in respect of such transferred Registrable Securities, in each case, so long as such Investor is not relieved of any liability or obligations hereunder, without the prior consent of the Company. Any transfer or assignment made other than as provided in the first sentence of this Section 3.5 shall be null and void. Subject to the foregoing and except as otherwise provided herein, the provisions of this Agreement shall inure to the benefit of, and be binding upon, the successors, permitted assigns, heirs, executors and administrators of the parties hereto. The Company shall not consummate any recapitalization, merger, consolidation, reorganization or other similar transaction whereby stockholders of the Company receive (either directly, through an exchange, via dividend from the Company or

otherwise) equity (the "Other Equity") in any other entity (the "Other Entity") with respect to Registrable Securities hereunder, unless prior to the consummation thereof, the Other Entity assumes, by written instrument, the obligations under this Agreement with respect to such Other Equity as if such Other Equity were Registrable Securities hereunder.

3.6. Entire Agreement. This Agreement, together with any exhibits hereto, constitute the entire agreement between the parties relating to the subject matter hereof and all previous agreements or arrangements between the parties, written or oral, relating to the subject matter hereof are superseded.

3.7. Waiver. No failure on the part of either party hereto to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of either party hereto in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver thereof; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

3.8. Severability. If any part of this Agreement is declared invalid or unenforceable by any court of competent jurisdiction, such declaration shall not affect the remainder of the Agreement and the invalidated provision shall be revised in a manner that shall render such provision valid while preserving the parties' original intent to the maximum extent possible.

3.9. Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement. All references in this Agreement to sections, paragraphs and exhibits shall, unless otherwise provided, refer to sections and paragraphs hereof and exhibits attached hereto.

3.10. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be enforceable against the parties that execute such counterparts (including by facsimile or other electronic means), and all of which together shall constitute one instrument.

3.11. Term and Termination. The Investors' rights to demand the registration of the Registrable Securities under this Agreement, as well as the Company's obligations hereunder other than pursuant to Section 2.6 hereof, shall terminate automatically once all Registrable Securities cease to be Registrable Securities pursuant to the terms of this Agreement.

[*Remainder of Page Intentionally Left Blank; Signature Page Follows*]

IN WITNESS WHEREOF, the parties hereto have executed this Registration Rights Agreement effective as of the day, month and year first above written.

TALIS BIOMEDICAL CORPORATION

By: /s/ Brian Coe

Name: Brian Coe

Title: Chief Executive Officer

IN WITNESS WHEREOF, the parties hereto have executed this Registration Rights Agreement effective as of the day, month and year first above written.

667, L.P.

By: BAKER BROS. ADVISORS LP, management company and investment adviser to 667, L.P., pursuant to authority granted to it by Baker Biotech Capital, L.P., general partner to 667, L.P., and not as the general partner

By: /s/ Scott L. Lessing

Scott L. Lessing
President

BAKER BROTHERS LIFE SCIENCES, L.P.

By: BAKER BROS. ADVISORS LP, management company and investment adviser to BAKER BROTHERS LIFE SCIENCES, L.P., pursuant to authority granted to it by Baker Brothers Life Sciences Capital, L.P., general partner to BAKER BROTHERS LIFE SCIENCES, L.P., and not as the general partner

By: /s/ Scott L. Lessing

Scott L. Lessing
President

Schedule A

The Investors

667, L.P.
BAKER BROTHERS LIFE SCIENCES, L.P.

To the above Investors:
Baker Brothers Investments
860 Washington Street
New York, NY 10014
Attn: Scott Lessing
Email: slessing@BBInvestments.com

With a copy to:

Akin Gump Strauss Hauer & Feld LLP
Attn: Jeffrey Kochian
Email: jkochian@akingump.com
One Bryant Park
New York, NY 10036-6745

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the 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 of our report dated March 30, 2021, with respect to the financial statements of Talis Biomedical Corporation, included in this Annual Report (Form 10-K) for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Redwood City, California
March 30, 2021

Exhibit 31.1

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

I, Brian Coe, certify that:

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

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

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

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

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

Date: March 30, 2021

/s/ Brian Coe

Brian Coe
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

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

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

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

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

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

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

Date: March 30, 2021

/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, 2020 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 30, 2021

/s/ Brian Coe

Brian Coe
Chief Executive Officer
(Principal Executive Officer)

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

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K of Talis Biomedical Corporation (the "Company") for the year ending December 31, 2020 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 30, 2021

/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.