# 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, 2022

OR

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

FOR THE TRANSITION PERIOD FROM TO

Commission File Number: 001-40047

# **Talis Biomedical Corporation**

(Exact name of Registrant as specified in its Charter)

(State or other jurisdiction of incorporation or organization)

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incorporation or organization)
3400 Bridge Parkway
Redwood City, California
(Address of principal executive offices)

**46-3122255** (I.R.S. Employer Identification No.)

**94065** (Zip Code)

(650) 433-3000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:		
Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Comment of the contract of the	TLIC	The Meeder Cteel, Meelest L.C.

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

Emerging growth company

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  $\boxtimes$  NO  $\square$ 

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  $\boxtimes$  NO  $\square$ 

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
 □

 Non-accelerated filer
 ⊠

 Smaller reporting 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  $\square$  NO  $\boxtimes$ 

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.  $\Box$ 

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to \$240.10D-1(b).

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the Registrant's common stock on The Nasdaq Stock Market on June 30, 2022, was \$7,342,048. The calculation of the aggregate market value of voting and non-voting common equity excludes shares held by executive officers, directors and stockholders that the Registrant concluded were affiliates of the Registrant on such date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant or that such person is controlled by or under common control with the Registrant.

As of March 15, 2023, there were 56,730,589 shares of the Registrant's common stock and preferred stock outstanding, consisting of 26,866,915 shares of common stock and 29,863,674 shares of Series 1 convertible preferred stock, which is a voting common stock equivalent, subject to certain limitations.

**DOCUMENTS INCORPORATED BY REFERENCE**Portions of the Registrant's definitive proxy statement relating to its 2023 Annual Meeting of Stockholders (the "2023 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K. The 2023 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report relates.

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# **Special Note Regarding Forward-Looking Statements**

This Annual Report on Form 10-K (this Annual Report) contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our expectations regarding our revenue, expenses and other operating results;
- the timing or outcome of any of our domestic and international regulatory submissions;
- our planned regulatory clearance pathways;
- our efforts to successfully develop and commercialize our products and services, including our ability to successfully conduct clinical trials and studies and expand our product menu;
- 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;
- our ability to manufacture a regulatory cleared product at a low cost;
- impact from future regulatory, judicial, and legislative changes or developments in the United States and foreign countries;
- our ability to establish, maintain and grow our commercial capabilities and acquire customers;
- our expectations regarding our sales models;
- the costs and success of our research and development efforts, including the potential effects of inflation;
- our ability to increase demand for our products and services, obtain and maintain favorable coverage and reimbursement determinations from third-party payers and expand geographically;
- the performance of our third-party suppliers and manufacturers;
- our ability to effectively grow, including our ability to retain and recruit personnel, and maintain our culture;
- the impact of the ongoing COVID-19 pandemic on our business, clinical trials, financial conditions, liquidity and results of operations;
- our ability to compete effectively with existing competitors and new market entrants;
- the impact on our business of economic or political events or trends;
- the size and growth potential of the markets for our products and services, and our ability to serve those markets; and
- the rate and degree of market acceptance of our products and services.

In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report and are subject to risks and uncertainties. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our

statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. We discuss many of the risks associated with the forward-looking statements in this Annual Report in greater detail under the heading "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. You should carefully read this Annual Report and the documents that we reference in this Annual Report and have filed as exhibits to this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this Annual Report by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

# **Summary of Risk Factors**

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

- We have realigned our business strategy to focusing on developing tests that decentralize testing primarily in the women's and sexual health markets, which will require pursuing marketing authorization through the FDA's standard 510(k) clearance process. We may not be able to obtain marketing authorization for these tests, which would adversely affect our business, financial condition and results of operations.
- We will likely need to raise additional capital to fund our existing operations, further develop our diagnostic system, commercialize products, if and when approved, and expand our operations.
- We have no products approved for commercial sale. We have no or limited experience in developing, marketing and commercializing diagnostic systems and tests, and we are continuing to evaluate the sales model for the Talis One system, which may make it difficult to evaluate the success of our business and to assess our future viability.
- We rely on a significant number of third-party manufacturers and suppliers for our instrument and cartridges, which has created and may
  continue to create delays due to the complexity of our manufacturing lines and supply chain, as well as exposure to manufacturing and supply
  limitations or interruptions and quality and quantity issues.
- We may be unable to validate our manufacturing for the Talis One instrument and cartridges at scale, which may impact our ability to support our research and development pipeline and future commercialization.
- The COVID-19 pandemic has and could continue to materially adversely affect our business, financial condition and results of operations.
- If our products do not perform as expected, including due to errors, defects or reliability issues, our reputation and market acceptance of our products could be harmed, and our operating results, reputation and business will suffer.
- Our commercial success could be compromised if our customers do not receive coverage and adequate reimbursement for our products, if and when approved.
- Modifications to our products may require new 510(k) clearances, PMA approvals, or other marketing authorizations, or may require us to cease marketing or recall the modified products until clearances, approvals, or other marketing authorizations are obtained.
- If we are not able to obtain, maintain, defend or enforce patent and other intellectual property protection for products, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.
- Some of our intellectual property has been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies, and compliance with such regulations may limit our exclusive rights and our ability to contract with non-U.S. manufacturers.
- We have incurred significant losses since our inception, and we anticipate that we will continue to incur losses for the foreseeable future, which could harm our future business prospects.

•	If we are unable to regain compliance with the listing requirements of the Nasdaq Capital Market, our common stock may be delisted from the
	Nasdaq Capital Market which could have a material adverse effect on our financial condition and could make it more difficult for you to sell
	your shares.

#### 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 system that could be deployed to a variety of testing settings in the United States and around the world to diagnose infectious disease in the moment of need, at the point of care. The Talis One system comprises a compact instrument, single-use test cartridges and software supporting a central cloud database which work together. The system is designed to provide central laboratory levels of accuracy and be operated by an untrained user.

#### **Corporate Information**

We were formed as a limited liability company under the Illinois Limited Liability Company Act in March 23, 2010 under the name SlipChip LLC. In June 2013, SlipChip LLC merged with and into SlipChip Corporation, a Delaware corporation, with each member of SlipChip LLC exchanging their respective membership interest for shares of common stock of SlipChip Corporation. In February 2018, we changed our corporate name to Talis Biomedical Corporation. Our principal executive offices are located at 3400 Bridge Parkway, Redwood City, California 94065, and our telephone number is (650) 433-3000. Our corporate website address is <a href="http://talisbio.com">http://talisbio.com</a>.

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

#### General

Recent surveys of women's and sexual health providers that we have conducted confirm the continued and strong interest in adoption of point-of-care systems, such as the Talis One system. We believe the Talis One system is well positioned to meet this growing demand in both traditional and non-traditional care settings. Although there are several commercially available point-of-care systems, we believe that few, if any, sufficiently meet the needs of healthcare providers to drive broad adoption of, and transition to, point-of-care testing from central lab testing for a broad range of infectious diseases. 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 Talis One tests to address some of the most critical infectious diseases in women's and sexual health, initially with a panel for Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis (CT/NG/TV), as well as a respiratory panel consisting of tests for influenza A, influenza B and COVID-19 (Respiratory Panel). In order to bring the Talis One system to market as soon as possible, we are leveraging progress made to-date to direct our efforts on the pursuit of 510(k) clearances under the federal Food, Drug and Cosmetic Act (FDCA) for our highly differentiated platform and development of multiple test panels. We plan to conduct clinical trials to support clearance of the Respiratory Panel and CT/NG/TV test, as well as other sexually transmitted infections (STIs), such as herpes simplex virus (HSV), vaginal infections including bacterial vaginosis (Vaginal Infections Panel), and urinary tract infections (UTI).

We designed the Talis One system to address limitations of existing point-of-care diagnostic testing technologies for infectious diseases. Our system combines robust sample preparation with highly optimized and rapid isothermal

nucleic acid amplification technology to enable rapid detection of infectious pathogens in a variety of unpurified patient sample types. We designed the Talis One system to have the following capabilities which we believe will create a competitive advantage over other commercially available point-of-care technologies:

- Highly accurate—The Talis One system incorporates a shelf-stable, single-use test cartridge designed to fully integrate a nucleic acid amplification test (NAAT) with sample preparation, including nucleic acid extraction and purification. Sample preparation is well known to be a critical factor to achieve high sensitivity and specificity, along with low limits of detection for target pathogens, in molecular diagnostics. We believe this sample preparation step, which is performed in an automated fashion on our cartridge, has the potential to result in higher sensitivity and specificity than point-of-care technologies that do not perform the sample preparation step. Our Talis One system reaches limits of detection as low as 500 viral particles per milliliter. We can achieve similarly high performance on the Talis One system for bacteria with limits of detection of bacterial pathogens as low as one infectious unit per milliliter (IFU/mL) in a variety of unpurified patient sample types, including nasal swab, vaginal swab, saliva and urine.
- Rapid turnaround time—The Talis One system is designed to provide a positive or negative result in less than 30 minutes, depending upon the test and the concentration of the pathogen in the sample. We believe this turnaround time meets target customers' needs for a system fast enough to fit into their clinical practice.
- *Ease of use*—We designed the Talis One system for operation by untrained users and to function in a CLIA-waived environment such as physicians' offices, urgent care clinics, and decentralized care settings and hospitals. 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.
- *Cartridge Capabilities*—The cartridge is designed with five separate reaction chambers. There is the ability to add up to an additional nine chambers for a total of 14 reaction chambers, which we believe could potentially enable a full menu of detection modes, from single organism to syndromic panel tests. The cartridge design allows for both robust sample purification and multiplexing capabilities that are both not generally offered by other point-of-care diagnostic platforms.
- Cloud-enabled—Unlike other point-of-care instruments, the Talis One system incorporates a cellular modem within the instrument, designed to connect to the cloud to help customers manage clinical data and workflow using our Sia Dx feature. Sia Dx is designed to allow (i) remote and secure access to the cloud to obtain key data required to collect, screen, collate, report and monitor disease infection and pandemic spread on a micro and macro level and (ii) remote management of instruments in the field, such as providing automated software updates and enabling 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. Sia Dx has been built into the Talis One system but will require that we submit additional data to the FDA for review prior to implementation.
- *Scalable for different throughput requirements*—The Talis One system is designed to provide a scalable system for different volume and throughput requirements. The instruments are portable and designed for multi-instrument deployments to satisfy different testing volume requirements and can be stacked three instruments by three instruments without disturbing the cellular connection to the cloud.
- Low cost to manufacture—We designed the Talis One system to be low-cost and manufactured at scale. We believe this could facilitate (i) scale-up in manufacturing and provide a competitive advantage in cost-sensitive environments and (ii) customers acquiring multiple Talis One instruments to meet their volume requirements.

### **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:

Complete development of and, if marketing authorizations are obtained, commercialize tests for infections requested by the women's health and sexually transmitted infections markets in the United States

- We are developing tests for respiratory infections, including influenza A and influenza B. In 2022, we delivered a pre-submission to the U.S. Food and Drug Administration (FDA) for the Respiratory Panel, and we intend to pursue marketing authorization through the 510(k) clearance pathway. The FDA's marketing authorization requirements for the Respiratory Panel will impact the timing to develop and commercialize this combination panel, if authorized.
- We are also developing a full menu of tests for infections related to women's health and sexually transmitted infections. We are focusing initially on our CT/NG/TV test, for which we plan to initiate a clinical study to support a 510(k) pre-market notification.
- We are subsequently targeting other STIs, such as a panel for sexually transmitted inflection that would include CT/NG/TV, a Vaginal
  Infection Panel, a panel for UTI, and single target tests for infectious agents such as HSV and Group B streptococcus (Group B Strep).

Increase the flexibility of our manufacturing capabilities to support the development and commercialization of the Talis One system with a clear path to meaningful margins in the future

- We have invested in automated cartridge manufacturing lines to consistently produce cartridges that meet industry standards and our anticipated commercial needs.
- We have also invested in internal cartridge manufacturing lines that (i) provide us with flexibility to support our internal research and
  development and upcoming clinical trials, (ii) improve our understanding of the manufacturing process and (iii) help maintain our cartridge
  inventory.
- We continue to refine and improve high throughput in our manufacturing lines to ensure that we maintain our ability to manufacture at scale with acceptable cost of goods for commercialization.

# Pursue commercialization of our Talis One system in the United States

 We intend to initially launch the Talis One system in the United States and will further refine our commercialization strategy as regulatory milestones are cleared.

# Continue to invest in capabilities to drive sustainable growth

- We intend to focus on innovation to improve the technical performance of our Talis One system and develop an expanded test menu.
- We intend to continue our research and development activities and to leverage proprietary innovations to develop additional systems in the future designed to solve diagnostic challenges for our customers.
- We continue to strive for operational efficiencies and manufacturing capabilities to further drive economies of scale and lower manufacturing costs. We are restructuring our contract manufacturing partnerships and leveraging internal processes to enable greater flexibility and a pathway to what we believe will be industry-leading cost of goods sold.

# **Industry background**

Infectious disease remains among the top health problems facing populations around the world. Mortality rate for all infectious disease in the United States ranged between 42 and 63 deaths per 100,000 population, accounting for 5.4% of overall mortality for the period of 1980-2014.

The drawbacks of centralized laboratory testing

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

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

# Limitations of current point-of-care diagnostic technologies

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

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

- Low performance as measured by sensitivity, specificity and limit of detection can result in misdiagnosis and poor clinical outcomes. Several point-of-care molecular diagnostic systems 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.
- Systems requiring significant user interaction or monitoring will not work well with clinical workflow. Some sold as point-of-care solutions require users to transfer solutions midway through a run or handle the instrument, test cartridge and/or sample multiple times, in order to process one test. The typical physician's office does not have laboratory personnel who can monitor an instrument, nor personnel trained in sample custody tracking.
- Systems 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 systems and consumables is a primary concern for customers.
- Limited test menus fail to meet the needs of clinicians. The adoption of diagnostic technologies is contingent upon the technology having both clinical utility, and economic rationale. Without a broad and relevant testing menu, testing systems may not sufficiently meet the clinical needs of customers to justify the expense. We believe the ability to develop our planned additional tests will create a competitive barrier to entry for other systems.

# The Talis One system

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

# Talis One cartridge

At the core of our system is the Talis One cartridge, a versatile shelf-stable and single-use test cartridge designed to fully integrate proprietary highly-optimized nucleic acid isothermal amplification tests 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 chemical, enzymatic, and mechanical lysis, e.g., 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 reagent plug technology, which is designed to enable implementation of new tests on the same cartridge backbone simply by inserting plugs with different target test reagents. The reagent plugs in our cartridges are optically clear, permitting the instrument to visualize and detect fluorescent signals from the amplification test. Patented test wells employ a fluidic design and include a mechanism to heat-seal the cartridge for amplicon containment designed to prevent contamination of the work surfaces.

The cartridge, with modifications, is designed to support up to 14-well multiplexing, which we believe will enable development of expanded panels and syndromic applications. The specific cartridge that we developed for the CT/NG/TV test 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  $7 \times 10 \times 14$  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 the Sia Dx software which enables the communication of test results to a central cloud database that can be remotely and securely accessed to obtain key data required to collect, screen, collate, report, and monitor disease infection and pandemic spread on a micro and macro level. The cellular and ethernet connectivity built into each Talis One instrument is also designed to enable Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant transmission, storage, and review. Such centralized storage could permit (i) creation of a public health interface granting access to select information to governmental entities and/or (ii) automatic transmission of notifiable diseases to public health authorities. The cloud-based data could serve to help institutions better manage clinical practice and also to improve infection control. With substantially increased adoption over time, the data may offer a mapping of infection patterns that public health and research institutions can use to address care on a larger scale. Additionally, for organizations that may desire multiple instrument placements, such as in multiple exam rooms, multiple departments or distributed testing sites, authorized administrators may be able to monitor, in real-time, the status of any instrument in the organization, as well as manage users, passwords, and certain security features. The continuous connectivity of the Talis One instruments is also designed to enable us to provide automated updates including security patches, instrument configurations, and

firmware and software updates, the latter of which could be deployed to enable the instrument to recognize and run newly released tests.

### Talis One workflow

The Talis One system is capable of being integrated into the clinical workflow as follows: (1) label cartridge with patient information, (2) dispense sample into loading port and close lid, (3) insert cartridge into instrument, and (4) follow on-instrument instructions to initiate testing, results will automatically display after less than 30 minutes. The workflow may vary for alternate sample types.

The Talis One workflow follows a few simple steps from sample preparation to results. The system is designed to return results in less than 30 minutes and requires two minutes or less of hands-on time for the operator. After the sample is collected and the cartridge is introduced into the instrument, the instrument confirms the operability of the cartridge, runs the test 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 test kits

We are a development stage company and, to date, our only source of revenue has been from the sale of the third-party COVID-19 antigen tests (Antigen Tests) which concluded at the end of 2022, and we have not generated revenue from the sales of our own product. As described below, we are developing Talis One tests for infections related to women's health, STIs and respiratory infections. Our first test to be marketed will be a test for CT/NG/TV pursuant to 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 test development roadmap to address the most common clinically relevant tests that require high sensitivity and specificity and for which timely results provide significant clinical benefit. In addition to the CT/NG/TV test, our women's and sexual health roadmap includes plans to develop and seek marketing authorization for (1) a test for HSV; (2) a multitarget panel test for UTI; (3) the Vaginal Infection Panel; and (4) a single target test for Group B Strep.

## **Infectious Diseases**

We are developing our Talis One system to be used for infections related to women's health, STIs and respiratory infections. We intend to complete clinical development of our Talis One system for CT/NG/TV and submit a 510(k) pre-market notification to the FDA after the successful completion of our clinical trials. We further intend to explore authorization to affix a CE Mark from the EMA soon 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 the Vaginal Infection Panel, UTI and HSV.

The American Congress of Obstetricians and Gynecologists recommends annual CT/NG screening of all sexually active women age 25 and younger and for women over age 25 with risk factors. In addition to promoting our test menu to our existing customers, we will engage in a focused commercialization effort directed towards obstetricians and gynecologists, where we estimate that a substantial majority of CT/NG testing occurs. Traditionally, testing is carried out by centralized laboratories, and we believe that there is a significant opportunity to move these tests to the point-of-care at the office of the obstetrician and gynecologist or in urgent care clinics or primary care facilities. We believe testing at the point-of-care could (i) improve decision making and enable the provider to use this information to treat the patient in the same visit and (ii) 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.

The Talis One COVID-19 test was the first product that we developed for respiratory infections. Although we do not currently plan a broad commercial launch for the stand-alone COVID-19 test, we plan to seek marketing authorization for the Respiratory Panel through a 510(k) clearance process.

# **Future** applications

We are developing new algorithms and a bioinformatics pipeline to design rapid isothermal tests 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. We are investigating adding multi-color and semi-quantitative detection capabilities to the Talis One instrument to support our test product roadmap.

#### **Commercialization and Manufacturing**

We are developing relevant in-vitro diagnostic tests for a variety of respiratory infections and infections related to women's health and STIs. We estimate that the total potential annualized addressable global market opportunity for molecular testing of infectious diseases is over \$5.4 billion for 2022 and is expected to grow to over \$7.1 billion by 2026. We intend to initially launch in the US and will explore commercialization strategies outside of the United States in the future.

We intend to offer our Talis One system to customers via direct purchase of the instrument and through reagent rental. 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.

In 2022, we discontinued further investment in commercializing our stand-alone COVID test. In conjunction with this decision, we eliminated our sales force and reduced our commercial team supporting our product development and marketing needs. Leveraging progress we have made to-date with our stand-alone COVID test, we are conducting investigational field studies with the Talis One system to gain user experience and feedback on the platform's physical components, workflow, and software. Results from these studies will help inform the development of our planned product roadmap.

To support future commercialization of the Talis One system, we invested in automated manufacturing to provide us with the advantages of quality, speed and cost at full scale. In 2022, we demonstrated our ability to manufacture cartridges and instruments at the quality and pace needed with a clear path to what we believe will be attractive gross margins in the future. In order to drive further efficiency and cost reduction in the manufacturing process, we have begun restructuring our relationships with our contract manufacturing partners. We believe we have sufficient instrument and cartridge inventory and inhouse capacity to support our internal development and clinical trial needs through initial commercialization.

#### Competition

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

Our competitors include those offering molecular, antibody and antigen tests. Competitors in the reference lab category include Laboratory Corporation of America Holdings (commonly referred to as LabCorp) and Quest Diagnostics Incorporated, along with many hospital laboratories. Our competitors in the point-of-care and/or at-home category, for molecular and/or antigen tests include Abbott Laboratories, bioMérieux SA, Cepheid (a subsidiary of Danaher Corporation), Thermo Fischer Scientific Inc., Roche Molecular Systems, Inc., and QuidelOrtho.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, regulatory clearance approval and compliance, and sales and distribution than we do. Smaller or early-stage companies developing tests may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies or customer networks. If our competitors (i) develop and commercialize diagnostic products or services that are more accurate, more convenient to use or more cost-effective than our products or services and/or

(ii) obtain FDA or other regulatory clearance or approval for their products more rapidly than we may obtain clearance or approval or other marketing authorizations for ours, our commercial opportunity could be reduced or eliminated, especially if our competitors establish a strong market position before we are able to enter a particular market.

#### **Government Contract**

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

In July 2020, we were awarded a \$25.4 million contract from the National Institutes of Health (NIH) for Phase 2 of its RADx initiative (NIH Contract), of which \$9.6 million had been received as of December 31, 2022, for the validation, approval, and scale-up of capacity for manufacturing of the Talis One instrument and test cartridges. Due to delays in meeting certain milestones, we received several extensions to the NIH Contract that concomitantly extended the time to perform the remaining milestones and reduced the potential milestone payments. The NIH Contract expired on January 30, 2022, and we did not achieve the final two milestones. We intend to explore additional government grants to help support our product roadmap.

# **Operations**

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

# Supply chain management

We utilize multiple vendors for our supply chain. Currently, many of the materials, enzymes and reagents used in our systems and cartridges are from single source suppliers. However, we continually evaluate redundancy vendors for reagents and other materials, where possible. We believe we have sufficient inventory for the majority of our materials to support our research and development efforts and planned clinical trials but will supplement our inventory, as needed. We continue to manage inventory levels, our supplier terms and other supply chain risks to help ensure an uninterrupted supply as we approach commercialization.

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. In March 2023, we entered into a termination agreement with thinXXS, pursuant to which we (i) terminated the thinXXS Agreement, (ii) received possession and title to automated manufacturing lines and certain related materials, and (iii) entered into a license agreement under which we received a patent license to thinXXS intellectual property that may be incorporated into the Talis One system.

# **Intellectual property**

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

shared registration or examination agencies such as the European Patent Office or European Intellectual Property Office).

#### Datante

As of March 1, 2023, we solely own 15 issued U.S. patents, 17 pending U.S. patent applications, 23 issued foreign patents, and 128 pending foreign patent applications. Our patent portfolio generally includes patents and patent applications relating to microfluidic systems, our rapid isothermal amplification method, integrated cartridges and instrument for the Talis One system, as well as components thereof and methods of operating the same. In addition to patents and applications related generally to the Talis One system, our portfolio includes patents and applications drawn to test reagents for specific targets, including CT and NG. Issued U.S. patents in our portfolio of company-owned and in-licensed patents and patent applications (if issued) are expected to expire between 2035 and 2045.

#### **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 names, Talis One and Sia Dx.

#### Trade secrets

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

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

# Government regulation and product approval

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

### Regulation in the United States

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

The FDA classifies all medical devices into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I and Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of Class II devices, including performance standards, post-market surveillance, clinical investigations, patient registries and additional conditions set forth in FDA guidance documents. While most Class I devices are exempt from the 510(k) pre-market notification requirement, manufacturers of most Class II devices are required to submit to the FDA a pre-market notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) pre-market notification is generally known

as a 510(k) clearance. Devices deemed by the FDA to pose the greatest risks are placed in Class III, requiring approval of a PMA application. At this time, we have no Class III devices in the pipeline nor plans to add Class III's.

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

The U.S. Secretary of the Department of Health and Human Services (HHS) may declare public health emergencies that have a significant potential to affect national security or the health and security of U.S. citizens. On February 4, 2020, the novel coronavirus was declared a public health emergency, and it was declared that circumstances existed justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus that causes COVID-19. These EUAs will terminate upon declaration that the public health emergency circumstances have ceased, or the product provided pursuant to EUA has otherwise achieved commercial authorization for the emergency indication for use, such as through 510(k) clearance, *de novo* process, or PMA approval.

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

### 510(k) clearance process

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

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

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the pre-market notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance

pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA also announced that it intends to finalize guidance to establish a pre-market review pathway for "manufacturers of certain well-understood device types" as an alternative to the 510(k) clearance pathway and that such pre-market review pathway would allow manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process.

In May 2019, the FDA solicited public feedback on its plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates, including whether the FDA should publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation. More recently, in September 2019, the FDA finalized the aforementioned guidance to describe an optional "safety and performance based" pre-market review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway, by demonstrating that such device meets objective safety and performance criteria established by the FDA, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process.

# Pervasive and continuing FDA regulation

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

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

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

- warning letters;
- customer notifications for repair, replacement or refunds;
- fines, injunctions, consent decrees and civil penalties;
- mandatory recall or seizure of our products;
- administrative detention or banning of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for 510(k) clearance or PMA of new product versions;
- revocation of 510(k) clearance or PMAs previously granted; and
- criminal prosecution and penalties.

#### International Regulation

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

# Other healthcare laws

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

The federal Anti-Kickback Statute (AKS) prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual, for an item or service or the purchasing, leasing, ordering, or arranging for or recommending the purchase, lease or order of any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs. The term remuneration has been interpreted broadly to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the AKS has been violated. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.

The federal civil and criminal false claims laws, such as the civil False Claims Act (FCA), prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment or approval by the federal government, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. Additionally, the FCA authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud. Because the complaint is initially filed under seal, the action may be pending for some time before the

defendant is even aware of the action. If the government intervenes and is ultimately successful in obtaining redress in the matter, or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of life sciences companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. In addition, the government may assert that a claim including items or services resulting from a violation of the federal AKS constitutes a false or fraudulent claim for purposes of the civil FCA. The government has obtained multi-million and multi-billion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with

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

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

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

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

# Coverage and reimbursement

applicable fraud and abuse laws.

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 tests per year; urgent care chains that serve on the front lines of COVID-19 diagnosis, needing millions of rapid tests to triage symptomatic patients; and traditional medical establishments including hospitals, ambulatory surgery centers, cancer treatment and dialysis centers, independent practice associations, accountable care organizations, and public health clinics that need rapid and high-quality testing to best serve their patients.

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

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

CMS announced plans in March 2020 to cover the cost of COVID-19 diagnostic testing under the Medicare program and identified the amount at which it would reimburse for such tests, which has been adjusted numerous times. For example, Medicare adjusted its payment methodology effective January 1, 2021, such that it will pay \$100 per test only to those laboratories that complete high throughput COVID-19 diagnostic tests within two calendar days of the specimen being collected and will only pay \$75 per test to laboratories that take longer than two days to complete such test. This change is indicative of the evolving nature of the coverage and reimbursement of COVID-19 tests. In addition, there has been federal and state legislation and other reform initiatives regarding the coverage and reimbursement for COVID-19 diagnostic testing in response to the COVID-19 outbreak which continue to evolve. For example, effective January 15, 2022, private health insurance companies and group health plans are required to cover eight free over-the-counter athome COVID-19 diagnostic tests authorized, cleared, or approved by the FDA per covered individual per month.

# **Data Privacy**

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

The CRPA, EU GDPR, and UK GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing may increase our compliance obligations and exposure for any noncompliance. For example, the CPRA, effective January 1, 2023, gives, among other things, California residents the ability to limit use of certain sensitive personal data, establishes restrictions on personal data retention, expands the types of data breaches that are subject to a consumer private right of action, and establishes a new California Privacy Protection Agency to implement and enforce the new law. In addition, U.S. federal and state consumer protection laws may require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

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

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

#### **Human capital resources**

As of December 31, 2022, we had a total of 102 full-time employees. Our employees are located in Redwood City, California, Chicago, Illinois and other locations within the United States. None of our employees are represented by any collective bargaining agreements. We believe that we maintain good relations with our employees. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

# **Available Information**

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

### Item 1A. Risk Factors.

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

# Risks related to our business and strategy

We have realigned our business strategy to focusing on developing tests that decentralize testing primarily in the women's and sexual health markets, which will require pursuing marketing authorization through the FDA's standard 510(k) clearance process. We may not be able to obtain marketing authorization for these tests, 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 system for infectious diseases. Prior to the COVID-19 pandemic, we focused our research and development efforts on developing the Talis One point-of-care system for use in women's health and STI tests, including CT/NG/TV. However, during the COVID-19 pandemic, we developed and received an EUA for the stand-alone Talis One COVID-19 test. Following our revocation request, the EUA was revoked by the FDA in August 2022. We have focused our resources on our multiplex products primarily in the women's and sexual health markets, initially on a CT/NG/TV test on the Talis One system. In order to gain user experience and feedback on the Talis One system's physical components, workflow and software, we have resumed IUO system evaluations of the Talis One system. We intend to submit 510(k) submissions to the FDA for our future test menu. We may not receive clearance or if we receive clearance, there are numerous factors to consider that make it difficult to evaluate our future business prospects and, therefore, we may not be able to achieve our goals and strategy. Failure to achieve marketing authorization for these tests would adversely affect our business, financial conditions and result of operations.

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 or clearance may not demonstrate strong performance characteristics, limiting the market demand for the system, which would adversely affect our business. See "—Risks related to regulatory matters.

We have no experience with the entire commercialization process for the Talis One system. We have gained some experience with the initial stages of the process, including demand generation, evaluations, and quoting, and we have recent commercialization experience selling and distributing the Antigen Tests as an authorized distributor. As a result, we have limited experience forecasting future financial performance for our products, including any third-party products that we may offer, such as the Antigen Tests, and our actual results may fall below our financial guidance or other projections, or the expectations of analysts or investors, which could cause the price of our common stock to decline. In addition, we are continuing to evaluate the appropriate acquisition model for our Talis One system and cannot predict the proportion of customers that would procure the Talis One instrument through capital purchase versus our planned equipment leasing model. Our results of operations could fluctuate with high variability depending on the changes in the proportion of our customers who directly purchase as compared to renting the equipment which will make it challenging to predict our operating results, particularly during the early stages of any future commercial launch following marketing approval.

Future commercialization of the Talis One system in the United States will require pursuing 510(k) clearance or another available approval path. The launch of new products is inherently uncertain and requires the completion of

commercialization activities that are complex, costly, time-intensive and uncertain, and require us to accurately anticipate patients', providers' and, if applicable, payors' attitudes and needs, the future competitive landscape, and emerging technology and industry trends. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals on a timely basis, or at all.

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

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

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

We may experience research and development, regulatory, marketing and other difficulties that could delay or prevent our introduction of enhanced or new products and result in increased costs and the diversion of management's attention and resources from other business matters. For example, any molecular diagnostic tests that we may develop or further enhance may not prove to be clinically effective, or may not meet our desired target product profile or be offered at acceptable cost and with the sensitivity, specificity and other test performance metrics necessary to address the relevant clinical need or commercial opportunity; our molecular diagnostic test performance in commercial settings may be inconsistent with our validation or other clinical data; we may not be successful in achieving market awareness and demand, whether through our own sales and marketing operations or entering into collaborative arrangements; the collaborative arrangements we enter into may not be successful or we may not be able to maintain those that are successful; healthcare providers may not use any tests that we may enhance or develop; or we may otherwise have to abandon a product, service ore development program 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 rely on a significant number of third-party manufacturers and suppliers for our instrument and cartridges, which has created and may continue to create delays due to the complexity of our manufacturing lines and supply chain, as well as exposure to manufacturing and supply limitations or interruptions and quality and quantity issues.

We do not have any commercial-scale manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of the Talis One system and our tests, as well as for commercial supply for any approved products, if ever. The manufacturing of our Talis One instrument and cartridge is a complex process that involves over 500 raw materials, intermediates and subassemblies. The complexity of the instrument and cartridge designs and number of parts involved has presented manufacturing challenges for us and our third-party manufacturers. In addition, our reliance on these third-party manufacturers exposes us to significant risk that we will not have sufficient quantities of our products at an acceptable cost or quality, which has and could delay, prevent or impair our commercialization efforts when we commercialize. We are also susceptible to increased costs of good associated with rising inflation rates. 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. Prior to commercialization, we will need to validate the lines which could cause us to incur substantial expenditures or delays in order to achieve acceptable quality, costs and output. In addition, delays that may occur with one supplier could have a ripple effect with other suppliers. Such ripple effects could increase costs or obligate us to purchase materials before they are required for commercial purposes which could increase costs, increase risk of scrap or damage relationships with our suppliers. Such delays or required expenditures could further delay the launch of our Talis One system, which would adversely impact our business, financial condition and results of operations.

As we have not yet completed process validation of our high-volume assembly lines with a cleared women's health or STI test, in accordance with FDA recommendations, it may be difficult to predict the cost of manufacturing our cartridges at scale. We are undertaking a number of initiatives designed to reduce the cost of manufacturing our instruments and diagnostic tests, including reducing the costs of supplies and restructuring our contract manufacturer relationships. However, there is no guarantee that we will be able to achieve planned cost reductions from such initiatives. For example, yield from the automated lines may be low resulting in many components to be scrapped or quality of final products may not meet our requirements, which may increase scrap and therefore, our costs. There have been unforeseen occurrences that have increased our costs for supplies used in manufacturing our cartridges and instruments, and there could be other unforeseen occurrences, such as increased prices of the components of our diagnostic tests, changes to labor costs or less favorable terms with third-party suppliers or contract manufacturing partners, including as a result of increased shipping costs caused by the substantial increase in fuel prices. As a result, even if our automated lines perform as anticipated, we may be unable to manufacture our products in a profitable

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.

Our third-party manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, unstable political environments, health pandemics, inflation or epidemics or rising costs of labor, materials and transportation. If we are unable to procure sufficient supplies for our instruments and cartridges, at the level of quality we need, and at a commercially reasonable cost, we may be unable to manufacture our products in sufficient quantities and such event would have a material adverse effect on our business, financial condition and results of operations.

If our third-party suppliers fail to deliver the required 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 potential future commercialization of our instrument and diagnostic tests, the supply of our instrument and diagnostic tests to

customers and the development of any future diagnostic tests will be delayed, limited or prevented, which could have a material adverse effect on our business, financial condition and results of operations.

Furthermore, all entities involved in the manufacture of our products are subject to extensive regulation. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with these regulations. In the event that any of our manufacturers fail to comply with such requirements or to perform their 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 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. We are in the process of changing our manufacturer for the Talis One instrument, which could result in delays due to failure to sufficiently transfer knowledge from the prior manufacturer to the new manufacturer, as well as delays setting up a new production line with a new manufacturer. If we desire to or are required to change manufacturers for any reason, we will also be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop or deliver products in a timely or affordable manner.

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

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

We may be unable to validate our manufacturing for the Talis One instrument and cartridges at scale, which may impact our ability to support our research and development pipeline and future commercialization.

In order to commercialize our products, if approved, we will need to manufacture the Talis One instrument and test cartridges 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. If we, or our manufacturing partners, are unable to successfully scale-up the manufacture of our products in sufficient quality and quantity, the development, testing and clinical trials of our women's health and STI products may be delayed or become infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. We have experienced delays related to the manufacture of the instrument and cartridges due to the complexity of the process. This has subsequently delayed our progress in developing future products by reducing access to material and requiring us to divert significant internal resources to focus on stabilizing the manufacturing process with our manufacturing partners. Also, due to the insufficient supply of instruments and cartridges and implementation of required design changes, our ability to commence formal reliability studies to determine product reliability when produced at scale has been delayed, and may continue to be delayed or paused, if we encounter any additional manufacturing issues.

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

The global outbreak of COVID-19 across many countries around the globe, including the United States, has significantly slowed global economic activity, caused significant volatility in financial markets, supply chain disruptions and increased costs associated with rising inflation rates. Although the FDA has approved therapies and vaccines for distribution, there remain uncertainties as to the overall efficacy of the vaccines, especially as new strains of the coronavirus continue to emerge, and the level of resistance these new strains have to the existing vaccines, if any.

Certain states and cities have taken and may re-institute measures to prevent or slow the spread of COVID-19, and its variants including by instituting quarantines, vaccination mandates, and testing requirements restrictions on travel, "stay-at-home" rules, restrictions on types of business that may continue to operate and/or restrictions on the types of construction projects that may continue. While vaccine availability and uptake has increased, the longer-term macro-economic effects on global supply chains, inflation, labor shortages and wage increases continue to impact many industries.

The COVID-19 pandemic presents material uncertainty and risk with respect to our financial condition and development efforts, 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, 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.

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 test 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, thus affecting the accuracy of a diagnostic result, 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 products will be approved for use by untrained personnel or 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 may mutate over time. Such mutations may negatively affect the accuracy of our tests or even make our tests obsolete if our tests are unable to detect future variants. The failure of our products to perform as expected could significantly impair our operating results and our reputation, including if we become subject to legal claims arising from any defects or errors in our products or test results.

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

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

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

If we initiate a recall, including a correction or removal, for one of our commercialized products, if and when approved, 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.

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 costeffective 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.

We have eliminated our sales and customer support capabilities which could impact our ability to commercialize our future products, if and when they are approved, and we may not be able to generate any revenue.

In 2022, we implemented two reductions in force of approximately 40% of our employees which has impacted our sales, service and support personnel, and thus our ability to market, sell and support future products, if any. We may not be successful in re-establishing our commercial organization, if and when we have approved products in the future, and we may not be able to generate any revenue.

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

- our inability to retain or hire adequate numbers of effective sales and marketing personnel, particularly following a reduction in force;
- the inability of sales personnel to obtain access to accounts, institutions and/or physicians or educate adequate numbers of these customers on the benefits of ordering our products;
- competitive disadvantages of our products relative to competitor products; and
- unforeseen costs and expenses associated with re-establishing an independent sales and marketing organization or scaling up our commercial organization.

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

Our ability to execute our growth strategy depends upon our ability to drive adoption of the Talis One system. In addition to direct capital sales of our instrument, we intend to implement methods for customers to access to our system through alternatives such as the rental of our instrument or a promotional instrument placement instead of purchase. Our ability to execute on these programs is unproven. We cannot assure that our rental program will gain market acceptance which will cause us to be dependent on capital equipment sales and may hinder or delay adoption of our system.

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

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

We anticipate facing competition primarily from centralized laboratories and diagnostic companies offering both point-of-care and at-home solutions. Competitors include those offering molecular, antibody and antigen tests. Competitors in the reference lab category include Laboratory Corporation of America Holdings (commonly referred to as LabCorp) and Quest Diagnostics Incorporated, along with many hospital laboratories. Our competitors in the point-of-care and/or at-home category, for molecular and/or antigen tests include Abbott Laboratories, bioMérieux SA, Cepheid (a subsidiary of Danaher Corporation), Thermo Fischer Scientific Inc., Roche Molecular Systems, Inc., and QuidelOrtho. There are also smaller or earlier-stage companies developing tests that may also prove to be significant competitors in the women's health and/or sexual health markets. Many of our potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, regulatory clearance approval and compliance, and sales and distribution than we do. Mergers and acquisitions involving diagnostics companies may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies or customer networks. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize diagnostic products or services that are more accurate, more convenient to use or more cost-effective

than our products or services. Our competitors also may obtain FDA or other regulatory clearance or approval for their products more rapidly than we may obtain clearance or approval or other marketing authorizations for ours, which could result in our competitors establishing a strong market position before we are able to enter a particular market.

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

To remain competitive, we must continually research and develop improvements to our products. However, we may not be able to develop and commercialize improvements to our products in a timely manner. Our competitors may develop and commercialize competing or alternative products and improvements faster than we are able to do so, which would negatively affect our ability to increase or sustain our revenue or achieve profitability.

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

Our estimates of the annual addressable markets for our women's health and STI 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. The market and competitive landscape are continuously changing. Any number of factors that are outside of our control could make our estimates invalid.

There can be no assurance that demand for our women's health and STI tests will continue to exist in the future after we commercialize. If the actual number of patients who would benefit from our products under development, the price at which we can sell future products or the annual addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business, financial condition and results of operations.

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

Our results of operations could be adversely affected by general conditions in both the local and global economy and financial markets, particularly as the United States and other countries balance concerns around debt, inflation, growth and budget allocations in their policy initiatives. There can be no assurance that global economic conditions and financial markets will not worsen and that we will not experience any adverse effects that may be material to our cash flows, results of operations, financial position or our ability to access capital, such as the adverse effects resulting from a prolonged shutdown in government operations both in the United States and internationally. Our business is also affected by local economic environments, including inflation, recession, financial liquidity and currency volatility or devaluation. Political changes, including war or other conflicts, some of which may be disruptive, could interfere with our supply chain, our customers and all of our activities in a particular location. A severe or prolonged global economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our manufacturers and suppliers, possibly resulting in supply disruption. In addition, geopolitical, economic and military conditions around the world may directly affect our business. Any hostilities involving any of the countries in which we or our third-party suppliers operate, including terrorist activities, political instability or violence in the region or the interruption or curtailment of trade or transport between such country and its trading partners could adversely affect our business and results of operations. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

Our future success depends, and will likely continue to depend, on our ability to retain, recruit, develop and motivate key personnel. Although we have employment agreements with our senior management, they may terminate their

employment with us at any time. The loss of members of our senior management, research and development, science and engineering, manufacturing and marketing teams could delay the achievement of our research, product development and commercialization objectives and harm our business.

We do not maintain fixed-term employment contracts or key man life insurance with any of our employees. Competition for qualified personnel is intense. The life sciences industry has been challenged by shortages of qualified technical personnel, especially those with experience in infectious disease and/or *in vitro* diagnostics, resulting in increased competition for new hires and increased employee turnover. In addition, we have a limited number of employees to manage and operate our business and cannot ensure that we will be able to maintain adequate staff to (i) develop our products, (ii) run our operations or (iii) accomplish our objectives. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract, develop, retain and motivate qualified personnel could materially harm our operating results and growth prospects.

If we fail to achieve the expected financial and operational benefits of our recent reductions in force, our business and financial results may be harmed.

In 2022, in connection with our refocus on the women's health and STI markets, we implemented two reductions in force, of approximately 40% of our employees, designed to align our remaining resources to focus on (i) developing women's health and STI tests on the Talis One system, (ii) our internal manufacturing expertise to support the commercial launch of the Talis One system and (iii) reducing costs and preserving cash to extend our runway to commercialize our women's health and STI tests. We believe these changes will preserve capital and help ensure that we are appropriately resourced to advance our pipeline of women's health and STI tests on the Talis One system. We may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the reductions in force.

These reductions in force may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of these reductions in force. In addition, while positions have been eliminated certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. These reductions in work force could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. If we are unable to realize the anticipated benefits from these reductions in force, or if we experience significant adverse consequences from these reductions in force, our business, financial condition, and results of operations may be materially adversely affected.

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

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

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

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

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

support a variety of functions. In addition, our third-party service providers depend upon technology and telecommunications systems provided by outside vendors.

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

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

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

In the ordinary course of our business, we and our third-party service providers will collect, store, use, transmit, disclose, or otherwise process proprietary, confidential, and sensitive data, including personal data (which includes intellectual property and trade secrets). In addition, upon commercialization, we will offer online customer-facing portals accessible through public web portals, through which our customers may process protected health information (PHI). It is critical that we process PHI and other sensitive data in a secure manner to maintain the confidentiality, availability and integrity of such confidential information. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems, and cloud-based data center systems. These applications and related data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We rely upon third-party service providers and technologies to operate critical business systems to process confidential information and personal data in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email and other functions. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive data with or from third parties.

Cyberattacks, malicious internet-based activity, and online and offline fraud and other similar activities that threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. These threats are prevalent and continue to increase, are becoming increasingly difficult to detect and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations and the supply chain.

We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware

attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

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

We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and data. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We have previously been, and may in the future become, the target of cyber-attacks by third parties seeking unauthorized access to our or our customers' data or to disrupt our operations or ability to provide our services. For example, we have been subject to phishing incidents, and we may experience additional incidents in the future.

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

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

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient of protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Our risks are likely to increase as we continue to expand our business, grow our customer base, and process, store, and transmit increasingly large amounts of proprietary and sensitive data.

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

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

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

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

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

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

We may 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. When we commercialize our products, we intend to 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 require warehousing for our diagnostic tests, sample collection kits and supplies. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our diagnostic tests and increased cost and expense to our business. In addition, we have and may continue to experience higher costs for transportation and warehousing and significant inflation that could adversely affect our operating margins and results of operations, if these costs continue to rise after we commercialize our products. 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 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. Even if we are successful in attaining a license, we may abandon development of a program utilizing licensed technology which may adversely affect our business relationships with our licensors or disrupt our business and financial position.

Further, rights to certain of the components and technology incorporated into our products are, and in the future, may be held by others and 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.

See the risk factor titled "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." for additional risks related to these licenses, collaborations and strategic alliances.

We may acquire other businesses or engage in other strategic transaction discussions with third parties, each of 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 companies, diagnostic tests or technologies that we believe either fit within our business model and can address the needs of our customers and potential customers or will otherwise provide strategic benefits to us. 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. Additionally, we may engage with third parties, including potential acquirers, in discussions regarding strategic transactions. The time required to engage with any such third parties could require significant attention from management, disrupt the ordinary functioning of our business and adversely affect our operating results.

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 focused initially on the development of the stand-alone Talis One COVID-19 test, 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 particularly in the women's health and STI health markets. 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 market authorization policies, regulations or laws 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.

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

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

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

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

The potential end-users of our women's health and STI tests include hospitals, physician practices, urgent care centers, public health and retail clinics that need rapid and high-quality testing to best serve their patients. If these end-users do not receive adequate reimbursement for the cost of our products from their patients' healthcare insurers or payors, the use of our products could be negatively impacted. Furthermore, the net sales of our products could also be adversely affected by changes in reimbursement policies of government or private healthcare payors.

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

In the United States, we expect that our customers will use standard industry billing codes, known as CPT codes, to bill for our tests. If these codes were to change, there is a risk of an error being made in the claim adjudication process. Such errors can occur with claims submission, third-party transmission or in the processing of the claim by

the payor. 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 women's health and STI tests will qualify for coverage that is currently available for other women's health and STI 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 addition, the availability of other forms of testing in the future, such as athome tests, could impact the reimbursement rate and market acceptance for our women's health and STI 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 payors 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 products may require new 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 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 will be required 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 Investigational Device Exemption (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;
- market authorization policies, regulations or laws of the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for market authorization; 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 510(k) clearance or PMA approval of new products or modified products;
- operating restrictions;
- withdrawal of 510(k) clearances or PMA approvals that have already been granted; and
- refusal to grant export approval for our products; or criminal prosecution.

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

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

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

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

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

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

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

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

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

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result.

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

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

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

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

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

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

Data privacy and information security have become significant issues in the United States, countries in Europe, and in other countries in which we operate. The legal and regulatory framework for privacy and security issues is rapidly evolving, and is expected to increase our compliance costs and exposure to liability. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws, and other similar laws (e.g., wiretapping laws). These privacy laws include, without limitation, the following laws and regulations: Section 5 of the Federal Trade Commission Act, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the California Privacy Rights Act of 2020 (CPRA). HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. The CPRA imposes obligations on businesses to which it applies that include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CPRA allows for statutory fines for noncompliance (up to \$7,500 per violation) and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CPRA exempts some data processed in the context of clinical trials, the CPRA may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents. In addition, the CPRA extends to personal information of business representatives and employees and established a new regulatory agency to implement and enforce the law. Other states, like Colorado, Connecticut, Utah, and Virginia, have passed comprehensive data privacy laws which differ from the CPRA and all of which went into effect in 2023. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts and may increase legal risk and compliance costs for us and the third parties upon whom we rely. Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data. Our inability or failure to do so could result in adverse consequences. If we are or become subject to these laws and/or new or amended data privacy laws, the risk of enforcement actions against us could increase because we may be subject to obligations

under applicable regulatory frameworks and the number of individuals or entities that could initiate actions against us may increase (including individuals via a private right of action), in addition to further complicating our compliance efforts. In addition, privacy advocates and industry groups have proposed, and may propose in the future, standards with which we are legally or contractually bound to comply.

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

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Most jurisdictions have adopted similarly stringent data protection laws which include data localization and cross-border data transfer limitations. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have prevented companies from transferring personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. Other jurisdictions require all processing of sensitive personal information be done inside the borders of that jurisd

We may also be bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CPRA, require our customers to impose specific contractual restrictions on their service providers. We may publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our obligations related to data privacy and security are quickly changing, becoming increasingly stringent and creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in direct conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model. Our business model materially depends on our ability to process personal data, so we are particularly exposed to the risks associated with the rapidly changing legal landscape. For example, we may be at heightened risk of regulatory scrutiny, and any changes in the regulatory framework could require us to fundamentally change our business model.

Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to operate our business and proceedings against us by

governmental entities or others. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the third-party providers (such as contract research organizations) who share this information with us, may contractually limit our ability to use and disclose the information

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

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

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

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

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

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

items or services resulting from a violation of the federal AKS constitutes a false or fraudulent claim for purposes of the civil FCA;

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

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

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

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

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

well-understood device types" as an alternative to the 510(k) clearance pathway and that such pre-market review pathway would allow manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process.

In May 2019, the FDA solicited public feedback on its plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates, including whether the FDA should publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

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

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

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

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

The misuse or off-label use of our products 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 are not permitted to market our products for off-label uses. For example, the EUA for our Talis One COVID-19 Test System, prior to its revocation, was for the *in vitro* qualitative detection of RNA from the SARS-CoV-2 virus in nasal swab specimens from individuals suspected of COVID-19 by a healthcare provider. We were not permitted to market our Talis One COVID-19 Test System for use in screening of asymptomatic populations, for use in pooling samples for testing, or for use with different specimen samples (other than nasal swab specimens). Such uses would

have been considered "off-label." We have trained and will train our marketing and direct sales force to not promote our products for uses outside of any FDA-authorized indications for use. We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment, he or she deems it appropriate. There may be increased risk of inaccurate results if physicians attempt to use our tests off-label. Furthermore, such off-label uses could harm our reputation in the marketplace among physicians and patients.

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

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

We have received grant funding from the U.S. federal government, including through a grant from the NIH, National Institute of Allergy and Infectious Diseases, a sub-award from the Biomedical Advanced Research and Development Authority Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) program, a sub-award from the NIH RADx program, and an NIH RADx grant. We anticipate that a portion of the funding for the development of our technologies will come from these agreements, which provide for grant funds ultimately from the government. In addition, activities covered under the awards may ultimately cost more than is covered by the grants and sub-awards or require a longer performance periods to complete than are remaining on our agreements; if we are unable to secure additional funding or allow for additional time for completion, we would have to incur additional costs to complete the activities or terminate the activities before completion. Moreover, the continuation of our agreements depends in large part on our ability to meet development milestones previously agreed to and on our compliance with certain operating procedures and protocols. These agreements may be suspended or terminated should we fail to achieve key milestones or fail to comply with the operating procedures and processes approved by the government and its audit agencies. There can be no assurance that we will be able to achieve these milestones or continue to comply with these procedures and protocols. For example, although we extended the time to perform certain milestones under the NIH Contract, we also had to reduce the potential milestone payments, and we were unable to satisfy all of the remaining milestones before the NIH Contract expired. In addition, changes in government budgets and agendas may result in a decreased and deprioritized emphasis on supporting the development of our programs. While the NIH has provided funding for 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 tre

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

We and our suppliers and manufacturers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations, and the manufacturer of our products, involve the production and use of hazardous and flammable materials and waste, including chemicals and biological and radioactive materials. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or

injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

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

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

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

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, the legislation enacted on December 22, 2017, informally known as the Tax Cuts and Jobs Act (TCJA) repealed the tax-based shared responsibility payment imposed by the ACA, on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." Additionally, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any additional healthcare reform measure of the Biden administration will impact the

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers and suppliers of 2% per fiscal year, starting in 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. Furthermore, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare

payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In addition, there has been numerous governmental reform activity in response to the COVID-19 pandemic. It is possible that additional governmental action is taken to address the COVID-19 pandemic, which may impact our business.

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

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

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

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

As of December 31, 2022, 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 2037, and \$202.2 million of U.S. federal NOLs that can be carried forward indefinitely under current law. As of December 31, 2022, we also had aggregate U.S. federal research and development (R&D) credits of approximately \$9.6 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 *ex parte* reexamination proceedings before the United States Patent and Trademark Office (USPTO), and corresponding post-grant proceedings in 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.

We recently settled a trademark suit as described under the heading "Legal Proceedings" above. In the future, we may also be subject to other 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 machines, manufactures, 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 inlicense 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 or business collaborators, 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, mischaracterize 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. Further, there can be no assurance that the pending patent application in question will result in an issued patent for enforcement. 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, interpreted narrowly or amended to no longer cover our technology or products.

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 affecting the interpretation of the relevant scope of the claims. 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 paten

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur negative publicity, reputational harm, 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 inlicenses 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, mischaracterizing 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. 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;
- there may be prior art of which we or the examiner may not be aware that may affect the patentability of our invention claims, or, if issued, affect the validity of enforceability of a patent claim;
- 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 one or more of our patents are invalid in whole or in part;
- 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 system 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. Criteria determining patentable subject matter and enforcement thereof may be impacted from future judicial and legislative changes or developments in the United States and abroad. Additionally, 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 from the filing date of the earliest U.S. or international (PCT) application, to which priority is claimed (excluding provisional applications), thus 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 system 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

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 products. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. For example, we have identified certain third-party patents that may be asserted against us with respect to our technology. These patents may expire prior to commercial launch of our products. We believe that the relevant claims of these third-party patents are likely invalid or unenforceable, and we may choose to challenge those patents, though the outcome of any challenge that we may initiate in the future is uncertain. We may also decide in the future to seek a license to those third-party patents, but we might not be able to do so on reasonable terms. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Further, we may not be aware of all third-party intellectual property rights 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 a jurisdiction's 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 limitation of scope or 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 test chambers, within Talis One test cartridges 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 to US and international patent laws on a jurisdiction by jurisdiction basis is highly uncertain and 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 and international jurisdictions 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 on September 16, 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 March 16, 2013, 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 (typically 18 months), 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, enforcing 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 tests and products and may export otherwise infringing tests 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 tests 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 licenses. Similarly, if our trade secrets are dis

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 technical and commercial information, including but not limited to confidential and unpatented formulas, processes, know-how, customer and supplier lists, methods of distribution, and advertising strategies, important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented information, 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 invention rights to us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes or that the assignment agreements that have been entered into are self-executing. Despite these efforts, any of these parties may breach the agreements, intentionally or inadvertently, and disclose our proprietary information, including our trade secrets, or claim ownership in intellectual property that we believe is owned by us. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the U.S. and certain foreign jurisdictions are less willing or unwilling to protect trade secrets.

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

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

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

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

We may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting

obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

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

Our trademarks or trade names may be challenged, opposed, infringed, circumvented, invalidated, cancelled, declared generic, determined to be not entitled to registration, or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. For example, our application to register the trademark TALIS in the United States was the subject of an opposition before the USPTO and related litigation which was resolved with a settlement agreement imposing certain restrictions on our use and registration of our trademarks. 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 trade names by our licensees may jeopardize our

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 \$113.0 million and \$192.0 million for the twelve months ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of \$478.0 million. We expect our losses to continue as we continue to devote a substantial portion of our resources to efforts to develop women's health and STI test tests, for the commercial launch of the Talis One system, and thereafter to increase the adoption of our products, improve these products, scale our manufacturing capabilities and research, develop and commercialize new products.

We have devoted a substantial portion of our resources to the development and commercialization of the Talis One system, a molecular diagnostic system, 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 will likely need to raise additional capital to fund our existing operations, further develop our diagnostic system, commercialize products, if and when approved, and expand our operations.

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

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

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

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

- our rate of progress in, and cost of research and development activities associated with, products in research and early development;
- our ability to secure and maintain domestic and international regulatory approval for our products;
- our ability to successfully launch our products;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our products;
- 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 system 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 find our planned operations, it could have a material adverse effect on our

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

## Risks related to ownership of our common stock

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

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

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

These and other factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In recent years, stock markets in general, and the market for life

science technology companies in particular (including companies in the genomics, biotechnology, diagnostics and related sectors), have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. From February 12, 2021 through March 15, 2023, the closing price of our common stock has ranged between \$0.45 and \$27.80 per share. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance.

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

If we are unable to regain compliance with the listing requirements of the Nasdaq Capital Market, our common stock may be delisted from the Nasdaq Capital Market which could have a material adverse effect on our financial condition and could make it more difficult for you to sell your shares.

Our common stock is listed on the Nasdaq Capital Market, and we are therefore subject to its continued listing requirements, including requirements with respect to the market value of publicly held shares, market value of listed shares, minimum bid price per share, and minimum stockholders' equity, among others, and requirements relating to board and committee independence. If we fail to satisfy one or more of the requirements, we may be delisted from the Nasdaq Global Market.

On July 27, 2022, we received a notice (Notice) from The Nasdaq Stock Market (Nasdaq), that we are not currently in compliance with the \$1.00 minimum bid price requirement for continued listing on the Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(a)(1) (Minimum Bid Price Requirement). The Notice indicated that, consistent with Nasdaq Listing Rule 5810(c)(3)(A), we had 180 days, or until January 23, 2023, to regain compliance with the Minimum Bid Price Requirement by having the minimum bid price of our common stock meet or exceed \$1.00 per share for at least ten consecutive business days. On January 24, 2023, we transferred the listing of our securities to the Nasdaq Capital Market (Capital Market) and received a second notice from Nasdaq granting us an additional 180-day period, or until July 24, 2023, to regain compliance with the Minimum Bid Price Requirement. We have committed to effectuate a reverse stock split by the end of the second compliance period, if necessary, to regain compliance with the Minimum Bid Price Requirement. Neither notice nor the transfer to the Capital Market have an immediate effect on the listing of our common stock, and our common stock will continue to trade on the Capital Market under the symbol "TLIS" at this time.

If we do not regain compliance with the Minimum Bid Price Requirement by the end of the second compliance period, our common stock will become subject to delisting. In the event that we receive notice that our common stock is being delisted, the Nasdaq listing rules permit us to appeal a delisting determination to a hearings panel.

There can be no assurance, however, that we will be able to regain compliance with the Minimum Bid Price Requirement, and even if we do, there can be no assurance that we will be able to maintain compliance with the continued listing requirements for the Capital Market or that our common stock will not be delisted in the future. In addition, we may be unable to meet other applicable listing requirements of the Capital Market, including maintaining minimum levels of stockholders' equity or market values of our common stock in which case, our common stock could be delisted notwithstanding our ability to demonstrate compliance with the Minimum Bid Price Requirement.

Delisting from the Capital Market may adversely affect our ability to raise additional financing through the public or private sale of equity securities, may significantly affect the ability of investors to trade our securities and may negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities.

We are involved in securities class action litigation and are at risk of additional similar litigation in the future that could divert management's attention, may be expensive and adversely affect our business and could subject us to significant liabilities.

Our share price is volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We are a party to securities class action litigation described under the heading "Legal Proceedings" below. The defense of these claims may be expensive and divert

our management's attention and resources and any unfavorable outcome could have a material adverse effect on our business and results of operations. Any adverse determination in these claims, or any amounts paid to settle these claims could require that we make significant payments. In addition, we may in the future be the target of other securities class actions or similar litigation.

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

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

There were 8,402,626 shares of common stock issuable upon the exercise of options outstanding and 326,364 shares of common stock issuable upon vesting of restricted stock units as of December 31, 2022. We registered all of the shares of common stock issuable upon exercise of such outstanding options or other equity incentives we may grant in the future, for public resale under the Securities Act of 1933, as amended (Securities Act). The shares of common stock will become eligible for sale in the public market to the extent such options are exercised, subject to compliance with applicable securities laws.

Further, based on shares outstanding as of December 31, 2022, holders of approximately 37,489,210 shares, or 66% of our capital stock have certain registration rights with respect to the resale of such shares. We filed a registration statement on Form S-3 registering the resale of all of the 37,489,210 shares held by such holders, which registration statement was declared effective on May 24, 2022. We are required to maintain the effectiveness of this registration statement and the holders of such securities are entitled to one underwritten offering per calendar year, in each case, subject to certain conditions, limitations and exceptions.

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

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

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

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

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

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

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

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

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

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

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

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

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

We have broad discretion in the use of our cash and cash equivalents and may not use them effectively.

We have broad discretion in the application and use of our cash and cash equivalents, including the net proceeds from our initial public offering, and you will not have the opportunity as part of your investment decision to assess whether our cash and cash equivalents were used or are being used effectively. Because of the number and variability of factors that determine the application and use of our cash and cash equivalents, our ultimate use may vary or has varied substantially from our original intended uses. For example, due to significant delays in obtaining an EUA for the Talis One COVID-19 Test System and to produce the Talis One system at scale, which in turn delayed the commercialization of the Talis One system, we have used a larger proportion of the net proceeds from our initial public offering for research and development expenses and a smaller proportion for commercial activities than our original estimates in our prospectus filed with the SEC on February 12, 2021. Investors will need to rely upon the judgment of our management with respect to the use of our cash and cash equivalents. Our failure to apply our cash and cash equivalents effectively could compromise our ability to pursue our business strategy and we might not be able to yield a significant return, if any, and our business, financial condition, results of operations and prospects could be harmed, and the market price of our common stock could decline.

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

As of March 15, 2023, our executive officers, directors and five percent or greater stockholders and their respective affiliates, beneficially own, in the aggregate, approximately 80% of our outstanding voting stock. Further, 66% of our outstanding voting stock is owned by entities affiliated with Baker Bros. Advisors LP (Baker Bros.). In addition, the holders of our Series 1 convertible preferred stock, which, subject to certain limitations, is a voting common stock equivalent, may elect to convert shares of Series 1 convertible preferred stock into shares of Series 2 convertible preferred stock, which is a non-voting common stock equivalent. These shares of Series 2 convertible preferred stock are then convertible into shares of our common stock, subject to certain beneficial ownership limitations.

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

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

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

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

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

and restated certificate of incorporation states that these choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Securities Act, the Securities Exchange Act of 1934 (Exchange Act) or any other claim for which the federal courts have exclusive jurisdiction. This amended and restated certificate of incorporation will further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

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

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

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

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

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

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this

provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

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

### Item 1B. Unresolved Staff Comments.

None.

### Item 2. Properties.

Our corporate headquarters are currently located in Redwood City, California (Redwood City Office), where we occupy approximately 38,000 square feet of office and laboratory space under a lease that ends in December 2032. We also occupy approximately 26,400 square feet of laboratory space in Chicago, Illinois, under a lease that ends July 2032. In March 2023, we entered into a lease termination agreement for the Redwood City Office that requires that we vacate the facility by May 12, 2023. In March 2023, we entered into a sublease agreement for 13,165 square feet of office and laboratory space in Redwood City, California, in the same life science campus as our Redwood City Office. The sublease term commences on May 1, 2023 and ends May 31, 2030. The lease termination agreement and sublease agreement are contingent upon the landlord for the current Redwood City Office entering into a new lease agreement for the space with a third-party tenant. We believe that the new Redwood City facility and Chicago facility meet our current needs, and we believe we can find suitable additional space in the future on commercially reasonable terms.

### Item 3. Legal Proceedings.

From time to time, we have been and 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.

On or about January 7, 2022, John Modrak filed a class action in the United States District Court for the Northern District of California against us, certain of our officers and directors, and J.P. Morgan Securities LLC, BofA Securities, Inc., Piper Sandler & Co., and BTIG, LLC, underwriters of our February 2021 initial public offering ("IPO"), captioned as Modrak v. Talis Biomedical Corp., et al., No. 3:22-cv-00105, purportedly on behalf of shareholders who purchased shares of our stock that were registered in our IPO. On February 18, 2022, Karen Mitcham filed a substantively identical lawsuit in the same court captioned as Mitcham v. Talis Biomedical Corp., et al., No. 3:22-cv-01039-JD, against us, and the same officers and directors as the Modrak lawsuit. The complaints alleged that our registration statement and prospectus issued in connection with our IPO was false and misleading and omitted to state material adverse facts related to the comparator test used in our primary study, our EUA application for our Talis One COVID-19 Test System, and associated regulatory approval and commercialization. The complaints sought unspecified damages under Section 11 and Section 15 of the Securities Act of 1933 ("Securities Act"), and reasonable attorneys' and expert witnesses' fees and other costs.

These two cases have been consolidated and co-lead plaintiffs have been appointed as mandated by the applicable federal securities laws.

On December 9, 2022, the Court granted our motion to dismiss and plaintiffs leave to amend their consolidated complaint. On January 13, 2023, the plaintiffs filed an amended complaint, asserting claims for violation of Section 11 of the Securities Act against all defendants and Section 15 of the Securities Act against the individual defendants and seeking unspecified damages, reasonable attorneys' fees and other costs. The consolidated complaint does not assert claims against the above-referenced underwriters. We have moved to dismiss these claims and that motion is pending. We dispute these claims and intend to defend these matters vigorously. These claims remain at an early stage, and the extent and outcome of these claims cannot be predicted at this time.

# Item 4. Mine Safety Disclosures.

Not applicable.

### **PART II**

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

### Market information

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

On July 27, 2022, the Company received a notice (the "Notice") from the Nasdaq Stock Market ("Nasdaq") that the Company is not in compliance with Nasdaq Listing Rule 5450(a)(1), as the minimum bid price of the Company's common stock had been below \$1.00 per share for thirty-one (31) consecutive business days as of the date of the Notice.

On January 24, 2023, the Company transferred the listing of its securities to the Nasdaq Capital Market (the "Capital Market") and received notice from Nasdaq on the same date indicating that, while the Company has not regained compliance with the Bid Price Requirement, Nasdaq has determined that the Company is eligible for an additional 180-day period, and has extended the Company until July 24, 2023 to regain compliance. We have committed to effectuate a reverse stock split by the end of the second compliance period, if necessary, to regain compliance with the Minimum Bid Price Requirement. The Notice has no other immediate effect on the listing of the Company's common stock, which will trade on the Capital Market under the symbol "TLIS."

### Holders

As of March 15, 2023, we had approximately 66 holders of record of our common stock and one holder of record of our Series 1 convertible preferred stock.

### Dividend policy

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

Recent sales of unregistered securities

None.

Use of Proceeds from our Initial Public Offering of Common Stock

In February 2021, our Registration Statement on Form S-1 (File No: 333-252360) was declared effective by the SEC. We received approximately \$233 million in net proceeds from our initial public offering. Through December 31, 2022, we have used all of the net proceeds from the offering primarily to fund our ongoing research and development activities, manufacturing scale-up project and pre-launch inventory.

Due to significant delays in obtaining the EUA for the Talis One COVID-19 Test System and to produce the Talis One system at scale, which in turn delayed the commercialization of the Talis One system, we have used a larger proportion of the net proceeds from our initial public offering for research and development expenses and a smaller proportion for commercial activities than our original estimates in our prospectus filed with the SEC on February 12, 2021 pursuant to Rule 424(b)(4). Other than the foregoing, there have been no other no material changes in the planned use of proceeds from our initial public offering from that described in the related prospectus filed February 12, 2021 with the SEC pursuant to Rule 424(b)(4) under the Securities Act.

# Item 6. [Reserved]

# Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read together with our audited financial statements and related notes included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the "Risk Factors" section of this Annual Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

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

### Overview

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 requires 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 system that could be deployed to a variety of testing settings in the United States and around the world to diagnose infectious disease in the moment of need, at the point-of-care. The Talis One system comprises a compact instrument, single use test cartridges and software, supporting a central cloud database, which work together. The system is designed to provide central laboratory levels of accuracy and be operated by an untrained user.

Recent surveys of women's and sexual health providers that we have conducted confirm the continued and strong interest in adoption of point-of-care systems, such as the Talis One system. We believe that the Talis One system is well positioned to meet the growing demand in both traditional and non-traditional care settings. Although there are several commercially available point-of-care systems, we believe that few, if any, sufficiently meet the needs of healthcare providers to drive broad adoption of, and transition to, point-of-care testing from central lab testing for a broad range of infectious diseases. 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 Talis One tests to address some of the most critical infectious diseases in women's and sexual health, initially with a panel for Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis (CT/NG/TV), as well as a respiratory panel consisting of tests for influenza A, influenza B and COVID-19 (Respiratory Panel). In order to bring the Talis One system to market as soon as possible, we are leveraging progress made to-date to direct our efforts on the pursuit of 510(k) clearances under the federal Food, Drug and Cosmetic Act (FDCA) for our highly differentiated platform and development of multiple test panels. We plan to conduct clinical trials to support clearance of the Respiratory Panel and CT/NG/TV test, as well as other sexually transmitted infections (STIs), such as herpes simplex virus (HSV), vaginal infections including bacterial vaginosis (Vaginal Infections Panel), and urinary tract infections (UTI).

Our products will require marketing authorization from the U.S. Food and Drug Administration (FDA) prior to commercialization. On November 5, 2021, we received an EUA from the FDA for the emergency use of the Talis One system for our stand-alone COVID-19 test, and on May 12, 2022, we received the CE Mark authorization for the stand-alone Talis One COVID-19 test under the European In-Vitro Diagnostic Devices Directive (IVDD). Due to the COVID-19 global pandemic, we obtained marketing authorization for our stand-alone Talis One COVID-19

test under an EUA. After assessing current market dynamics and the financial environment, we suspended commercial investment in the stand-alone Talis One COVID-19 test, as we believe the investments required to commercialize in the United States COVID-19 market outweigh the potential economic return. On August 23, 2022, in response to our withdrawal request filed on August 12, 2022, the FDA revoked our EUA for the stand-alone Talis One COVID-19 test, as we no longer plan to pursue commercialization of the stand-alone Talis One COVID-19 test in the United States. For our women's health and STI tests, we plan to pursue 510(k) clearance or other forms of marketing authorization under the FDA's standard medical device authorities. In order to bring the Talis One system to market as soon as possible, we plan to submit the Talis One instrument for pre-market notification under 510(k) of the Federal Food, Drug, and Cosmetic Act (FDCA) using our respiratory test, followed by submissions to the FDA for 510(k) clearance for a test panel for CT/NG/TV.

We have invested in automated cartridge manufacturing lines which are currently located at our contract manufacturers' sites and are operated by our contract manufacturing partners. By the end of 2022, we had made improvements in our manufacturing process and demonstrated with our stand-alone COVID-19 test that these high-speed assembly lines can consistently produce cartridges that meet industry standards. In addition, we have resumed investigational use only (IUO) system evaluations of the Talis One system using our COVID-19 test, the results of which have confirmed acceptable cartridge performance when used by third parties, accuracy and validity rates consistent with our internal quality control testing, and positive feedback on the user experience. We will continue to (i) focus on flexible manufacturing to support our research and development functions, clinical trials and to gain internal expertise of our manufacturing process and capabilities and (ii) refine and improve high throughput manufacturing lines to ensure we maintain the ability to manufacture at scale with acceptable cost of goods sold for commercialization.

In addition to the automated cartridge manufacturing lines, we have also established internal manufacturing lines that we expect will accelerate product development and support the product lifecycle. These lines allow us to (i) make process improvements and cost reductions in-house before transferring production back to our contract manufacturing partners, (ii) innovate more quickly to support internal test development and (iii) support cartridge inventory levels pre-commercialization. In order to drive further efficiency and cost reduction in the manufacturing process, we have begun restructuring our relationships with our contract manufacturing partners.

We outsource a substantial portion of our manufacturing. Design work, prototyping and pilot manufacturing are performed in-house before outsourcing to third-party contract manufacturers. Our outsourced production strategy is intended to drive rapid scalability. Certain of our suppliers of components and materials are single source suppliers. During 2022, we had two suppliers provide more than 10% of our materials and equipment purchases. To support a 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.

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, providing general and administrative support for these operations, and providing selling support as the need has arisen. We have principally financed our operations through the issuance and sale of shares of our convertible preferred stock to outside investors in private equity financings as well as the issuance of convertible promissory notes and receipts from government grants. Prior to our initial public offering, we received \$351.5 million from investors in our preferred stock financings and the sale of convertible promissory notes that converted in such financings. Additionally, on February 17, 2021, we raised \$232.5 million (after deducting underwriting discounts, commissions and offering expenses) through an initial public offering.

We have incurred recurring losses since our inception, including net losses of \$113.0 million and \$192.0 million for the twelve months ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of \$478.0 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 system and tests for multiple diseases;
- initiate clinical trials for, or additional pre-clinical development of, our Talis One system;
- further develop and refine the manufacturing processes for our Talis One system and potentially the design of our Talis One system;

- change or add manufacturers or suppliers of materials used for our Talis One system;
- seek marketing authorizations;
- seek to identify and validate diagnostic tests for additional disease states;
- obtain, maintain, protect and enforce our intellectual property portfolio;
- re-establish and deploy a sales force;
- seek to attract and retain new and existing skilled personnel;
- create additional infrastructure to support our operations as a public company and incur increased legal, accounting, investor relations and other expenses; and
- experience delays or encounter issues with any of the above.

As of December 31, 2022, we had unrestricted cash and cash equivalents of \$130.2 million. Based on our planned operations, we expect that our unrestricted cash and cash equivalents of \$130.2 million as of December 31, 2022 will be sufficient to fund our operations through at least the next 12 months from the date our financial statements are issued. Given our recent reductions in force and other expense reductions planned this year, we believe, though there can be no assurance, that we can fund our operations into 2025. This target could change as we gain more clarity on the timing and trajectory of the Talis One system launch.

In addition, if we obtain marketing authorization for our system, 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. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of development, manufacturing and commercialization activities. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operating activities through one or a combination of grant revenue, equity or debt financings, or collaborations or partnerships with other companies. 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.

In March and August 2022, in connection with our refocus on the women's health and STI markets, we implemented two separate reductions in force, designed to align our remaining resources to focus on (i) developing women's health and STI tests on the Talis One system, (ii) our internal manufacturing expertise to support our strategic plans and (iii) reducing costs and preserving cash to extend our runway to commercialize our women's health and STI tests. The 2022 reductions in force amounted to approximately 40% of our headcount. We incurred \$2.5 million of expenses related to these reductions in force during the twelve months ended December 31, 2022, substantially all of which consisted of one-time charges related to the staff reduction, including cash expenditures and other costs. Going forward, we estimate annualized savings of \$12.0 million in compensation expenses related to the 2022 reductions in force.

### COVID-19 pandemic

The global outbreak of COVID-19 across many countries around the globe, including the United States, has significantly slowed global economic activity, caused significant volatility in financial markets, supply chain disruptions and increased costs associated with rising inflation rates. Although the U.S. Food and Drug Administration has approved therapies and vaccines for distribution, there remain uncertainties as to the overall efficacy of the vaccines, especially as new strains of the coronavirus continue to emerge, and the level of resistance these new strains have to the existing vaccines, if any.

Certain states and cities have taken and may re-institute measures to prevent or slow the spread of COVID-19, and its variants including by instituting quarantines, vaccination mandates, and testing requirements restrictions on travel, "stay-at-home" rules, restrictions on types of business that may continue to operate and/or restrictions on the types of construction projects that may continue. While vaccine availability and uptake has increased, the longer-term macro-economic effects on global supply chains, inflation, labor shortages and wage increases continue to impact many industries.

The COVID-19 pandemic presents material uncertainty and risk with respect to our financial condition and development efforts, 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, 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.

# Components of our results of operations

### Revenue

To date, we have not generated any revenue from sales of our Talis One system. We expect to generate revenue in the future from product sales of our Talis One instruments and single use cartridges, following regulatory approval, but there can be no assurance that we will be successful in our development and commercialization efforts. 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 system 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 system support to the extent customers require further system and workflow optimization following system implementation. When we place a system under a reagent rental agreement, we plan to install equipment in the customer's facility without a fee and the customer agrees to purchase our cartridges at a stated price over the term of the reagent rental agreement. Some of these agreements could include minimum purchase commitments. Under a reagent rental model, we plan to retain title to the equipment and such title is transferred to the customer at the conclusion of the initial arrangement. The cost of the instrument under the agreement is expected to be recovered in the fees charged for consumables, to the extent sold, over the term of the agreement.

We cannot predict when, or to what extent we will generate revenue from the commercialization and sale of our system. Although we obtained an EUA for our stand-alone Talis One COVID-19 test and the CE Mark authorization under the IVDD, the EUA was revoked in August 2022 by the FDA following our withdrawal request. We have not generated any revenue from the sales of such system, and we do not intend to invest in commercialization of the stand-alone Talis One COVID-19 test due to current commercial market dynamics for molecular COVID-19 tests in the United States. We rely, and expect to continue to rely, on third parties for the manufacture of the Talis One system and our tests, as well as for commercial supply. Our contract manufacturers may not have the ability to produce quality product at scale to meet commercial demand which could delay commercialization efforts. Further, we may not succeed in obtaining regulatory approval for our women's health and STI products, or any other future tests. Growth and predictability of recurring revenue is impacted by the timing of commercialization and expansion of our products. It is our goal and expectation that recurring revenue will grow over time, both in absolute dollars and as a percentage of our revenue.

# Product revenue, net

In January 2022, we began distributing the Antigen Tests. We currently derive all of our product revenue from the sales of the Antigen Tests in accordance with the provisions of Accounting Standards Codifications (ASC), Topic

606, *Revenue from Contracts with Customers*. Our product revenue is recognized upon the transfer of control of our test kits to the customer. This program has concluded at the end of 2022.

#### Grant revenue

For the twelve months ended December 31, 2022 and 2021, our revenue from government grants includes a May 2018 grant from the NIH to support our advancement of a Diagnostics via Rapid Enrichment, Identification, and Phenotypic Antibiotic Susceptibility Testing of Pathogens from Blood project (NIH grant), a July 2020 subaward grant from the University of Massachusetts Medical School for Phase 1 of the NIH's Rapid Acceleration of Diagnostics - Advanced Technology Platforms (RADx) initiative and a contract from the NIH directly for Phase 2 of the RADx initiative (NIH Contract).

The NIH Contract for the RADx initiative expired on January 30, 2022. The Company successfully met milestone requirements and recognized \$0.7 million of grant revenue during the twelve months ended December 31, 2022. There is no additional funding available under the NIH Contract.

Under the NIH grant, we recognized \$0.5 million during the twelve months ended December 31, 2022. There is the possibility of an additional \$1.2 million in payments through April 2023.

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

# **Operating expenses**

### Cost of product sold

We began to recognize costs of product sold in January 2022 when we began selling the Antigen Tests. Costs of product sold include material costs, direct labor, provisions for inventory write-downs and shipping and handling costs incurred.

### Research and development expenses

Research and development expenses consist primarily of internal and external costs incurred for our research activities, the development of our system, 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 system;
- 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; and
- expenses related to regulatory affairs.

Until future commercialization is considered probable and the future economic benefit is expected to be realized, we do not capitalize pre-launch inventory costs and costs of property and equipment 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 pre-launch inventory costs to research and development expenses, or if used in marketing evaluations, record such cost to selling, general and administrative expense. We record property and equipment costs to research and development expenses when the asset does not have an alternative future use. 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.

Research and development activities are central to our business model. We previously focused our research and development efforts on the stand-alone Talis One COVID-19 test but have refocused on the development of tests for women's and sexual health infections, including a panel for STIs and other infections, such as HSV, the Vaginal Infection Panel, and UTI. We expect to continue to incur significant research and development expenses in the future as we continue the research and development of our system and tests for other infectious diseases and disease states, initiate clinical trials for future tests, further develop and refine the manufacturing processes for our system, and continue commercialization efforts. There are numerous factors associated with the successful commercialization of any test we may develop in the future for other diseases or disease states, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development.

### Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation and bonus, for personnel in our executive, finance, sales and product management, commercial operations, human resources and legal functions. Selling, general and administrative expenses also include professional fees for legal, auditing, tax and consulting services, insurance fees, information technology, and facility-related expenses, which include direct depreciation expenses and allocated expenses for rent and maintenance of facilities and other operating expenses. Selling, general and administrative expenses include impairment expense for the excess of the carrying value of our right-of-use assets over their estimated fair value. Estimated fair value is determined based upon an estimate of discounted future cash flows or other appropriate measures of estimated fair value.

### Other income (expense)

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

# **Results of operations**

Comparison for the twelve months ended December 31, 2022 and 2021

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

	Twelve Months Ended December 31,					
(in thousands)		2022	2021			Change
Revenue						
Grant revenue	\$	1,160	\$	8,193	\$	(7,033)
Product revenue, net		3,652		_		3,652
Total revenue, net	\$	4,812	\$	8,193	\$	(3,381)
Operating expenses:						
Cost of goods sold		8,391		_		8,391
Research and development		70,831		157,591		(86,760)
Selling, general and administrative		40,729		42,418		(1,689)
Total operating expenses	\$	119,951	\$	200,009	\$	(80,058)
Loss from operations		(115,139)		(191,816)		76,677
Other (expense) income, net		2,127		(220)		2,347
Net loss and comprehensive loss	\$	(113,012)	\$	(192,036)	\$	79,024

# Grant revenue

During the twelve months ended December 31, 2022, \$0.7 million and \$0.5 million of revenue was recognized related the RADx initiative and NIH grant, respectively. During the twelve months ended December 31, 2021, \$7.7 million and \$0.5 million of revenue was recognized related the RADx initiative and NIH grant, respectively.

### Product revenue, net, cost of product sold

We began to generate sales during January 2022 after we entered into a distribution agreement to sell the Antigen Tests, which has concluded by the end of 2022. The increase in product revenue and cost of product sold is due to increased volume in units sold whereas we did not conduct product revenue generating activities during the same period in 2021. During the year ended December 31, 2022, the Company established a reserve against \$4.4 million of inventory in excess of forecasted demand recorded within cost of product sold.

### Research and development expenses

Research and development expenses for the twelve months ended December 31, 2022 and 2021 were \$70.8 million and \$157.6 million, respectively, a decrease of \$86.8 million. Substantially all of our research and development expenses incurred were related to the development of and manufacturing scale-up for the Talis One system including tests to detect COVID-19 as well as other respiratory, women's health and sexual health tests. The decrease of \$86.8 million was primarily driven by expense declines of \$52.8 million for the automation of consumable manufacturing, \$24.8 million in instrument component costs, and \$12.0 million in pre-EUA inventory as we completed our manufacturing scale-up investments. Further decreases include \$3.8 million for personnel related expenses and outside services as a result of our March 2022 and August 2022 spending reduction programs. These decreases were primarily offset by an increase of \$7.5 million in depreciation expense, primarily due to acceleration of the useful life of certain lab equipment as the Company made the decision to no longer pursue the commercialization of the stand-alone Talis One COVID-19 test in the United States. In the near term, R&D spend will be focused on activities necessary for 510(k) submission and clearance as well as clinical trials needed to receive FDA clearance.

# Selling, general and administrative expenses

Selling, general and administrative expenses were \$40.7 million for twelve months ended December 31, 2022, compared to \$42.4 million for the twelve months ended December 31, 2021, a decrease of \$1.7 million. The decrease was primarily due to decreases of \$6.7 million related to personnel related expenses including salaries and benefits and stock-based compensation expenses as a result of our March 2022 and August 2022 reductions in force. This decrease was offset by impairment expense of \$3.6 million related to our long-lived assets based on fair value estimates using a discounted cash flows approach on forecasted future cash flows and an increase of \$1.4 million in insurance expenses.

### Liquidity and capital resources

Sources of liquidity

We have funded our operations primarily through public equity offerings, private placements of equity securities and through government grants.

On February 17, 2021, we completed our initial public offering (IPO), pursuant to which we issued and sold 15,870,000 shares of our common stock, at a public offering price of \$16.00 per share. The net proceeds from the IPO were \$232.5 million after deducting underwriting discounts and commissions and other offering expenses.

As of December 31, 2022, we had unrestricted cash and cash equivalents of \$130.2 million. We believe our unrestricted cash and cash equivalents balance as of December 31, 2022 is sufficient to fund our operations for at least the next 12 months from the date our financial statements are issued. Given our recent reductions in force and other expense reductions planned this year, we believe, although there can be no assurance, that we can fund our operations into 2025. This target could change as we gain more clarity on the timing and trajectory of the Talis One system launch. In addition, if we obtain marketing authorization for our system, 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. 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 tests and development and manufacturing activities. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operating activities through one or a combination of nondilutive corporate development and licensing opportunities, grant revenue, equity or debt financings, or collaborations or partnerships with other companies. Adequate funding may not be available to us on acceptable terms, or at all.

In March and August 2022, in connection with our refocus on the women's health and STI markets, we implemented two separate reductions in force, designed to align our remaining resources to focus on (i) developing women's health and STI tests on the Talis One system, (ii) our internal manufacturing expertise to support our strategic plans and (iii) reducing costs and preserving cash to extend our runway to commercialize our women's health and STI tests. The 2022 reductions in force amounted to approximately 40% of our headcount. We incurred \$2.5 million of expenses related to these reductions in force during the twelve months ended December 31, 2022, substantially all of which consisted of one-time charges related to the staff reduction, including cash expenditures and other costs. Going forward, we estimate annualized savings of \$12.0 million in compensation expenses related to the 2022 reductions in force.

# Nasdaq Deficiency Notice

On July 27, 2022, we received a notice (Notice) from The Nasdaq Stock Market (Nasdaq) that we were not in compliance with Nasdaq Listing Rule 5450(a)(1), as the minimum bid price of our common stock had been below \$1.00 per share for 31 consecutive business days as of the date of the Notice.

On January 24, 2023, the Company transferred the listing of its securities to the Nasdaq Capital Market (Capital Market) and received notice from Nasdaq indicating that, while the Company has not regained compliance with the Bid Price Requirement, Nasdaq has determined that the Company is eligible for an additional 180-day period, or until July 24, 2023, to regain compliance. We have committed to effectuate a reverse stock split by the end of the second compliance period, if necessary, to regain compliance with the Minimum Bid Price Requirement. The Notice has no other immediate effect on the listing of the Company's common stock, which will trade on the Capital Market under the symbol "TLIS."

If, at any time during this second 180-day compliance period, the closing bid price of the common stock is at least \$1 per share for a minimum of 10 consecutive business days, Nasdaq will provide the Company with written confirmation of compliance. If compliance cannot be demonstrated by July 24, 2023, Nasdaq will provide the Company with written notification that the common stock will be delisted. At that time, the Company may appeal Nasdaq's determination to a Hearings Panel.

We intend to actively monitor the bid price of our common stock and will consider available options to regain compliance with the Nasdaq listing requirements, including a reverse stock split.

### Future funding requirements

We do not have any commercial-scale manufacturing facilities and expect to continue to rely on third parties to manufacture the Talis One system and related test cartridges. We have entered into, and expect to enter into additional, agreements with contract manufacturers to support our manufacturing scale-up. We have engaged a third-party logistics provider to manage the movement of materials between suppliers and contract manufacturers and for finished goods warehousing.

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 the Talis One system, if ever, we expect to finance our future cash needs through one or a combination of nondilutive corporate development and licensing opportunities, grant revenue, equity or debt financings, or collaborations or partnerships with other companies.

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, accrued expenses and operating lease costs. We currently have no other ongoing material financing commitments, such as lines of credit or guarantees. We expect to incur significant research and development and commercialization expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of any future collaborators. We expect to incur additional costs associated with operating as a public company. Accordingly, we may choose to obtain additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Since our inception, we have incurred significant losses and negative cash flows from operations. We have an accumulated deficit of \$478.0 million through December 31, 2022. We expect to incur substantial additional losses

in the future as we conduct and expand our research and development, manufacturing and commercialization activities. Based on our planned operations, we expect that our unrestricted cash and cash equivalents of \$130.2 million as of December 31, 2022, will be sufficient to fund our operations for at least 12 months after our financial statements are issued. Given our recent reductions in force and other expense reductions planned this year, we expect to fund operations into 2025. This target could change as we gain more clarity on the timing and trajectory of the Talis One system launch. 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 future regulatory approval for our products;
- the number and development requirements of tests for other diseases or disease states that we may pursue;
- our ability to manufacture the Talis One system at scale to meet eventual market demand, if any;
- the amount of capital, and related timing of payments, required to build sufficient inventory of our Talis One system and test cartridges in advance of and during commercial launch;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for the Talis One system;
- limitations of, or interruptions in, the quality or quantity of materials from our third-party suppliers;
- our ability to implement an effective manufacturing, marketing and commercialization operation;
- the scope, progress, results and costs of our ongoing and planned operations;
- the costs associated with expanding our operations;
- 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 any future commercial launch of the Talis One system;
- the revenue, if any, received from commercial sales of our products, if and when approved, including additional working capital requirements if we pursue a reagent rental model for our Talis One instrument, or from commercial sales of third-party products, including the Antigen Tests;
- the costs to defend any shareholder suits or other third-party litigation;
- our ability to establish strategic collaborations; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims.

# Cash flows

The following table summarizes our cash flows for each of the periods presented (in thousands):

	Year Ended December 31,				
	2022			2021	
		(in thou	sands)		
Net cash used in operating activities	\$	(100,136)	\$	(171,384)	
Net cash used in investing activities		(1,615)		(2,866)	
Net cash provided by financing activities		406		234,429	
Net (decrease) increase in cash, cash equivalents and restricted cash	\$	(101,345)	\$	60,179	

# Operating activities

During the year ended December 31, 2022, net cash used in operating activities was \$100.1 million, resulting from our net loss of \$113.0 million and \$8.9 million decrease in accounts payable, accrued expenses and other liabilities driven by the completion of our manufacturing scale-up project. These outflows were offset by non-cash items of \$20.6 million, including \$8.8 million of depreciation expense primarily driven by the acceleration of the useful life of certain lab equipment as a result of manufacturing changes brought about by the decision to changes in business strategy, \$5.4 million of stock based compensation expense, \$3.6 million impairment of long-lived assets and \$2.8 million of non-cash lease expense.

During the year ended December 31, 2021, net cash used in operating activities was \$171.4 million, resulting from our net loss of \$192.0 million partially offset by non-cash items of \$11.8 million including stock-based compensation of \$9.2 million as we increased headcount to support our commercialization. Our net loss was further offset by a decrease of \$12.0 million in prepaid research and development driven by the completion of our manufacturing scale up project as of December 31, 2021 and an increase of \$2.2 million in accrued expenses and other liabilities. These cash inflows were offset by an increase in other long term assets and liabilities of \$5.6 million.

## Investing activities

During the years ended December 31, 2022 and 2021, we used \$1.6 million and \$2.9 million of cash for investing activities related to purchases of property and equipment.

### Financing activities

During the year ended December 31, 2022, net cash provided by financing activities was \$0.4 million, consisting of \$0.3 million in proceeds from common stock issued pursuant to the Company's employee stock purchase plan and \$0.1 million in proceeds from stock option exercises.

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

### **Contractual obligations**

## Leases

See Note 6. Commitments and contingencies, to our audited financial statements included in Item 8 of this Annual Report for a summary of our operating lease commitments as of December 31, 2022.

In March 2023, we entered into a lease termination agreement with the landlord of our Redwood City, CA facility. Also in March 2023, we entered into a sublease agreement with an initial term of 7 years for office space in Redwood City, CA, with expected occupancy to commence in the second quarter of 2023.

### Purchase commitments

Currently, we have no material long-term purchase commitments. We have entered into contracts in the normal course of business with certain contract manufacturing organizations and other third parties for manufacturing services.

# Critical accounting policies and estimates

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

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

### Inventory

We value our inventory at the lower of cost or net realizable value and determines the cost of inventory using the first-in, first-out method. Lower of cost or net realizable value is evaluated by considering obsolescence, excessive levels of inventory, deterioration and other factors.

In order to assess the ultimate realization of inventories, we are required to make judgments as to future demand requirements compared to current or committed inventory levels. We periodically review our inventories for shelf life, excess or obsolescence and writes-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual net realizable value is less than the carrying value, or if it is determined that inventory utilization will further diminish based on estimates of demand, additional inventory write-downs may be required. Inventory write-offs are recorded in cost of product sold and a new lower-cost basis for the inventory is established. Excess and obsolete inventory is primarily based on estimated forecasted sales, usage levels, and expiration dates.

### Research and development expenses

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

All materials, equipment, and external consulting costs associated with developing aspects of the production line that do not have an alternative future use are expensed as research and development costs until regulatory approval or clearance is obtained, and commercialization is probable. Materials, equipment, and external consulting costs associated with developing aspects of the production line that are deemed to have an alternative future use are capitalized as property and equipment, assessed for impairment and depreciated over their related useful lives. These research and development costs, including expenditures for property and equipment with no alternative future use, are classified as operating cash outflows within our statements of cash flows.

# Stock-based compensation

We measure stock-based compensation expense for stock options and restricted stock units (RSUs) granted to our employees and directors on the date of grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award, on a

straight-line basis. We also recognize stock-based compensation expense associated with our employee stock purchase plan (ESPP) based on the grant date fair value required under authoritative guidance. Forfeitures are recorded as they occur.

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

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

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

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

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

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

- contemporaneous independent valuations performed at periodic intervals by an independent third-party valuation firm;
- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;

- · the progress of our research and development programs, including the status and results of preclinical studies for our system;
- 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.

#### Leases

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

### Recoverability of long-lived assets

We review the carrying amount of our long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of an asset or an asset group may not be fully recoverable. If indicators of impairment exist, an impairment loss would be recognized when the estimated undiscounted future cash flows expected to result from the use of the asset or asset group and its eventual disposition are less than its carrying amount. The impairment charge is determined based upon the excess of the carrying value of the asset over its estimated fair value, reducing the carrying value of the related asset to no less than its fair value. Estimated fair value is determined based upon an estimate of discounted future cash flows or other appropriate measures of estimated fair value. Estimates in our fair value calculation may include estimates made for discount rate, rental rate and escalations or downtime periods associated with our right-of-use assets as well as others. A 5% change in the estimated rental rate, escalations or downtime periods would not materially impact the fair value of the right-of-use assets. In addition, a 200 basis point change in the selected discount rate would not materially impact the fair value of the right-of-use assets. For purposes of recognition of impairment for long-lived assets, we group assets and liabilities at the lowest level for which cash flows are separately identifiable.

# Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our audited financial statements included within Item 8 of this Annual Report.

### Recently adopted accounting standards

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments — Credit Losses* 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. We early adopted ASU 2016-13 on January 1, 2022 with no impact on our accumulated deficit, current financial position, results of operations and comprehensive loss or cash flows.

In November 2021, the FASB issued ASU 2021-10, *Government Assistance – Disclosures by Business Entities about Government Assistance* to require business entities to disclose information about certain government assistance they receive to provide comparable and transparent information to investors and other financial statement users to enable them to understand an entity's financial results and prospects of future cash flows. The Company

adopted ASU 2016-13 on January 1, 2022 with no material impact on its accumulated deficit, current financial position, results of operations and comprehensive loss, cash flows or disclosures.

### **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.

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, which is December 31, 2026, 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 \$1.24 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**

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### 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, 2022 and 2021, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

# **Basis for Opinion**

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

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

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

/s/ Ernst & Young LLP

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

Chicago, Illinois March 22, 2023

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

	December 31,			
		2022		2021
Assets				
Current assets:				
Cash and cash equivalents	\$	130,191	\$	232,545
Accounts receivable, net		308		183
Prepaid expenses and other current assets		2,783		3,387
Total current assets		133,282		236,115
Property and equipment, net		3,312		10,528
Operating lease right-of-use-assets		30,920		12,907
Other long-term assets		1,776		6,278
Total assets	\$	169,290	\$	265,828
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	\$	3,768	\$	5,122
Accrued compensation		4,212		6,369
Accrued liabilities		989		6,383
Operating lease liabilities, current portion		3,703		1,232
Total current liabilities		12,672		19,106
Operating lease liabilities, long-term portion		29,879		12,745
Total liabilities		42,551		31,851
Commitments and contingencies (Note 6)				
Stockholders' equity:				
Series 1 convertible preferred stock, \$0.0001 par value—60,000,000 shares authorized as of December 31, 2022 and 2021; 29,863,674 shares issued and outstanding as of December 31, 2022 and 2021, respectively; aggregate liquidation preference of \$3 as of December 31, 2022 and 2021		3		3
Common stock, \$0.0001 par value; 200,000,000 shares authorized at December 31, 2022 and 2021; 26,795,800 and 26,408,031 shares issued and outstanding at December 31, 2022 and 2021, respectively		3		3
Additional paid-in capital		604,687		598,913
Accumulated deficit		(477,954)		(364,942)
Total stockholders' equity		126,739		233,977
Total liabilities and stockholders' equity	\$	169,290	\$	265,828
		100,200		200,020

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

		Year ended December 31,			
	_		2022		2021
Revenue					
Grant revenue	\$	,	1,160	\$	8,193
Product revenue, net	_		3,652		<u> </u>
Total revenue, net	\$	,	4,812	\$	8,193
Operating expenses:					
Cost of product sold			8,391		_
Research and development			70,831		157,591
Selling, general and administrative			40,729		42,418
Total operating expenses			119,951		200,009
Loss from operations			(115,139)		(191,816)
Other income (expense), net			2,127		(220)
Net loss and comprehensive loss	\$	;	(113,012)	\$	(192,036)
Net loss per share, basic and diluted	\$	,	(4.24)	\$	(8.48)
Weighted average shares used in the calculation of net loss per	_				
share, basic and diluted:	<u> </u>		26,633,241		22,655,339

See accompanying notes to the financial statements

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

	Conv Preferre		Series 1 C		Commo	n Stock		Additional Paid-in	Ac	cumulated	s	tockholders'
	Shares	Value	Shares	Value	Shares	Value		Capital		Deficit		Equity
Balance at December 31, 2020	53,509,351	\$ 290,945	_	_	2,126,254	_	- 5	64,335	\$	(172,906)	\$	(108,571)
Issuance of Common Stock upon exercise of stock options	_	_	_	_	789,225	_	-	1,444		_		1,444
Issuance of Common Stock pursuant to employee stock purchase plan	_	_		_	67,120	_	-	439		_		439
Issuance of Common Stock upon initial public offering, net of issuance costs of \$21,349	_	_	_	_	15,870,000		2	232,546		_		232,548
Conversion of convertible preferred stock into common stock and Series 1 convertible preferred stock upon initial public offering	(53,509,35 1)	(290,945)	29,863,674	3	7,555,432		1	290,942		_		290,946
Stock-based compensation expense	_	_	_	_	_	_	-	9,207		_		9,207
Net loss	_	_		_	_	_	-	_		(192,036)		(192,036)
Balance at December 31, 2021	_	_	29,863,674	\$ 3	26,408,031	\$	3 \$	598,913	\$	(364,942)	\$	233,977
Issuance of Common Stock pursuant to equity incentive plan	_	_	_	_	122,547	_	-	98		_		98
Issuance of Common Stock pursuant to employee stock purchase plan	_	_	_	_	265,222	_	-	308		_		308
Stock-based compensation expense	_	_	_	_	_	_	-	5,368		_		5,368
Net loss	_	_	_	_	_	_	-	_		(113,012)		(113,012)
Balance at December 31, 2022	_		29,863,674	\$ 3	26,795,800	\$	3 \$	604,687	\$	(477,954)	\$	126,739

See accompanying notes to the financial statements

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

	Year ended December 31,			
	 2022		2021	
Operating activities	 			
Net loss	\$ (113,012)	\$	(192,036)	
Adjustments to reconcile net loss to net cash used in operating				
activities:				
Stock-based compensation	5,368		9,207	
Depreciation and amortization	8,830		1,578	
Non-cash lease expense	2,771		1,043	
Impairment of long-lived assets	3,593		_	
Changes in operating assets and liabilities:				
Accounts receivable	(125)		288	
Prepaid expenses and other current assets	604		(281)	
Prepaid research and development	_		12,014	
Other long-term assets and liabilities	741		(5,615)	
Accounts payable	(1,194)		216	
Accrued expenses and other liabilities	(7,712)		2,202	
Net cash used in operating activities	\$ (100,136)	\$	(171,384)	
Investing activities				
Purchase of property and equipment	(1,615)		(2,866)	
Net cash used in investing activities	\$ (1,615)	\$	(2,866)	
Financing activities				
Proceeds from stock option exercises	98		1,444	
Proceeds from stock issuances pursuant to employee stock purchase plan	308		439	
Proceeds from initial public offering, net of issuance costs	_		232,546	
Net cash provided by financing activities	\$ 406	\$	234,429	
Net (decrease) increase in cash, cash equivalents and restricted cash	 (101,345)		60,179	
Cash, cash equivalents and restricted cash at beginning of year	233,312		173,133	
Cash, cash equivalents and restricted cash at end of year	\$ 131,967	\$	233,312	
Supplemental disclosure of noncash activities				
Right-of-use assets obtained in exchange for operating lease liabilities	\$ 19,245	\$	13,499	

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

	December 31,			
	2022		2021	
Cash and cash equivalents	\$ 130,191	\$	232,545	
Restricted cash - other long-term assets	1,776		767	
Total cash, cash equivalents and restricted cash	\$ 131,967	\$	233,312	

See accompanying notes to the financial statements

# Talis Biomedical Corporation Notes to the financial statements

### 1. Organization and nature of business

Talis Biomedical Corporation (the Company) is a molecular diagnostic company focused on advancing health equity and outcomes through the delivery of accurate infectious disease testing in the moment of need, at the point of care. The Company plans to develop and commercialize innovative products on its sample-to-answer Talis One system to enable accurate, low cost, and rapid molecular testing. The Company was incorporated in 2013 under the general laws of the State of Delaware and is based in Redwood City, California (CA) and Chicago, Illinois (IL).

In November 2021, the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for use of the stand-alone Talis One COVID-19 test in a variety of healthcare settings, and on May 12, 2022, we received the CE Mark certification under the European In-Vitro Diagnostic Devices Directive (IVDD) for the stand-alone Talis One COVID-19 test. On August 23, 2022, in response to our withdrawal request filed on August 12, 2022, the FDA revoked our EUA for the stand-alone Talis One COVID-19 test, as we no longer plan to pursue commercialization of the stand-alone Talis One COVID-19 test in the United States.

In January 2022, the Company began to act as an authorized distributor for third-party COVID-19 antigen tests (Antigen Tests). The Company intends to conclude this program, upon the earlier of (i) selling its limited remaining Antigen Tests and (ii) the expiration date of the Antigen Tests.

# **Initial Public Offering**

In February 2021, the Company completed an initial public offering (IPO) in which the Company issued and sold 15,870,000 shares of common stock at a public offering price of \$16.00 per share. The aggregate proceeds received by the Company from the IPO was \$232.5 million after deducting underwriting discounts, commissions and offering expenses of approximately \$21.3 million. Upon the closing of the IPO, affiliated preferred shares with a carrying value of \$225.4 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.

# Liquidity

The Company has incurred significant losses and negative cash flows since inception, including net loss of \$113.0 million for the year ended December 31, 2022. As of December 31, 2022, the Company had unrestricted cash and cash equivalents of \$130.2 million and \$1.8 million of restricted cash.

Management expects to continue to incur additional substantial losses in the foreseeable future primarily as a result of the Company's research and development activities and future commercialization of the Talis One system. The Company's activities are subject to significant risks and uncertainties, including failing to secure additional funding to continue to operationalize the Company's current technology and to advance the development of its products. The Company expects its existing unrestricted cash and cash equivalents as of December 31, 2022 will be sufficient to fund its operations through at least one year from the date these financial statements are issued. The Company expects to finance its future operations with its existing unrestricted cash and cash equivalents and through strategic financing opportunities that could include, but are not limited to, one or a combination of nondilutive corporate development and licensing opportunities and grant agreements, the incurrence of debt, future offerings of its equity, or collaborations or partnerships with other companies. 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 or at all.

In March 2022 and August 2022, we implemented two separate reductions in force (RIF) designed to reduce our operating expenses, preserve cash and align our remaining resources to focus on, among other things, developing women's health and sexual transmitted infection (STI) tests on the Talis One system and internal manufacturing expertise to support our strategic plans. During the year ended December 31, 2022, we incurred \$1.0 million of expenses related to the March 2022 RIF and \$1.5 million of expenses related to the August 2022 RIF recorded

within operating expenses on our statements of operations and comprehensive loss, substantially all of which consisted of charges related to the staff reduction, including cash expenditures and other costs during each RIF. There were no remaining obligations as of December 31, 2022.

### 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 (GAAP) and the rules and regulations of the 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 GAAP requires management to make judgments, estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and on various other assumptions, including knowledge about current events and expectations about actions the Company may take in the future, that the Company believes are reasonable under the circumstances. Actual results could vary from the amounts derived from management's estimates and assumptions.

During the year ended December 31, 2022, the Company shortened the useful life of certain lab equipment as a result of manufacturing changes brought about by the decision to no longer pursue the commercialization of the stand-alone Talis One COVID-19 test in the United States. This change in estimate resulted in \$6.6 million of accelerated depreciation expense during the twelve months ended December 31, 2022.

### Reclassifications

The accompanying statement of cash flows for the twelve-month period ended December 31, 2021 and the accompanying balance sheet as of the year ended December 31, 2021 reflects the Company's reclassification of grants receivables and unbilled grants receivables to accounts receivable, to conform to the presentation of the current period. The statement of cash flows for the twelve-month period ended December 31, 2021 reflects the Company's reclassification of the change in lease assets and liabilities into other long-term assets and liabilities, to confirm to the presentation in the current period.

### Fair value measurements

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

disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable.

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

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

For nonfinancial assets, measurement at fair value in periods subsequent to their initial recognition is applicable if they are determined to be impaired. These assets generally include property and equipment and operating lease right-of-use assets. If measured at fair value in the balance sheets, these would generally be classified within Level 3 of the fair value hierarchy.

### Cash and cash equivalents

The Company considers cash equivalents to be highly liquid investments with an original maturity at purchase of three months or less. These cash equivalents include holdings in money market funds that are invested in United States (U.S) Treasury obligations which are stated at fair value.

### Restricted cash

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

### Accounts receivable, net

Accounts receivable include trade receivables, unbilled receivables and grant receivables. The allowance for doubtful accounts reflects the current estimate of credit losses expected to be incurred over the life of the accounts receivable. The Company considers various factors in establishing, monitoring, and adjusting its allowance for doubtful accounts, including the aging of the accounts and aging trends and specific exposures related to particular customers. Accounts receivable are charged off after all reasonable means to collect the full amount have been exhausted. The Company has an immaterial allowance for doubtful accounts as of December 31, 2022 and 2021.

### Concentration of credit risk and other risks and uncertainties

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

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.

Global economic conditions remain volatile resulting from the continuing and evolving effects of the COVID-19 pandemic, inflationary pressures, rising interest rates, the ongoing military conflict between Russia and Ukraine and related sanctions imposed against Russia and otherwise. The Company continues to evaluate the potential impact of

these global issues on our current and future business operations, including our expenses, clinical trials and addressable markets as well as on our industry and healthcare system.

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

### Inventory

Inventory, which consists of finished goods, is valued at the lower of cost or net realizable value. The Company determines the cost of inventory using the first-in, first-out method. Lower of cost or net realizable value is evaluated by considering obsolescence, excessive levels of inventory, deterioration and other factors.

In order to assess the ultimate realization of inventories, the Company is required to make judgments as to future demand requirements compared to current or committed inventory levels. The Company periodically reviews its inventories for shelf life, excess or obsolescence and writes-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual net realizable value is less than the carrying value, or if it is determined that inventory utilization will further diminish based on estimates of demand, additional inventory write-downs may be required. Inventory write-downs are recorded in cost of product sold and a new lower-cost basis for the inventory is established. Excess and obsolete inventory is primarily based on estimated forecasted sales, usage levels, and expiration dates and is recorded within cost of product sold. During the year ended December 31, 2022, the Company established a reserve against \$4.4 million of inventory in excess of forecasted demand.

# Property and equipment

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

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

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

Construction in progress relates to new equipment having alternative future use that is being used to expand our research and development capabilities. Construction in progress includes the cost of construction and other direct costs attributable to the construction.

# Impairment of long-lived assets

A long-lived asset may be impaired when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset's carrying amount. Any required impairment loss would be measured as the amount by which the asset or asset group's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset to its fair value and a charge to operating expense. The Company reviews the carrying amount of its long-lived assets, including property and equipment, for impairment whenever events indicate that the carrying amount of the assets may not be fully recoverable.

During the year ended December 31, 2022, management concluded that the Company's decrease in market capitalization was a triggering event for potential impairments of our assets. A \$3.6 million impairment of

long-lived assets charge was recorded within selling, general and administrative expenses on the statement of operations and comprehensive loss for the year ended December 31, 2022. The operating lease impairment charge reduces the carrying value of the associated right-of-use assets to the estimated fair values. The fair values are estimated using a discounted cash flows approach on forecasted future cash flows derived from current market data including discount rate, rent and rent escalation rates, downtime and abatement assumptions. The fair value of our right-of-use assets may change as a result of a change in any of these inputs. There was no impairment recorded for the year ended December 31, 2021.

### Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease. The Topic requires a lessee to determine if an arrangement is a lease or contains a lease at contract inception, to recognize right-of-use ("ROU") assets and lease liabilities arising from operating and financing leases with terms longer than 12 months on the balance sheets and to disclose key information about leasing arrangements. The Company's lease agreements may include variable lease payments which are not included in the initial measurement of the right-of-use asset or lease liability due to the uncertainty of the payment amount and is recorded as lease cost in the period incurred. Lease expense is recognized on a straight-line basis over the lease term.

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

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

### **Revenue Recognition**

### Product revenue, net

The Company currently only generates revenues from its sales of third-party Antigen Tests. The Company obtains control of the product and assumes inventory risk before it is transferred to the customer and therefore reports revenue on the gross amount billed to the customer. The Company has recognized sales from two primary customer types: (i) direct customers including hospitals, urgent care centers, physician, public health and retail clinics, and (ii) sub-distributors.

The Company recognizes revenue under Accounting Standards Codification Topic 606 (ASC 606), *Revenue from Contracts with Customers*, when a customer obtains control of promised goods or services, with a transaction price that reflects the consideration which the entity expects to receive in exchange for those goods or services. Transaction price does not include amounts subject to uncertainties unless it is probable that there will be no significant reversal of revenue when the uncertainty is resolved. If necessary, revenue is recorded net of variable consideration based on the amounts the Company expects to be earned or to be claimed on the related sales. The Company estimates the amount of its product sales that may result in returns or in price adjustments and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The returned assets cannot be re-sold and have no value to the Company.

The Company identifies the contract with a customer and determines the performance obligations and the contract price. The contract price is allocated to the distinct performance obligations in the contract and revenue is recognized when the performance obligations have been satisfied. A performance obligation is considered to be satisfied once the control of a product is transferred to the customer or the service is provided to the customer,

meaning the customer has the ability to use and obtain the benefit of the goods or service, generally at product shipment.

The Company recognizes receivables in an amount expected to be collected in a transaction. The Company's payment terms are generally net 30 days of billing. Contracts do not contain significant financing components based on the typical period of time between delivery of products and collection of contract consideration. Certain types of customers may pay in advance of product delivery. In those instances, payment and delivery typically occur in the same month. The Company invoices its customers upon shipment of product and records its sales upon shipment in accordance with its standard terms and conditions, unless underlying customer contracts specify otherwise. When necessary, the Company invoices and collects sales tax from its customers for sales of products. The Company has elected to exclude sales tax from the measurement of the transaction price.

### Contract balances

A receivable is recognized in the period the Company delivers goods or provides services or when the Company's right to consideration is unconditional. The Company usually does not record contract assets because the Company has an unconditional right to payment upon satisfaction of the performance obligation, and therefore, a receivable is more commonly recorded than a contract asset. Receivables from contracts with customers are included within accounts receivable, net on the balance sheets.

Contract liabilities include payments received in advance of performance under a contract and are satisfied as the associated revenue is recognized. When performance obligations are not transferred to a customer at the end of a reporting period, cash received associated with the amount allocated to those performance obligations is reflected as contract liabilities on the balance sheets and is deferred until control of these performance obligations is transferred to the customer. There are no contract liabilities as of December 31, 2022.

### Contract costs

Under ASC 606, the Company is required to capitalize incremental costs to obtain customer contracts if the costs relate directly to a contract that can be specifically identified and expect to be recovered. These costs are required to be amortized to expense consistent with the transfer of the goods or services to the customer to which the asset relates. As a practical expedient, the Company recognizes any incremental costs to obtain a contract as an expense when incurred if the amortization period of the asset is one year or less. The Company did not have any capitalized contract costs as of and for the twelve months ended December 31, 2022.

### Grant revenue and receivables

Grants awarded to the Company for research and development by government entities are outside the scope of ASC 606. 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.

# Costs of product sold

Costs of product sold include material costs, direct labor, provisions for inventory write-downs and shipping and handling costs incurred. The Company reports product shipment costs within cost of products sold in the accompanying statements of operations.

### Research and development costs

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

The Company does not capitalize pre-launch inventory costs until future commercialization is considered probable and the future economic benefit is expected to be realized. Capitalizing pre-launch inventory costs will not occur prior to obtaining an EUA or other FDA marketing authorization, commercialization is considered probable and future economic benefit can be asserted. The Company records such costs as research and development expenses, or if used in marketing evaluations records such costs as selling, general and administrative expenses. All materials, equipment, and external consulting costs associated with developing aspects of the production line that do not have an alternative future use are expensed as research and development costs until regulatory approval or clearance is obtained and commercialization is probable. Materials, equipment, and external consulting costs associated with developing aspects of the production line that are deemed to have an alternative future use are capitalized as property and equipment, assessed for impairment and depreciated over their related useful lives.

In 2021, the Company completed work on production lines to automate the production of its Talis One cartridges for the COVID-19 test. The Company incurred \$69.6 million as part of the Company's effort to scale-up its manufacturing capacity including costs incurred for high capacity production equipment in the twelve months ended December 31, 2021. During the year ended December 31, 2021 the Company charged \$11.8 million of pre-launch inventory relating to cartridges and \$21.7 million of pre-launch inventory relating to instrument components to research and development expense, respectively.

The Company makes estimates of its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances at that time through discussions internally and with service providers to confirm the accuracy of progress and stage of completion. The Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed requires judgment and actual results may vary.

### Preferred stock

As part of the Company's IPO, certain shares of the Company's historical convertible preferred stock converted into shares of the Company's Series 1 convertible preferred stock. The Company records the Series 1 convertible preferred stock at par value on the date of conversion. The Company has classified its Series 1 convertible preferred stock as permanent equity within the accompanying balance sheet at December 31, 2022 and 2021 due to the immaterial liquidation value of the shares.

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

### Income taxes

The Company accounts for income taxes under the liability method. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been included in the Company's financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards, using enacted tax rates expected to be in effect in the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible.

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

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

The Inflation Reduction Act of 2022 (the "Act") was signed into U.S. law on August 16, 2022. The Act includes various tax provisions, including an excise tax on stock repurchases, expanded tax credits for clean energy incentives, and a corporate alternative minimum tax that generally applies to U.S. corporations with average adjusted financial statement income over a three year period in excess of \$1 billion. The Company does not expect the Act to materially impact its financial statements.

The Tax Cuts and Jobs Act (TCJA) requires taxpayers to capitalize and amortize research and experimental (R&D) expenditures under section 174 for tax years beginning after December 31, 2021. This rule became effective for the Company during the year ended December 31, 2022. The Company will amortize these costs for tax purposes over 5 years if the R&D was performed in the U.S. and over 15 years if the R&D was performed outside the U.S.

### Stock-based compensation

The Company maintains an equity incentive plan as a long-term incentive for employees, consultants, and directors. We generally issue new common shares upon exercise of options and vesting of RSUs. The Company accounts for all stock-based awards granted to employees and directors based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The measurement date for stock awards, including stock options and restricted stock units (RSUs) is the date of grant. Awards granted by the Company are routine in nature including new hire, annual, and promotional grants that are not designed to be spring-loaded, and therefore the market price is not adjusted when estimating the grant-date fair value of these awards. From time to time, the Company may grant stock options to employees, including executive officers, and consultants that vest upon the satisfaction of service-based, performance-based or market-based vesting conditions.

For awards that vest based on multiple conditions, the Company estimates the fair value on its grant date using the Black-Scholes option valuation model or the Monte Carlo Simulation valuation model, depending on the terms and conditions of the particular award.

- For awards where vesting occurs based on a service condition only, the Company recognizes compensation expense using the straight-line method over the requisite service period.
- For awards where vesting occurs based on either a service condition or a performance condition, 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.
- For awards where vesting occurs based on either a service condition or a market condition, compensation expense is recognized over the
  requisite service period. If the market condition is satisfied prior to the completion of the requisite service period, any remaining
  unrecognized compensation expense will be accelerated at that time. The Company does not reverse compensation expense associated with
  these awards if the market condition is not met.

The Company recognizes stock-based compensation expense for the portion of awards that have vested. Forfeitures are accounted for as they occur.

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

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

## Net loss per share attributable to common stockholders

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration of potential dilutive securities. The Series 1 convertible preferred stock are participating securities but because they do not have the obligation to share in the loss of the Company, are excluded from the calculation of basic net loss per share. Stock options, unvested RSUs, Series 1 convertible preferred stock, and shares estimated to be purchased under the Company's employee stock purchase plan (ESPP) are considered potentially dilutive common stock. The Company computes diluted net loss per share after giving consideration to all potentially dilutive common stock outstanding during the period, determined using the treasury-stock and if-converted methods, except where the effect of including such securities would be antidilutive.

For the years ended December 31, 2022 and 2021, the Company reported a net loss. The potentially dilutive common stock would have been anti-dilutive and therefore basic and diluted loss per share attributable to common stockholders were the same.

### Comprehensive loss

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

### 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

There is no accounting guidance currently pending that we expect to have a material impact on our consolidated financial statements or disclosures.

# Recently Adopted Accounting Standards

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses* 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. The Company early adopted ASU 2016-13 on

January 1, 2022 with no impact on its accumulated deficit, current financial position, results of operations and comprehensive loss or cash flows.

In November 2021, the FASB issued ASU 2021-10, *Government Assistance – Disclosures by Business Entities about Government Assistance* to require business entities to disclose information about certain government assistance they receive to provide comparable and transparent information to investors and other financial statement users to enable them to understand an entity's financial results and prospects of future cash flows. The Company adopted ASU 2016-13 on January 1, 2022 with no material impact on its accumulated deficit, current financial position, results of operations and comprehensive loss, cash flows or disclosures.

# 3. Fair value measurements

The following table summarizes the Company's financial assets carried at fair value and measured on a recurring basis by level within the fair value hierarchy (in thousands):

		December	r 31, 202	2			
Level 1		Level 2		Level 3			Total
\$ 127,404	\$	_	\$		_	\$	127,404
\$ 127,404	\$	_	\$		_	\$	127,404
	<u> </u>		24 222	_			
		December	r 31, 202	l			
Level 1		Level 2	r 31, 202	Level 3			Total
 Level 1			r 31, 202				Total
\$ Level 1 205,071	\$		r 31, 202			\$	Total 205,071
\$ \$	\$ 127,404	\$ 127,404 \$	Level 1     Level 2       \$ 127,404     \$ —       \$ 127,404     \$ —	Level 1     Level 2       \$ 127,404     \$ — \$       \$ 127,404     \$ — \$	\$ 127,404 \$ — \$ \$ 127,404 \$ — \$	Level 1         Level 2         Level 3           \$         127,404         \$         —           \$         127,404         \$         —	Level 1         Level 2         Level 3           \$         127,404         \$         —         \$         —         \$           \$         127,404         \$         —         \$         —         \$

# 4. Balance sheet components

# Property and equipment, net

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

	December 31,				
		2022		2021	
Lab equipment	\$	12,521	\$	8,077	
Office and computer equipment		548		507	
Furniture and fixtures		828		407	
Leasehold improvements		1,253		814	
Total		15,150		9,805	
Less accumulated depreciation		(12,822)		(3,992)	
Total		2,328		5,813	
Construction in progress		984		4,715	
Property and equipment, net	\$	3,312	\$	10,528	

# Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	 December 31,			
	 2022		2021	
Accrued research and development costs	\$ 351	\$	5,303	
Other liabilities	638		1,080	
	\$ 989	\$	6,383	

### 5. Revenue

### Product revenue, net

The Company currently operates in one reportable segment. There were no sales to customers outside of the United States during the year ended December 31, 2022. The Company had one customer that individually comprised over 10% of product revenues, net for the twelve months ended December 31, 2022.

### **Grant Revenue**

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. In April 2022, the Company exercised its fourth one-year option under the grant, extending the term through April 2023 with \$1.2 million in additional funding available under the extension.

During each of the twelve months ended December 31, 2022 and 2021, the Company recognized \$0.5 million of revenue related to this grant.

NIH Rapid Acceleration of Diagnostics - RADx Initiative contracts

In July 2020, the Company was awarded a subaward grant from the University of Massachusetts Medical School for Phase 1 of the NIH's RADx initiative and a 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. In 2021, the Company and the NIH amended the contract for the completion of the RADx initiative, extending the term of the contract to January 30, 2022 and decreased the potential milestone payment from \$4.0 million to \$2.0 million. The contract expired on January 30, 2022.

During the year ended December 31, 2022 and 2021, the Company recognized revenue of \$0.7 million and \$7.7 million related to the RADx initiative, respectively.

### 6. Commitments and contingencies

### **Operating leases**

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

In January 2021, the Company entered an operating lease for laboratory and office space in Redwood City, CA. The Company received access to the premises and the lease commenced in June 2022. In June 2022, the Company recorded a right-of-use asset of \$23.9 million on the Company's balance sheet, including \$4.7 million for a prepayment made to the landlord in 2021. The lease is classified as an operating lease and 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 lease is approximately \$2.6 million annually with fixed escalations of 3.0% per annum.

During the year ended December 31, 2022, the Company recorded a \$3.6 million long-lived asset impairment charge related to right-of-use assets. Refer to Note 2, "Long-lived asset impairment" for more information.

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

	December 31,		
Lease Costs	 2022		2021
Operating lease costs	\$ 4,100	\$	1,984
Variable lease costs	834		110
Total operating lease costs	\$ 4,934	\$	2,094
Cash flows			
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows used for operating leases	\$ 1,360	\$	1,050

	Decemb	December 31,		
	2022	2021		
Weighted-average remaining lease term	9.8 years	10.2 years		
Weighted-average discount rate	7.0 %	5.2 %		

The undiscounted future lease payments for operating leases as of December 31, 2022 were as follows (in thousands):

Year ending December 31,	Operating Leases
2023	\$ 3,832
2024	4,381
2025	4,503
2026	4,628
2027	4,757
2028 and thereafter	24,988
Total future minimum lease payments	\$ 47,089
Less: imputed interest	(13,507)
Present value of operating lease liabilities	33,582
Less: current portion of lease liabilities	(3,703)
Noncurrent portion of lease liabilities	\$ 29,879

# Standby letters of credit

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

In conjunction with the Chicago, IL laboratory and office space lease, the Company is required to hold an additional LOC in the amount of \$0.8 million to secure this lease through its expiration. The Company is required to maintain a cash balance of \$0.8 million as collateral for the LOC, which is classified in other long-term assets on the balance sheet as of December 31, 2022, because it is unavailable for a period longer than one year from the balance sheet date.

Neither LOC had not been drawn upon through December 31, 2022.

#### **Indemnification agreements**

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, customers and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. The Company also provides indemnification to directors and officers of the Company to the maximum extent permitted under applicable Delaware law. The maximum potential amount of future payments that the Company could be required to make under these indemnification agreements is, in many cases, unlimited. As December 31, 2022, 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 at the date of the financial statements and the amount of the loss can be reasonably estimated. When management determines that it is not probable, but rather reasonably possible that a liability has been incurred at the date of the financial statements, management discloses such contingencies and the possible loss or range of loss if such estimate can be made. Any estimated range is based on currently available information and involves elements of judgment and significant uncertainties. Any estimated range of possible loss may not represent the maximum possible loss exposure. Circumstances change over time and actual results may vary significantly from estimates.

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 and other negotiations can have an adverse impact on the Company because of litigation and settlement costs, diversion of management resources and other factors. Legal costs are expensed as incurred.

## 7. Stockholders' equity

#### Convertible preferred stock

Upon the closing of the IPO, 42,705,056 affiliated convertible preferred stock with a carrying value of \$225.4 million were converted into 29,863,674 Series 1 convertible preferred stock. The remaining 10,804,295 outstanding historical convertible preferred stock were converted into 7,555,432 shares of common stock. As of December 31, 2022 and 2021, there were no shares of Series 2 non-voting convertible preferred stock outstanding. The Series 1 convertible preferred stock and Series 2 non-voting convertible preferred and outstanding have various rights, privileges and features. The Company determined that none of the features required bifurcation from the underlying shares, either because they are clearly and closely related to the underlying shares or because they do not meet the definition of a derivative.

The rights, preferences, and privileges of the Company's Series 1 convertible preferred stock and Series 2 non-voting convertible preferred stock are as follows:

# Voting

The holders of our Series 1 convertible preferred stock are entitled to one vote per share. Holders of shares of our common stock and Series 1 convertible preferred stock will vote together as a single class on all matters (including the election of directors) submitted to a vote of stockholders. The Series 1 convertible preferred stock does not have cumulative voting rights. Holders of our Series 2 non-voting convertible preferred stock have no voting rights except as required by law or as set forth in our amended and restated certificate of incorporation.

## Conversion

The Series 1 convertible preferred stock is convertible, at the election of the holder, into Series 2 non-voting convertible preferred stock on a one-for-one basis at any time following the third anniversary of the closing of the IPO. Shares of Series 1 convertible preferred stock automatically convert to common stock on a one-for-one basis at

any time at the discretion of the holder, or upon any sale or transfer of such shares of Series 1 convertible preferred stock.

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

#### Dividends

The Series 1 convertible preferred stock and Series 2 non-voting convertible preferred stock have the right to receive dividends first or simultaneously with payment of dividends on common stock. As of December 31, 2022, no such dividends had been declared or accrued.

#### Liquidation preference

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

#### Protective provisions

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

#### Redemption rights

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

### Registration rights

In March 2021, the Company entered into a registration rights agreement (the Registration Rights Agreement) with Baker Brothers Life Sciences, L.P. and 667, L.P. (the Baker Funds), holders of the Company's Series 1 convertible preferred stock and related parties. The obligations of the Company regarding such registration rights include, but are not limited to, file a registration statement with the SEC for the registration of registrable securities, reasonable efforts to cause such registration statement to become effective, keep such registration statement effective for up to 30 days, prepare and file amendments and supplements to such registration statement and the prospectus used in connection with such registration statement, and notify each selling holder, promptly after the Company receives notice thereof, of the time when such registration statement has been declared effective or a supplement to any prospectus forming a part of such registration statement has been filed. The terms of the Registration Rights Agreement 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. On May 10, 2022, the Company filed a registration statement on Form S-3 with the SEC to register the registration Rights Agreement, the Baker Funds also have the right to one underwritten offering per calendar year, but no more than two underwritten offerings or block trades in any

twelve-month period, to effect the sale or distribution of their registrable securities, subject to specified exceptions, conditions and limitations. The Registration Rights Agreement also includes customary indemnification obligations in connection with registrations conducted pursuant to the Registration Rights Agreement.

#### Common Stock

The Company's February 2021 amended and restated certificate of incorporation authorized the issuance of up 200,000,000 shares of common stock, each having a par value of \$0.0001 and entitled to one vote per share. No dividends have been declared or paid during the years ended December 31, 2022 and 2021

On July 27, 2022, the Company received a notice (Notice) from the Nasdaq Stock Market (Nasdaq) that the Company is not in compliance with Nasdaq Listing Rule 5450(a)(1), as the minimum bid price of the Company's common stock had been below \$1.00 per share for thirty-one (31) consecutive business days as of the date of the Notice.

On January 24, 2023, the Company transferred the listing of its securities to the Nasdaq Capital Market (Capital Market) and received notice from Nasdaq indicating that, while the Company has not regained compliance with the Bid Price Requirement, Nasdaq has determined that the Company is eligible for an additional 180-day period, or until July 24, 2023, to regain compliance. We have committed to effectuate a reverse stock split by the end of the second compliance period, if necessary, to regain compliance with the Minimum Bid Price Requirement. The Notice has no other immediate effect on the listing of the Company's common stock, which will trade on the Capital Market under the symbol "TLIS."

#### 8. Stock-based compensation

## 2013 Equity Incentive Plan

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

#### 2021 Equity Incentive Plan

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

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

In February 2021, the Company's Board of Directors adopted the ESPP, and our stockholders approved the ESPP. The price at which stock is purchased under the ESPP is equal to 85% of the fair market value of the Company's common stock on the first or the last day of the offering period, whichever is lower. Generally, each offering under the ESPP will be for a period of six months as determined by the Company's Board of Directors. Employees may invest up to 15% of their qualifying gross compensation through payroll deductions. In no event may an employee purchase more than 4,750 shares of common stock during any six-month offering period.

The ESPP is a compensatory plan as defined by the authoritative guidance for stock compensation; therefore, stock-based compensation expense of \$0.3 million and \$0.4 million related to the ESPP has been recorded for the years ended December 31, 2022 and 2021, respectively.

### 2021 Inducement Plan

In November 2021, the Company's Board of Directors adopted the 2021 Inducement Plan (Inducement Plan). The Inducement Plan was adopted without stockholder approval pursuant to Nasdaq Listing Rule 5635(c)(4). Under the Inducement Plan, the Company may grant nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other awards to individuals not previously employees or directors of the Company, as an inducement toward entering into employment with the Company. The maximum number of shares of common stock that may be issued under the Inducement Plan is 3,000,000 shares.

#### Stock option activity

A summary of option activity during the year ended December 31, 2022 is as follows:

	Number of Units Outstanding	E	Weighted Average exercise Price per Unit	Weighted Average Remaining Contractual Term (in years)	]	Aggregate Intrinsic Value thousands)
Outstanding at December 31, 2021	8,590,411	\$	5.48	8.8	\$	6,196
Granted	4,367,446	\$	1.08			
Exercised	(65,862)	\$	1.50			
Forfeited	(3,030,143)	\$	4.86			
Expired	(1,459,226)	\$	5.03			
Outstanding at December 31, 2022	8,402,626	\$	3.52	8.6	\$	_
Options vested and expected to vest at December 31,						
2022	8,402,626	\$	3.52	8.6	\$	_
Options vested and exercisable at December 31, 2022	2,831,700	\$	4.97	8.0	\$	_

\*.7 \* 1 . 1

As of December 31, 2022, the total unrecognized stock-based compensation related to stock options was \$9.9 million, which is expected be recognized over a weighted-average period of approximately 3 years. Total options vested during the year were 1,812,221 with a total fair value of \$6.0 million.

As of December 31, 2022, the Company has granted service-based stock option awards which may accelerate vesting upon performance-based or market-based conditions.

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-employee directors were as follows:

	Year ended De	ecember 31,
	2022	2021
Expected term (in years)	8.3	5.8
Expected Volatility	71.3%	73.1%
Risk-free interest rate	2.9%	1.1%
Expected Dividend yield	—%	—%

The weighted-average grant date fair value per share was \$0.79 and \$4.51 for options granted during the years ended December 31, 2022 and 2021, respectively.

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

#### Restricted stock units

A summary of RSU activity during the year ended December 31, 2022 is as follows:

	Number of Units Outstanding	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2021	407,720	\$ 5.72
Granted	351,900	\$ 1.20
Vested	(61,760)	\$ 5.70
Forfeited	(371,496)	\$ 4.06
Outstanding at December 31, 2022	326,364	\$ 2.75

As of December 31, 2022, the total unrecognized stock-based compensation related to RSUs was \$0.8 million, which is expected to be recognized over a weighted average period of approximately 3 years. Outstanding RSUs as of December 31, 2022 includes 5,075 RSUs that were vested, but not yet delivered.

## 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,		
	 2022		2021
Research and development	\$ 1,313	\$	2,388
Selling, general and administrative	4,055		6,819
Total stock-based compensation	\$ 5,368	\$	9,207

## 9. Related-party transactions

### Financing activity

During the year ended December 31, 2021, the Company received proceeds of \$106.2 million from the issuance of common stock to related parties as part of the Company's IPO, including the Company's majority shareholder, the Baker Funds, six officers and two members of the Board of Directors.

#### **Registration rights**

In March 2021, the Company entered into the Registration Rights Agreement with the Baker Funds, holders of Series 1 convertible preferred stock and related parties (see Note 7, Stockholders Equity - Registration Rights).

#### 10. Income taxes

The Company had no income tax expense for the year ended December 31, 2022 and 2021, due to its history of operating losses. During the years ended December 31, 2022 and 2021 the Company recorded a net loss of \$113.0 million and \$192.0 million, respectively.

The effective tax rate for the years ended December 31, 2022 and 2021 is different from the federal statutory rate primarily due to the tax benefit of the Company's net loss and comprehensive loss not being more likely than not to be realized. The following is a reconciliation of the statutory federal income tax rate to the Company's effective tax rate:

	December	r 31,
Effective income tax rate:	2022	2021
Expected income tax benefit at the federal statutory rate	21.0%	21.0%
State taxes, net of federal benefit	6.0	7.7
Research and development tax credits	0.9	0.8
Permanent differences	(0.5)	(0.2)
Change in valuation allowance	(27.4)	(29.3)
Total provision for income taxes	—%	—%

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

	 December 31,		
	 2022		2021
Deferred tax assets:			
Federal and state operating loss carryforwards	\$ 66,709	\$	60,966
Research and development tax credits	8,384		6,655
Lease liabilities	9,420		4,221
Manufacturing line and production equipment	27,875		29,153
Inventory related costs	12,669		11,076
Compensation related items	2,838		2,877
Capitalized research and development costs	17,880		_
Property and equipment	1,200		_
Other	905		141
Total gross deferred tax asset	147,880		115,089
Valuation allowance	(140,411)		(111,024)
Net deferred tax asset	7,469		4,065
Deferred tax liabilities:			
Property and equipment	_		(167)
Operating lease right-of-use asset	(7,469)		(3,898)
Total deferred tax liabilities	(7,469)		(4,065)
Net deferred tax asset	\$ 	\$	_

The Company determines its valuation allowance on deferred tax assets by considering both positive and negative evidence in order to ascertain whether it is more likely than not that deferred tax assets will be realized. Realization of deferred tax assets is dependent upon the generation of future taxable income. Because of the Company's history of operating losses, the Company believes that the realization of its deferred tax assets is not more likely than not to be realized and, accordingly, has provided a valuation allowance. The valuation allowance increased by \$29.4 million and \$59.7 million for the years ended December 31, 2022 and 2021, respectively, primarily due to the increase in the Company's net loss and comprehensive loss.

NOLs and tax credit carryforwards as of December 31, 2022 are as follows (in thousands):

	Amount	Expiration Years
NOLs, federal (post December 31, 2017)	\$ 202,240	Do not expire
NOLs, federal (pre January 1, 2018)	30,901	2033 - 2037
NOLs, state	204,050	2033 to 2041
Research and development tax credits, federal	9,596	2035 to 2041
Research and development tax credits, state	7,759	Do not expire

Utilization of the NOL carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 as amended (Section 382) due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain

stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the NOL carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL carryforwards or research and development tax credit carryforwards before utilization. Until a study is completed no limitations have been recorded.

### Uncertain tax positions

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

	December 31,			
		2022		2021
Unrecognized tax benefits at the beginning of the period	\$	7,244	\$	4,841
Additions for current tax positions		1,729		2,403
Changes for previous tax positions		_		_
Unrecognized tax benefits at the end of the period	\$	8,973	\$	7,244

During the years ended December 31, 2022 and 2021, the Company recognized no interest and penalties associated with unrecognized tax benefits. There are no tax positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within twelve months of the reporting date.

The Company files income tax returns in the U.S. federal and various tax jurisdictions. The federal and state income tax returns from inception through December 31, 2022 remain subject to examination by federal and state authorities, where applicable. There are currently no pending income tax examinations.

## 11. Net loss per share

#### Net loss per share

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

	December 31,			
		2022		2021
Numerator:				
Net loss - basic and diluted	\$	(113,012)	\$	(192,036)
Denominator:				
Weighted-average number of shares of common stock outstanding - basic and diluted		26,633,241		22,655,339
Net loss per share - basic and diluted	\$	(4.24)	\$	(8.48)

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

share. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	As of December 31,		
	2022	2021	
Series 1 convertible preferred stock	29,863,674	29,863,674	
Options to purchase common stock	8,402,626	8,590,411	
Shares estimated to be purchased under 2021 ESPP	251,805	196,558	
Unvested RSUs	326,364	407,720	
Total	38,844,469	39,058,363	

#### 12. Employee benefit plans

The Company has a qualified deferred compensation plan under Section 401(k) of the Internal Revenue Code of 1986, as amended (401(k) Plan). Under the 401(k) Plan, employees may elect to defer a percentage of their salary, subject to Internal Revenue Service limits. The 401(k) Plan follows the Safe Harbor Deferral provisions, met with a Company Basic Matching Provision in which we provide an automatic matching contribution as follows: one-forone 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 \$0.9 million and \$1.1 million for the years ended December 31, 2022 and 2021.

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, 2022 or 2021.

## 13. Subsequent events

As part of the Company's expense reduction efforts, the Company has entered into agreements to reduce the amount of space it leases in Redwood City, CA. These agreements are conditional upon the Company's landlord subsequently entering into a lease agreement with a third-party tenant.

In March 2023, the Company entered a lease termination agreement, with the landlord of our Redwood City, CA facility. The termination agreement will accelerate the lease termination date to no later than May 12, 2023. The termination of this lease will reduce our operating lease right-of-use assets and lease liabilities as of the termination date. The Company will assess the impact of termination on the right-of-use assets and lease liabilities at the date upon which the agreement becomes enforceable. The Company expects to pay customary termination and broker fees associated with the termination, which are expected to be immaterial.

In March 2023, the Company entered a sublease for a future laboratory and office space in a Redwood City, CA facility. The sublease will continue for a term of 7 years, with no option to extend. The minimum annual commitment under the new sublease is approximately \$1.0 million with fixed escalations of 3.5% per annum. The Company is required to hold a letter of credit in the amount of \$0.7 million to secure this lease through expiration. The sublease is expected to commence for accounting purposes in the second quarter of 2023. The Company will assess the lease accounting at the date upon which the agreement becomes enforceable.

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. In March 2023, we entered into a termination agreement with thinXXS, pursuant to which we (i) terminated the thinXXS Agreement, (ii) received possession and title to automated manufacturing lines and certain related materials, and (iii) entered into a license agreement under which we received a patent license to thinXXS intellectual property that may be incorporated into the Talis One system. The Company expects to pay approximately \$3.2 million in license, materials and transfer services fees associated with the termination.

### 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 (CEO) and Chief Financial Officer (CFO), has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 as amended (the Exchange Act)) as of the end of the period covered by this Annual Report required by Exchange Act Rules 13a-15(b) or 15d-15(b).

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

### Management's report on internal control over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f) and 15d-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

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

# Changes in internal control over financial reporting

There have been no changes in the Company's internal control over financial reporting that have materially affected, or that are reasonably likely to materially affect, the Company's internal control over financial reporting during the three months ended December 31, 2022.

## Item 9B. Other Information.

On March 17, 2023, the Company entered into a termination agreement (the "Lease Termination Agreement") with Westport Office Park, LLC (the "Landlord") effective as of March 16, 2023, to terminate the Company's lease agreement with the Landlord dated January 20, 2021, as amended, for the Company's 38,000 square feet of office and laboratory space at 3400 Bridge Parkway in Redwood City, California (the "Original Lease Agreement"). Concurrently with the Company's entry into the Lease Termination Agreement, also on March 17, 2023, the

Company entered into a sublease agreement (the "Sublease Agreement") with Kriya Therapeutics, Inc. ("Kriya") for the Company's lease of 13,165 square feet of office and laboratory space at 1100 Island Drive in Redwood City, California (the "New Office").

The Lease Termination Agreement and Sublease Agreement are contingent upon the Landlord for the 3400 Bridge Parkway office entering into a new lease agreement for the space under the Original Lease Agreement with a third-party tenant and other customary closing conditions, which is expected to occur by the end of the first quarter of 2023. The Company expects to pay customary brokerage and termination fees that are immaterial. The Sublease Agreement provides for a lease term expiring May 31, 2030 with an initial annual rent of \$1.0 million with customary annual escalation provisions, and is secured by the Company's letter of credit in the amount of \$0.7 million.

The foregoing summaries of the Lease Termination Agreement and Sublease Agreement do not purport to be complete and are qualified in their entirety by the full text of the Lease Termination Agreement and Sublease Agreement, which are filed as Exhibits 10.18 and 10.19 to this Annual Report on Form 10-K and are incorporated herein by reference. The Company's entry into the Sublease Agreement and Lease Termination Agreement is being disclosed under this Item 9B of Form 10-K in lieu of Items 1.01 and 1.02, respectively, of Form 8-K.

In May 2020, the Company entered into a supply agreement with thinXXS Microtechnology GmbH, a German corporation and wholly-owned subsidiary of IDEX Corporation ("thinXXS"), 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 (the "Supply Agreement"). On March 22, 2023, the Company entered into a termination and release agreement with thinXXS (the "thinXXS Termination Agreement") and a separate license agreement with thinXXS (the "thinXXS License Agreement," and together with the Termination Agreement, the "thinXXS Agreements"), effective as of March 21, 2023. Pursuant to the terms of the thinXXS Agreements:

- the parties terminated the Supply Agreement;
- the Company will receive possession and title to the automated manufacturing lines and certain related materials;
- thinXXS granted the Company a world-wide, nonexclusive patent license to thinXXS intellectual property that may be incorporated into the Talis One system; and
- the parties agreed to customary terms providing for a general release of claims, as well as confidentiality and non-disparagement covenants.

Under the terms of the thinXXS Agreements, the Company may pay to thinXXS up to an aggregate of approximately \$3.2 million in license, materials and transition services fees.

The foregoing summaries of the thinXXS Agreements do not purport to be complete and are qualified in their entirety by the full text of the thinXXS Termination Agreement and thinXXS License Agreement, which are filed as Exhibits 10.21 and 10.22 to this Annual Report on Form 10-K and are incorporated herein by reference. The Company's entry into the thinXXS License Agreement and thinXXS Termination Agreement is being disclosed under this Item 9B of Form 10-K in lieu of Items 1.01 and 1.02, respectively, of Form 8-K.

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

Not applicable.

#### **PART III**

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

The information required by this item is incorporated by reference to our Proxy Statement with respect to our 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K (2023 Proxy Statement), under sections headed "Proposal 1. Election of Directors," "Information Regarding our Board of Directors and Corporate Governance," and "Information About our Executive Officers."

## Item 11. Executive Compensation.

The information required by this item is incorporated by reference to our 2023 Proxy Statement under the section headed "Executive and Director Compensation."

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

The information required by this item is incorporated by reference to our 2023 Proxy Statement under the section headed "Security Ownership of Certain Beneficial Owners and Management" and "Executive and Director Compensation—Securities Authorized for Issuance Under Equity Compensation Plans."

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

The information required by this item is incorporated by reference to our 2023 Proxy Statement under the section headed "Transactions with Related Persons and Indemnification," "Information Regarding our Board of Directors and Corporate Governance—Independence of the Board of Directors," and "Information Regarding our Board of Directors and Corporate Governance—Information Regarding Committees of the Board of Directors."

## Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to our 2023 Proxy Statement under the section headed "Ratification of Selection of Independent Registered Public Accounting Firm—Principal Accountant Fees and Services."

## **PART IV**

## Item 15. Exhibit and Financial Statement Schedules.

- (a) List the following documents filed as a part of the report:
  - (1) Financial Statements. The financial statements are set forth under "Item 8. Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.
  - (2) Schedules. The financial statement schedules required by Item 15(a) are omitted because they are not applicable, not required or the required information is included in the financial statements or notes thereto as filed in Item 8 of this Annual Report on Form 10-K.
  - (3) Exhibits. An index of Exhibits can be found in the exhibit index on page 120 of this report.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-40047), filed with the SEC on February 17, 2021).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-40047), filed with the SEC on February 17, 2021).
4.1	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on February 8, 2021).
4.2^	Amended and Restated Investor Rights Agreement, dated October 30, 2020, by and among the Registrant and certain of its stockholders (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021).
4.3	Nominating Agreement, dated November 1, 2019, by and among the Registrant, Baker Brothers Life Sciences, L.P. and 667, L.P. (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021).
4.4	Description of Securities (incorporated by reference to Exhibit 4.4 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 30, 2021).
4.5	Registration Rights Agreement, dated March 26, 2021, by and among the Registrant, Baker Brothers Life Sciences L.P. and 667, L.P. (incorporated by reference to Exhibit 4.5 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 30, 2021).
10.1+	Form of Indemnity Agreement, by and between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021).
10.2+	Talis Biomedical Corporation 2013 Equity Incentive Plan and Forms of Option Grant Notice, Option Agreement and Notice of Exercise thereunder, as amended (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on January 22, 2021).
10.3+	Talis Biomedical Corporation 2021 Equity Incentive Plan and Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 2, 2022).
10.4+	Talis Biomedical Corporation 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 2, 2022).
10.5+	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the Talis Biomedical Corporation 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File no. 001-40047) filed with the SEC on November 15, 2021).
10.6+	Talis Biomedical Corporation 2021 Inducement Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K (File No. 001-40047), filed with the SEC on November 15, 2021).
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	10.3 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 2, 2022).
10.8+	Talis Biomedical Corporation Severance and Change in Control Plan and Amended Form of Participation Agreement thereunder (incorporated by reference to Exhibit 10.8 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 15, 2022).
10.9+	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).
10.10+	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).
10.11+	Offer Letter, dated December 8, 2021, by and between the Registrant and Robert J. Kelley (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-40047), filed with the SEC on December 9, 2021).
10.12	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	Amended Supply Agreement, dated December 15, 2021, by and between the Registrant and thinXXS Microtechnology (incorporated by reference to Exhibit 10.17 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 15, 2022.
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	<u>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).</u>
10.17	<u>Lease Agreement, dated April 7, 2021, by and between the Registrant and SFF 3565 Haven, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File no. 001-40047) filed with the SEC on May 13, 2021).</u>
10.18*	Lease Termination Agreement, dated March 17, 2023, by and between the Registrant and Westport Office Park, LLC.
10.19*	Sublease, dated March 17, 2023, by and between the Registrant and Kriya Therapeutics, Inc.
10.20*	Consent to Sublease, dated March 17, 2023, by and between the Registrant, Westport Office Park, LLC, and Kriya Therapeutics, Inc.
10.21*	Termination and Release Agreement, dated March 22, 2023, by and between the Registrant and thinXXS Microtechnology AG.
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Talis Biomedical Corporation Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit

10.7+

10.22*	License Agreement, dated March 22, 2023, by and between the Registrant and thinXXS Microtechnology AG.		
23.1	Consent of Independent Registered Public Accounting Firm.		
24.1	Power of Attorney. Reference is made to the signature page hereto.		
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) Under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) Under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.		
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.		
101.INS	Inline XBRL Instance Document		
101.SCH	Inline XBRL Taxonomy Extension Schema Document		
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document		
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document		
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document		
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document		
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)		
+ * ^	Indicates management contract or compensatory plan.  Certain portions of this exhibit (indicated by "[***]") have been omitted as the Registrant determined (i) the omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.  Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K.		

# Item 16. Form 10-K Summary

Not applicable.

#### **SIGNATURES**

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

## TALIS BIOMEDICAL CORPORATION

By:

Date: March 22, 2023

/s/ Robert J. Kelley

Robert J. Kelley

Chief Executive Officer

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

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

Name	Title	Date
	Chief Executive Officer and Member of the	
/s/ Robert J. Kelley	Board of Directors (Principal Executive Officer)	March 22, 2023
Robert J. Kelley		
/s/ J. Roger Moody, Jr.	Chief Financial Officer (Principal Financial and Accounting Officer)	March 22, 2023
J. Roger Moody, Jr.		
/s/ Felix Baker, Ph.D.	Member of the Board of Directors	March 22, 2023
Felix Baker, Ph.D.		
/s/ Melissa Gilliam M.D., M.P.H.	Member of the Board of Directors	March 22, 2023
Melissa Gilliam M.D., M.P.H.		
/s/ Rustem F. Ismagilov, Ph.D.	Member of the Board of Directors	March 22, 2023
Rustem F. Ismagilov, Ph.D.		
/s/ Kimberly J. Popovits	Member of the Board of Directors	March 22, 2023
Kimberly J. Popovits		
/s/ Matthew L. Posard	Member of the Board of Directors	March 22, 2023
Matthew L. Posard		
/s/ Randal Scott, Ph.D.	Member of the Board of Directors	March 22, 2023
Randal Scott, Ph.D.		

# **LEASE TERMINATION AGREEMENT**

This Lease Termination Agreement (the "Agreement") dated as of March 16, 2023 ("Effective Date"), is executed by and between WESTPORT OFFICE PARK, LLC, a Delaware limited liability company, ("Landlord"), and TALIS BIOMEDICAL CORPORATION, a Delaware corporation, ("Tenant"), with respect to the following facts and circumstances:

- A. Landlord and Tenant are parties to that certain Lease Agreement dated January 20, 2021, as amended by that certain First Amendment dated as of January 4, 2022 (as amended, the "Lease"), with respect to a portion of the first (1st) floor and the entire second floor of the Building commonly known as 3400 Bridge Parkway, Redwood City, California 94065 (the "Premises"), as more particularly described in the Lease. Capitalized terms used and not otherwise defined herein shall have the meanings given those terms in the Lease.
- B. Although the Lease is scheduled to remain in effect until December 31, 2032, Tenant desires to have the term of the Lease terminate and expire as of the Early Termination Date (as defined below).
- C. Landlord is willing to have the term of the Lease terminate and expire on the Early Termination Date, in accordance with the terms and conditions set forth in this Agreement.

In consideration of the foregoing, and for other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. Early Termination of Lease. Landlord and Tenant hereby agree that the term of the Lease shall terminate and expire as of the close of business on the date (the "Early Termination Date") that is the latest of (i) the date of this Agreement, (ii) the date Tenant pays Landlord the Termination Fee (as defined below) by wire transfer of good funds, (iii) the date upon which the full execution and delivery of a New Lease (as defined below) on terms and conditions satisfactory to Landlord in its sole discretion occurs ("New Lease Condition"), and (iv) the Scheduled Date (as defined below), and the Early Termination Date shall be deemed the expiration date of the Lease for all purposes. If the Early Termination Date shall not have occurred on or before 6:00 p.m. Pacific Time on May 12, 2023 (the "Scheduled Date"), Landlord by written notice to Tenant may terminate this Agreement by delivery of written notice to Tenant at any time prior to the Scheduled Date; provided, however, if the New Lease Condition is not satisfied, Landlord shall provide such written notice no later than March 31, 2023. Landlord in its sole discretion may elect to waive the conditions in clauses (ii) and (iii) of this Section 1, but such waiver shall not be a waiver or release of Tenant's obligation to pay the initial payment or any other portion of the Termination Fee as and when required under Section 2, below, and require that Tenant vacate the Premises on or before the Vacating Date (as defined below). If, despite Tenant's commercially reasonable efforts, Kriya Therapeutics, Inc., as sublessor, and Tenant, as sublessee, have not executed and delivered a Sublease with respect to certain

subleased premises located at 1100 Island Drive, Suite 101, Redwood City, California, on terms and conditions satisfactory to Tenant in its reasonable discretion, by March 31, 2023, and/or if Landlord has not consented in writing to such Sublease, Tenant may terminate this Agreement by delivery of written notice of termination to Landlord no later than the Scheduled Date, in which event the Lease shall not terminate on the Early Termination Date pursuant to the terms above and the Lease shall continue in full force and effect as if this Agreement had not been executed.

- 1.1 For avoidance of doubt, if this Agreement terminates pursuant to the provisions of Section 1 above, then this Agreement shall be void and of no force or effect EXCEPT that if Landlord has received the Termination Fee referred to below, then the provisions of the last sentence of Section 2.1 below shall apply. The provisions of the immediately preceding sentence and the provisions of the last sentence of Section 2.1 below shall survive the termination of this Agreement and remain in full force and effect following the termination of this Agreement pursuant to Section 1 above.
- On or before the later of (i) the date seven (7) weeks following the date Landlord notifies Tenant in writing that the New Lease Condition has been satisfied (or waived by Landlord) and (ii) the Scheduled Date (such later date being referred to herein as the "Vacating Date"), Tenant shall (x) surrender to Landlord all right, title and interest of Tenant in the Premises (and the Lease), (v) vacate and surrender the Premises, broom clean, in good condition and repair, reasonable wear and tear excepted and (z) remove from the Premises Tenant's furniture, furnishings and equipment in accordance with Section 3 below and repair any damage to the Premises or Building arising from such removal. In the event the expiration date of the seven (7) week period referred to in clause (i) above extends beyond the Scheduled Date, then Tenant shall be deemed holding over in the Premises with Landlord's consent for the period (hereinafter referred to as the "Consent Holdover Period") commencing on May 13, 2023 and ending on the earlier of (A) the date Tenant complies with the terms of clauses (x), (y) and (z) above or (B) the expiration of the seven (7) week period referred to above, and during such Consent Holdover Period, the applicable terms, covenants and conditions of the Lease shall apply, including Tenant's obligation to pay to Landlord any Base Rent or Additional Rent, including, without limitation, any Operating Expenses or Taxes, during or allocable to the Consent Holdover Period; it being understood and agreed that during such Consent Holdover Period, Tenant's obligation to pay Base Rent and Additional Rent shall be at the same rate and terms as if the Lease had not vet terminated (and shall not be at the [\*\*\*] percent ([\*\*\*]%) rate set forth in Section 31.1 of the Lease). In the event that Tenant fails to vacate the Premises and surrender and deliver exclusive possession of the Premises to Landlord on or before the Vacating Date in accordance with the terms of this Agreement, then, following the Vacating Date and until Tenant vacates the Premises and surrenders and delivers exclusive possession of the Premises to Landlord, Tenant shall be deemed to be in holdover of the Premises without Landlord's consent and shall be subject to the terms of Article 31 of the Lease (except that for purposes of this sentence and application of Article 31 of the Lease to this sentence, the holdover period shall be deemed to commence on the day following the Vacating Date and clause (a) of the fifth sentence of Article 31 of the Lease shall be deemed deleted and the following shall be deemed substituted in place thereof: "(a) the date that is the Vacating Date, or").
  - 2. <u>Termination Fee</u>.

- 2.1 In consideration of Landlord's agreement to the expiration and termination of the Lease as of the Early Termination Date as provided in this Agreement, Tenant agrees to pay to Landlord, in good funds, within three (3) business days following the Effective Date, the amount of [\*\*\*] Dollars (\$[\*\*\*]) (the "Termination Fee"), in the same manner rent is paid under the Lease. If this Agreement is terminated pursuant to the terms of Section 1, then, to the extent Landlord has received the Termination Fee referred to above, Landlord shall refund such Termination Fee to Tenant within seven (7) business days following the termination of this Agreement and if Landlord fails to refund the entire Termination Fee to Tenant within such seven (7) business day period, then, without waiving any of Tenant's rights or remedies arising from Landlord's failure, Landlord shall credit to Tenant against Base Rent and Additional Rent next coming due under the Lease the balance of the Termination Fee that has not be refunded to Tenant until fully credited.
- 2.2 Tenant acknowledges that the early expiration and termination of the term of the Lease and Landlord's agreement to accept the Termination Fee is a valuable contemporaneous exchange of consideration for the release of Tenant from potential future rent and other obligations accruing under the Lease from and after the Early Termination Date that, but for the expiration and termination of the term of the Lease, Tenant would still be obligated to perform, including, without limitation, the payment of Rent, provided for in the Lease.
- 2.3 Landlord and Tenant agree that if there is a disgorgement of any portion of the Termination Fee or the avoidance in whole or in part of this Agreement, under any applicable law, including, but not limited to, chapter 5 of title XI of the United States Code, shall be considered a breach of this Agreement by Tenant and shall entitle Landlord to seek and recover from Tenant damages to the extent provided in the Lease (without giving effect to the terms of Section 1 of this Agreement and as if the Lease had not terminated pursuant to the terms of this Agreement) less any portion of the Termination Fee that is and will be retained by Landlord.
- 2.4 Landlord shall continue to hold the Letter of Credit in the amount of \$[\*\*\*] under the Lease (the "Letter of Credit"). From and after the Early Termination Date, Landlord shall continue to hold the Letter of Credit as security for Tenant's obligations under this Agreement and the Lease. The Letter of Credit is not an advance payment of any kind or a measure of Landlord's damages in case of any default by Tenant in the obligation to pay the Termination Fee or perform its other obligations under this Agreement. If Tenant fails to perform any of the covenants of this Agreement or the Lease (as modified by this Agreement) to be performed by Tenant, including without limitation the provisions relating to payment of the Termination Fee, payment of amounts due under the Lease (as modified by this Agreement), the removal of property from the Premises by the Vacating Date, the repair of any damage to the Premises caused by Tenant and any failure to deliver the Premises in the condition required by this Agreement, then Landlord shall have the right, but no obligation, to draw upon the Letter of Credit, or so much thereof as may be necessary, for the payment of any unpaid Termination Fee and/or to cure any other failure by Tenant. If Landlord draws upon the Letter of Credit or any part thereof for payment of such amounts or to cure any such other failure by Tenant, then Tenant shall either pay to Landlord on demand the cash amount so applied in order to restore the draw proceeds to the full amount thereof immediately prior to such application or cause the Letter of Credit to be replenished to its full amount thereunder. Landlord's obligations with respect to the Letter of Credit are those of a debtor and not a trustee. Landlord and Tenant agree

that this Agreement does not constitute a Lease and, accordingly, the Letter of Credit shall not constitute a security deposit and no provisions of law, including without limitation California Civil Code Section 1950.7, with respect to security deposits under leases shall apply to the Letter of Credit. If Tenant performs every provision of this Agreement and the Lease (as modified by this Agreement) to be performed by Tenant, the Letter of Credit shall be released to Tenant not later than the later of (i) the date thirty (30) days following payment in full of the Termination Fee or (ii) the date five (5) business days following the date Tenant complies with the terms of clauses (x), (y) and (z) of Section 1.2 above. Tenant hereby irrevocably directs Landlord to retain the Letter of Credit in accordance with the terms of this Section 2.4 above as a deposit to secure Tenant's obligations under this Agreement and the Lease (as modified by this Agreement) in lieu of Tenant receiving a return of the Letter of Credit. Tenant hereby grants Landlord a security interest in the Letter of Credit.

- 2.5 All payments of the Termination Fee shall be payable at such address as Landlord may specify from time to time by written notice delivered in accordance with the Lease. If Tenant fails to pay any installment of the Termination Fee within five (5) days after its due date (each, a "Termination Fee Event of Default"), Tenant shall pay Landlord a late charge equal to [\*\*\*] percent ([\*\*\*]%) of the amount due plus any attorneys' fees incurred by Landlord by reason of Tenant's failure to pay the Termination Fee when due hereunder to compensate Landlord for the extra cost incurred as a result of such late payment. The parties agree that the late charge represents a fair and reasonable estimate of the administrative, processing and accounting costs that Landlord will incur as a result of a late payment of any installment of the Termination Fee by Tenant. In addition to the late charge. Landlord shall have the right to charge interest on the past due payment of any installment of any Termination Fee at an annual interest rate of [\*\*\*] percent ([\*\*\*]%) per annum (but not in excess of the maximum legal rate permitted by law). Upon a Termination Fee Event of Default, Landlord may, at its option, without notice to Tenant, declare the remaining installments of the Termination Fee to be, and thereafter the whole sum of the Termination Fee shall forthwith become, due and payable. In addition to the rights, powers and remedies given in this Agreement or the Lease, Landlord may, in its sole and absolute discretion, at any time and from time to time, exercise any and all rights and powers to pursue any and all remedies now or hereafter given by law or equity. The failure to exercise, in case of one or more Termination Fee Events of Default, any right or remedy given in this Agreement, the Lease or by law or equity shall not preclude Landlord from exercising any right or remedy given in this Agreement, the Lease or by law or equity in case of one or more subsequent Termination Fee Events of Default. If an action is instituted on this Agreement by Landlord against Tenant, Tenant agrees to pay all costs of collection, including court costs and attorneys' fees in so collecting or attempting to so collect any amounts due by Tenant under this Agreement. The provisions of this Section 2.5, including without limitation Tenant's obligation to pay the Termination Fee, shall survive the expiration or earlier termination of the Lease Term.
- 3. Removal of Personal Property. As further consideration of Landlord's agreement to terminate the Lease, Tenant hereby sells, transfers and conveys to Landlord, and agrees to surrender with the Premises, on the Vacating Date (or earlier in Tenant's sole discretion), the furniture and other personal property set forth in Exhibit A attached hereto and incorporated herein by this reference (the "FF&E"), free and clear of all liens. Upon request by Landlord, on or after the Vacating Date Tenant shall execute a separate bill of sale to Landlord or Landlord's designee confirming the transfer of all right, title and interest of Tenant in the FF&E, but failure

to execute and deliver that bill of sale shall not limit the effectiveness of the conveyance provided for in this paragraph. Not later than the Vacating Date, Tenant shall remove all personal property and equipment remaining on the Premises other than the FF&E, in accordance with all applicable laws, at Tenant's sole cost and expense. Tenant shall vacate and surrender the Premises to Landlord no later than the Vacating Date in the condition required under this Agreement.

- 4. New Lease. This Agreement is conditioned upon Landlord entering into a new lease of the Premises with a third party tenant ("New Tenant") on terms and conditions satisfactory to Landlord in its sole discretion (the "New Lease"). This condition is solely for the benefit of Landlord. Unless Landlord waives this condition, if the New Lease has not been executed by Landlord and New Tenant prior to the Scheduled Date, Landlord may elect to terminate this Agreement by written notice to Tenant on or before the Scheduled Date, in which event this Agreement shall be null and void and of no force or effect (except that Landlord shall refund to Tenant the Termination Fee (to the extent such Termination Fee was paid to Landlord), in accordance with Section 2 above) and the Lease shall continue in full force and effect as if this Agreement had not been executed. The provisions of the immediately preceding sentence shall survive the termination of this Agreement pursuant to the terms of the immediately preceding sentence, if applicable.
- 5. Outstanding Rent and Other Charges. Tenant shall pay to Landlord all Rent and other charges specified in the Lease, including without limitation Tenant's Share of Operating Expenses, through the Early Termination Date. Any charges which cannot be ascertained prior to the Early Termination Date shall be estimated in good faith by Landlord and Tenant shall pay such estimated amount. All such amounts shall be used and held by Landlord for payment of such obligations of Tenant, with Tenant being liable for any additional costs upon demand by Landlord, or with any excess to be returned to Tenant after all such obligations have been expeditiously determined by Landlord and satisfied (which obligations shall expressly survive a termination of the Lease).

# 6. Releases.

Except for (i) Tenant's liability under the Lease for any rent payable with respect to the period prior to the Early Termination Date, including without limitation, Tenant's obligation to pay any unpaid additional rent, (ii) any obligation of Tenant which by the terms of the Lease survives the expiration or earlier termination of the Lease, (iii) the terms and conditions of the Lease, as modified by the provisions of Section 1.2 above, which require payment of rent or increased rent for any time period in which Tenant "holds over" or continues to occupy the Premises beyond the term of the Lease and/or provide for Tenant's liability for damages or indemnification by Tenant in connection with any such hold over or continued occupancy, (iv) the payments required to be made by Tenant pursuant to Section 2, above, and (v) Tenant's obligations under this Agreement with respect to the condition in which the Premises is to be delivered to Landlord on or before the Vacating Date (collectively, the "Excluded Claims"), effective upon the later of (a) the Early Termination Date, or (b) the date that is ninety-one (91) days after Landlord receives the full amount of the Termination Fee, Landlord forever releases and discharges Tenant from any and all rights, causes of action, actions, judgments, liens, indebtedness, damages, losses, claims, claims in bankruptcy, liabilities,

and demands of every kind and character in any way related to or arising from the Lease; <u>provided however</u>, that the conditional release granted by Landlord in this Section 6.1 shall: (x) at all times be subject to the provisions of Section 6.3 of this Agreement and (y) not become effective and shall be null and void if a Bankruptcy Event (as defined in Section 6.3 below) with respect to Tenant occurs on or before the ninetieth (90th) day after Landlord's receipt of the Termination Fee. Consistent with the foregoing conditional release (which does not include the Excluded Claims), Landlord expressly and voluntarily waives and relinquishes all rights and benefits under Section 1542 of the California Civil Code if in any way applicable to this Agreement. Section 1542 of the California Civil Code provides as follows:

"GENERAL RELEASE --CLAIMS EXTINGUISHED: A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY"

Landlord /s/ Jessica Brock Tenant /s/ Roger Moody

It is understood by Landlord that if the facts or law with respect to which the foregoing conditional release is given hereafter turn out to be other than or different from the facts or law in that connection not known to be or believed by Landlord to be true, then Landlord hereto expressly assumes the risk of the facts or law turning out to be so different, and agrees that the foregoing conditional release shall be in all respects effective and not subject to termination or rescission based upon such differences in facts or law.

6.2 Effective upon the earlier of (i) the Vacating Date or (ii) the date Tenant complies with clauses (x), (y) and (z) of Section 1.2 above, Tenant forever releases and discharges Landlord from any and all rights, causes of action, actions, judgments, liens, indebtedness, damages, losses, claims, claims in bankruptcy, liabilities and demands of every kind and character in any way related to or arising from the Lease. Without limiting the foregoing, Tenant represents that Landlord has not failed to perform (other than with respect to the installation of [\*\*\*] serving the Premises, which Landlord will install promptly following delivery of such [\*\*\*] in accordance with the Lease), and is not in any respect in default or otherwise liable in the performance of, any of its obligations under the Lease, nor in connection with the negotiation and execution of the Lease, the administration of the Lease, and the leasing, operations, or management of the Building. Consistent with the foregoing unconditional release, Tenant expressly and voluntarily waives and relinquishes as of the earlier of the dates in clauses (i) and (ii) of this Section 6.2, all rights and benefits under Section 1542 of the California Civil Code if in any way applicable to this Agreement. Section 1542 of the California Civil Code provides as follows:

"GENERAL RELEASE --CLAIMS EXTINGUISHED: A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY."

Landlord Tenant
/s/ Jessica Brock /s/ Roger Moody

It is understood by Tenant that if the facts or law with respect to which the foregoing release is given hereunder turn out to be other than or different from the facts or law in that connection not known to be or believed by Tenant to be true, then Tenant hereto expressly assumes the risk of the facts or law turning out to be so different, and agrees that the foregoing release shall be in all respects effective and not subject to termination or rescission based upon such differences in facts or law.

- 6.3 The parties agree (and Tenant acknowledges Landlord's express reliance thereon) that upon (i) Tenant filing a voluntary petition or becoming the subject of an involuntary petition seeking reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any present or future federal, state or foreign act or law relating to bankruptcy or insolvency, including without limitation, Chapters 7 and 11 of the United States Bankruptcy Code (collectively and each individually, a "Bankruptcy Event"), and (ii) the initiation in any such proceeding of an action to avoid or recover the payments made to Landlord under this Agreement (including, without limitation, the Termination Fee) pursuant to the provisions of Chapter 5 of the Bankruptcy Code or any similar state or foreign law, the release set forth in Section 6.1 above, at Landlord's election, shall be null and void and Landlord shall retain any and all claims that may exist under the Lease or otherwise against Tenant.
- Representations of Tenant. Tenant represents and warrants to Landlord, as of the Effective Date and as of the Early Termination Date, that (a) Tenant has not assigned or sublet all or any portion of its interest in the Premises under the Lease; (b) no other person, firm or entity has any right, title or interest in the Premises under the Lease; (c) Tenant has the full right, legal power and actual authority to enter into this Agreement without the consent of any person, firm or entity; (d) the individual(s) executing this Agreement on behalf of Tenant has the full right, legal power and actual authority to bind Tenant to the terms and conditions hereof, (e) as of the Effective Date, Tenant is not insolvent, (f) neither the payment of the Termination Fee nor the performance of any other obligation of Tenant under this Agreement shall cause Tenant to become insolvent, and (g) as of the Early Termination Date, there will be no mechanic's liens on account of work performed at the Premises or in the Building by Tenant or on Tenant's behalf or other liens encumbering all or any portion of the Premises, by virtue of any act or omission on the part of Tenant, its contractors, agents, employees, successors or assigns. Notwithstanding the termination of the Lease and the release of liability provided herein, the representations and

warranties set forth in this Section 7 shall survive the Early Termination Date and Tenant and the individuals executing this Agreement on behalf of Tenant shall be liable to Landlord for any inaccuracy or any breach thereof.

- 8. <u>Certain Provisions No Longer Effective</u>. Upon the full execution and delivery of this Agreement by Landlord and Tenant, the following rights of Tenant under the Lease (to the extent any are contained in the Lease) shall terminate and be of no further force or effect: any right to assign or transfer the Lease, any right to sublet or otherwise transfer any portion of the Premises, any right to extend the term of the Lease, any right to lease additional space in the Project, any rights to perform alterations in the Premises (except in connection with performing Tenant's obligations under this Agreement, but in that case all such alterations must be performed in accordance with the requirements of the Lease), and any restrictions on the use of portions of the Project other than the Premises; provided, however, if this Agreement terminates pursuant to Section 1 or Section 4 above, then the provisions of this Section 8 shall be void and of no force or effect.
- 9. <u>Brokers</u>. Landlord shall not be liable or responsible for any broker's and finder's fees in connection with any subleasing activities by Tenant on the Premises nor for any commission or other agreements between Tenant and any broker or finder
- 10. <u>No Other Modification</u>. Except as expressly modified by this Agreement, the Lease remains in full force and effect.
- 11. <u>Further Assurances</u>. Each party hereto shall execute, acknowledge and deliver to each other party all documents, and shall take all actions, reasonably required by such other party from time to time to confirm or effect the matters set forth herein, or otherwise to carry out the purposes of this Agreement.
- 12. <u>Attorneys' Fees</u>. In the event that any litigation shall be commenced concerning this Agreement by any party hereto, the party prevailing in such litigation shall be entitled to recover, in addition to such other relief as may be granted, its reasonable costs and expenses, including without limitation reasonable attorneys' fees and court costs, whether or not taxable, as awarded by a court of competent jurisdiction.
- 13. <u>Miscellaneous</u>. This Agreement shall bind, and shall inure to the benefit of, the successors and assigns of the parties. This document may be executed in counterparts with the same force and effect as if the parties had executed one instrument, and each such counterpart shall constitute an original hereof. No provision of this Agreement that is held to be inoperative, unenforceable or invalid shall affect the remaining provisions, and to this end all provisions hereof are hereby declared to be severable. Time is of the essence of this Agreement. This Agreement contains all of the covenants, conditions and agreements between the parties regarding the subject matter hereof and shall supersede all prior correspondence, agreements and understandings, both oral and written. This Agreement shall be governed by the laws of the State of California. The headings of articles, sections or paragraphs herein are for convenience only and shall not be relevant for purposes of interpretation of the Lease.

- 14. <u>Non-Disclosure of Terms</u>. Tenant acknowledges and agrees that the terms of this Agreement are confidential and constitute proprietary information of Landlord and that disclosure of the terms of this Agreement could adversely affect the ability of Landlord to deal with other leases and impair Landlord's relationship with other tenants. Accordingly, Tenant agrees that it, and its partners, officers, directors, employees, agents, accountants and attorneys, shall not intentionally and voluntarily disclose the terms and conditions of this Agreement to any other tenant or any person unless required by law, governmental agency (including, without limitation, the United States Securities and Exchange Commission), governmental regulation, court order or other civil process such as a subpoena.
- 15. <u>Estoppel</u>. As additional consideration to this Agreement, Tenant hereby certifies that (a) the Lease is in full force and effect, (b) to Tenant's knowledge there currently are no uncured defaults on the part of Landlord or Tenant under the Lease; however, Landlord is required to install a permanent backup generator serving the Premises and intends to perform such installation following delivery of such generator in accordance with the Lease, and (c) there currently are no existing offsets or defenses which Tenant has against the enforcement of the Lease by Landlord.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the Effective Date.

## LANDLORD:

WESTPORT OFFICE PARK, LLC, a Delaware limited liability company

By /s/ Jessica Brock
Name Jessica Brock
Title Authorized Signatory

## **TENANT:**

TALIS BIOMEDICAL CORPORATION, a Delaware corporation

By /s/ Roger Moody
Name Roger Moody
Title CFO

By /s/ Gillian Green
Name Gillian Green
Title Secretary

[Printed Name and Title]

If Tenant is a corporation, this instrument must be executed by the chairman of the board, the president or any vice president and the secretary, any assistant secretary, the chief financial officer or any assistant financial officer or any assistant treasurer of such corporation, unless the bylaws or a resolution of the board of directors shall otherwise provide, in which case the bylaws or a certified copy of the resolution, as the case may be, must be attached to this instrument.

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

#### **SUBLEASE**

#### 1100 Island Drive, Suite 101, Redwood City, CA 94065

This Sublease ("Sublease"), dated March 16, 2023 ( "Execution Date"), is entered into by and between Kriya Therapeutics, Inc., a Delaware corporation ("Sublandlord"), and Talis Biomedical Corporation, a Delaware corporation ("Subtenant").

## 1. BASIC SUBLEASE PROVISIONS

- 1.1. **Sublease Premises**. The Sublease Premises is located at 1100 Island Drive, Redwood City, CA ("**Building**"). The Sublease Premises demised hereunder consist of approximately 13,165 rentable square feet, located in Suite 101 on the first (1st) floor of the Building, and represents the entire premises demised to Sublandlord pursuant to the Master Lease and referred to in the Master Lease as the "Relocation Space" (the "**Master Premises**"). The Sublease Premises are depicted on **Exhibit A** to this Sublease.
  - 1.2. Master Landlord. Westport Office Park, LLC, a Delaware limited liability company
- 1.3. **Master Lease**. Lease dated on or about July 24, 2020, as amended by that First Amendment to Lease (Relocation) dated April 8, 2022. A redacted copy of the Master Lease is attached hereto as **Exhibit B**.
- 1.4. **Sublease Term**. Approximately seven (7) years and one (1) month, beginning on the Sublease Commencement Date and ending on the Expiration Date, unless this Sublease is sooner terminated pursuant to its terms or the Master Lease is sooner terminated pursuant to its terms.
- 1.5. **Sublease Commencement Date**. The later of: (i) May 1, 2023; and (ii) the date Master Landlord's written Consent (as defined below) to this Sublease is obtained, (iii) the date the Westport Contingency (as defined in Section 2.1(a) is satisfied or waived in writing by Subtenant; and (iv) the date Sublandlord delivers the Sublease Premises to Subtenant in vacant, broom clean condition and with the Relocation Improvements (as defined in the aforementioned First Amendment to Lease (Relocation)) Substantially Completed (as defined in the Relocation Space Work Letter attached as Exhibit C to the First Amendment to Lease (Relocation)) in accordance with the Approved Working Drawings (as defined in such Exhibit C to the First Amendment to Lease (Relocation).
  - 1.6. Expiration Date. May 31, 2030

# 1.7. Monthly Base Rent.

Months	Monthly Rent/RSF	Monthly Rent	Annual Rent
1-2*	Abated	\$0.00	N/A
3-10	\$7.95	\$104,661.75	N/A
11-22	\$8.23	\$108,324.91	\$1,299,898.92
23-34	\$8.52	\$112,116.28	\$1,345,395.36
35-46	\$8.81	\$116,040.35	\$1,392,484.20
47-58	\$9.12	\$120,101.77	\$1,441,221.24
59-70	\$9.44	\$124,305.33	\$1,491,663.96
71-82	\$9.77	\$128,656.01	\$1,543,872.12
83-Expiration Date	\$10.11	\$133,158.97	\$1,597,907.64

\*Base Rent for the first two (2) calendar months of the Sublease Term shall be abated, subject to the remaining provisions of this paragraph. For the avoidance of doubt, Subtenant shall pay all Additional Rent and Other Charges (as defined in Sections 4.3 and 4.4 below) due in connection with this Sublease during such abatement period. Notwithstanding anything set forth in this paragraph to the contrary, if Subtenant Defaults, and such Default results in the termination of the Sublease, then Sublandlord shall be entitled to recover, in addition to any other amounts due from Subtenant, the unamortized amount of the abated Base Rent, amortized on a straight-line basis over the Sublease Term.

#### 1.8. Subtenant's Share of Master Premises. 100%

1.9. **Subtenant's Use**. General office purposes, research and development, lab and general administrative uses consistent with the Master Lease. Notwithstanding the foregoing, Subtenant's Use may include manufacturing of R&D product, subject to Master Landlord's prior written approval.

## 1.10. Subtenant's Address.

Prior to the Sublease Commencement Date:

3400 Bridge Parkway Redwood City, CA 94065 Attention: Legal Department

With a copy to:

1375 West Fulton Market, Suite 700 Chicago, IL 60607 Attention: CEO

After the Sublease Commencement Date:

The Sublease Premises Attn: Office Manager

With copy to:

3400 Bridge Parkway Redwood City, CA 94065 Attention: Legal Department

and:

1375 West Fulton Market, Suite 700 Chicago, IL 60607 Attention: CEO

## 1.11. Sublandlord's Address.

Kriya Therapeutics, Inc. 3790 El Camino Real, Unit #614 Palo Alto, CA 94306

With an email copy to: legal@kriyatx.com

- 1.12. Letter of Credit. \$738,202.37 in the form of a letter of credit.
- 1.13. **Parking**; **Maximum Parking Allocation**. Forty-three (43) spaces, which is based on a ratio of 3.3 non-exclusive parking spaces per one thousand (1,000) square feet of rentable space in the Premises, at no additional cost.

#### 1.14. Brokers. For Sublandlord: Cushman & Wakefield

For Subtenant: Cornish & Carey Commercial dba Newmark Knight Frank

#### 1.15. Deliverables.

a. \$[\*\*\*], for the first full month of Base Rent due on Subtenant's Sublease

execution.

- b. The Letter of Credit, due no later than (5) days following receipt of the Consent from Master Landlord.
- c. Insurance certificates, due on the earlier of the Sublease Commencement Date and the Early Access Date.
- 1.16. <u>Definitions</u>. Each of the terms in the Basic Sublease Provisions are used in this Sublease as defined terms and have the meanings given in such sections. Other capitalized words and phrases for which no definition is given in this Sublease shall have the meanings given them in the Master Lease. Unless otherwise indicated, all section references are to the sections of this Sublease.

## 2. DEMISE OF SUBLEASE PREMISES

- 2.1. Sublandlord hereby subleases to Subtenant, and Subtenant hereby subleases from Sublandlord, the Sublease Premises upon and subject to the terms and conditions set forth in this Sublease, including, without limitation, the conditions set forth in Section 2.1(a) below. Sublandlord and Subtenant agree that the rentable area of the Sublease Premises for purposes of this Sublease shall be deemed to be the number of rentable square feet set forth in Section 1.1 of the Basic Sublease Provisions and shall not be subject to remeasurement except to the extent adjusted pursuant to the Master Lease. Subtenant also shall have the non-exclusive right from the Early Access Date through the expiration or earlier termination of the Sublease Term, as the same may be extended, to use in common with other tenants in the Project, the Common Areas (as defined in Section 1.3 of the Master Lease). Subtenant's right to use such Common Areas shall be to the same extent that Sublandlord has the right to use such Common Areas pursuant to the terms of the Master Lease.
- The Sublease Commencement Date hereunder is expressly conditioned upon (i) on or before March 31, (a) 2023, Westport Office Park, LLC ("Westport"), as landlord, and Subtenant, as tenant, entering into a Lease Termination Agreement with respect to a portion of the first floor and the entire second floor of the building commonly known as 3400 Bridge Parkway in Redwood City, California (the "3400 Premises"), and (ii) on or before May 12, 2023, Westport entering into a new lease of the 3400 Premises with a third party tenant on terms and conditions satisfactory to Westport (collectively, the "Westport Contingency"). If any of the conditions referred to in clauses (i) or (ii) of the immediately preceding sentence are not satisfied (or waived in writing by Subtenant) on or before the applicable outside date for satisfaction of such applicable condition, then Subtenant shall have the right to terminate this Sublease by giving written notice of such termination to Sublandlord (the "Termination Notice"), which Termination Notice shall include a representation by Subtenant that the conditions set forth in this Section 2.1(a) are not satisfied, in which event this Sublease shall be void and of no force or effect, Sublandlord shall promptly return to Subtenant the Letter of Credit and prepaid Base Rent delivered to Sublandlord (and Subtenant shall remove from the Sublease Premises any and all equipment, furniture, personal property, telecommunications equipment and leasehold improvements, if any, that Subtenant has placed, constructed or installed, or caused to be placed, constructed or installed, in the Sublease Premises. 16.1). If Subtenant does not deliver the Termination Notice by May 15, 2023, then this Sublease shall continue in full force and effect. This Sublease and the obligations of the parties hereunder also are expressly conditioned upon Sublandlord's obtaining the prior written consent of Master Landlord to this Sublease as provided in Section 16.1 below. Sublandlord shall have the right to condition providing Subtenant with access to the Sublease Premises upon Subtenant's delivery of written notice confirming that the Westport Contingency has been satisfied or

#### waived.

- 2.2. Subject to Sublandlord first obtaining Master Landlord's written consent and Subtenant's delivery of the Deliverables described in Section 1.15 to Sublandlord, Subtenant may access the Sublease Premises for the sole purpose of moving in and installing its equipment, furniture, personal property and telecommunication equipment (and also for the purpose of constructing or installing in the Sublease Premises any or all of the leasehold improvements referred to on <a href="Exhibit E">Exhibit E</a> attached hereto, subject, however, to Master Landlord and Sublandlord first consenting in writing (which may be via email or facsimile) to the construction or installation of such leasehold improvements in the Sublease Premises). Such possession shall be subject to all of the terms and conditions of this Sublease (including, without limitation, the obligation to deliver any insurance certificates required herein, and the indemnity obligations of Subtenant), except that Subtenant shall not be required to pay Rent during such early entry period. The date upon which Sublandlord actually delivers the Sublease Premises to Subtenant for the early entry period described herein shall be the "Early Access Date", and Subtenant shall coordinate such entry into the Sublease Premises with Sublandlord. Subtenant shall indemnify, defend, protect, and hold harmless the Sublandlord Parties from any and all loss, cost, damage, expense and liability (including without limitation court costs and reasonable attorneys' fees) incurred as a result of or arising from Subtenant's actions or access to the Sublease Premises pursuant to this Section 2.2; provided, however, such indemnification, defense, protection and hold harmless obligation of Subtenant shall not apply to any loss, cost, damage, expense or liability (including, without limitation, court costs and reasonable attorneys' fees) resulting from or caused by the gross negligence or willful misconduct of Master Landlord or Sublandlord or any of their respective agents, employees, affi
- 2.3. Notwithstanding anything to the contrary, if as of the date that Sublandlord would otherwise deliver possession or early access of the Sublease Premises to Subtenant, Subtenant has not delivered to Sublandlord the Deliverables described in Section 1.15, then Sublandlord will have no obligation to deliver possession or early access of the Sublease Premises to Subtenant, but the failure on the part of Sublandlord to so deliver possession or early access of the Sublease Premises to Subtenant in such event will not serve to delay the occurrence of the Sublease Commencement Date or the Early Access Date, or affect the commencement of Subtenant's obligations to pay Rent set forth in this Sublease.
- 2.4. Sublandlord may enter any part of the Sublease Premises at all reasonable hours, upon not less than one (1) full business day's prior notice except in the case of an emergency affecting the health or safety of persons or property, in which case no prior notice shall be required (a) to inspect, test, clean, or make repairs, alterations and additions to the Sublease Premises as Sublandlord believes appropriate,
- (b) post notices of non-responsibility, (c) to show the Sublease Premises to prospective lenders and purchasers, (d) to show the Sublease Premises to prospective subtenants or assignees at any time during the last six (6) months of the Sublease Term, (e) when Subtenant is in default beyond the applicable notice and cure periods hereunder, and/or, (e) if the Sublease Premises are permanently vacated by Sublessee, to prepare them for reoccupancy. Sublandlord shall take reasonable measures not to unreasonably interfere with Subtenant's operations in connection with such entries and shall comply with Subtenant's reasonable security requirements while in the Sublease Premises, or applicable part thereof.
- 2.5. Provided Subtenant is not in default hereunder, (i) Subtenant shall acquire furniture located in the Sublease Premises as of the Early Access Date (the "Existing Furniture") for the amount of [\*\*\*] (\$[\*\*\*]), which Existing Furniture is more particularly identified on Exhibit "X" attached to the bill of sale referred to below, (ii) Subtenant shall remove the Existing Furniture from the Sublease Premises in accordance with the terms of the Master Lease at Subtenant's sole cost and expense upon or prior to the Expiration Date, and (iii) Sublandlord shall transfer its interest in the Existing Furniture to Subtenant on an "as-is" basis, without any representations or warranties and such transfer shall be memorialized in a bill of sale in the form of Exhibit D (which bill of sale shall be executed by Sublandlord and delivered to Subtenant on the Early Access Date). Subtenant acknowledges that Sublandlord has made no representations or warranties whatsoever with respect to the Existing Furniture including, without limitation, with respect to the ownership, working order of the Existing Furniture or fitness of the Existing Furniture for a particular purpose, and Subtenant further acknowledges that Sublandlord shall have no obligation to alter, maintain,

repair, dis-assemble, re-assemble, move or install the Existing Furniture. Subtenant shall be responsible for any tax assessed upon the transfer of ownership of the Existing Furniture from Sublandlord to Subtenant.

2.6. Sublandlord hereby agrees that during the period commencing on the date Sublandlord delivers the Sublease Premises to Subtenant and ending on the Early Access Date and also during the Sublease Term, casework currently situated in the lab portion of the Sublease Premises may be used by Subtenant at no additional charge to Subtenant.

#### 3. SUBLEASE TERM

- 3.1. The Sublease Term shall commence on the Sublease Commencement Date. Promptly following Sublandlord's request therefor (which request shall not be made prior to the Sublease Commencement Date), Subtenant agrees to execute a Sublease Commencement Date Certificate for the Sublease Premises in the form attached as **Exhibit C** setting forth the actual Sublease Commencement Date and the Expiration Date. In the event Subtenant fails to execute such Sublease Commencement Date Certificate within ten (10) business days following delivery thereof to Subtenant, Subtenant shall be deemed to have approved all of the matters set forth in such certificate and such certificate shall be fully binding on Subtenant.
- 3.2. If for any reason Sublandlord is delayed in delivery of the Sublease Premises to Subtenant with the Relocation Improvements Substantially Completed, Sublandlord shall not be liable therefor, nor shall such failure affect the validity of this Sublease or the obligations of Subtenant hereunder, or extend the Expiration Date, but in such case the Sublease Commencement Date will not occur and Subtenant shall not be obligated to pay Rent until possession of the Sublease Premises with the Relocation Improvements Substantially Completed are tendered to Subtenant and Master Landlord has consented to this Sublease.
- 3.3. Unless sooner terminated or extended as provided herein, the Sublease Term shall end on the Expiration Date. However, the Sublease may be terminated prior to the Expiration Date if the Master Lease is terminated for any cause whatsoever (provided Master Landlord does not require Subtenant to attorn) or if this Sublease is terminated as otherwise provided for herein and in either such case the Sublease Term shall end upon such earlier termination. Subtenant shall have no option to elect an early termination of the Sublease Term. Sublandlord and Subtenant acknowledge and agree that notwithstanding the fact this Sublease demises the Sublease Premises for approximately the remainder of the term of the Master Lease, this Sublease shall be deemed to be a 'sublease' and not an 'assignment.'

## 4. RENT

- 4.1. The rent payable by Subtenant for the Sublease Premises shall consist of the Base Rent under Section 4.2, Additional Rent under Section 4.3 and Other Charges under Section 4.4. Base Rent, Additional Rent, Other Charges and any other sums payable by Subtenant under this Sublease are collectively referred to as "Rent." Subtenant's covenant to pay Rent shall be independent of every other covenant in this Sublease. Subtenant shall make all payments due to Sublandlord pursuant to this Sublease as follows: check, wire, or other form of payment specified in writing by Sublandlord from time to time.
- 4.2. Beginning on the Sublease Commencement Date (subject to Section 1.7) and continuing thereafter on the first day of each calendar month during the Sublease Term, Subtenant shall pay to Sublandlord in advance, and without notice, demand, deduction or offset, the monthly Base Rent specified in Section 1.7 above in lawful money of the United States of America. If the Sublease Commencement Date is a day other than the first day of a calendar month or the Expiration Date is a day other than the last day of a calendar month, the Base Rent for such month will be prorated, based on a thirty (30) day month. Subtenant shall deliver in advance the first full month of Base Rent to Sublandlord together with Subtenant's executed counterpart of this Sublease.

In addition to monthly Base Rent, as additional rent ("Additional Rent") Subtenant shall be responsible for paying to Sublandlord Subtenant's Share of any Operating Expenses and Taxes (collectively, "Direct Expenses") as such terms are defined in the Master Lease, payable by Sublandlord under the Master Lease during the Sublease Term, to reimburse Master Landlord for taxes, insurance, operating expenses, common area maintenance charges, management fees, capital expenditures for required repairs or improvements and/or other expenses included in Direct Expenses. Sublandlord will use commercially reasonable efforts to pass through to Subtenant in a timely manner any statement or estimate of Direct Expenses received from Master Landlord. To the extent Direct Expenses are payable on a monthly estimated basis under the Master Lease, the Additional Rent in respect thereto shall be paid as and when Base Rent is due based upon Master Landlord's estimates; and upon any reconciliation of estimated and actual Direct Expenses (including without limitation any credits against Sublandlord's rental obligations under the Master Lease), the corresponding Additional Rent shall be adjusted between Sublandlord and Subtenant (with appropriate reimbursements or additional payments) within thirty (30) days after delivery to Subtenant of any reconciliation statement under the Master Lease. For purposes of calculating Additional Rent, Sublandlord shall be entitled to rely conclusively on Master Landlord's determination of estimated and actual Direct Expenses; provided, however, that if any adjustment of Additional Rent paid under the Master Lease results in a payment or credit to Sublandlord under the Master Lease for the period of the Sublease Term, such payment or credit shall be paid over or credited to Subtenant following receipt or credit to Sublandlord. The expiration or earlier termination of this Sublease shall not affect the obligations of Sublandlord or Subtenant pursuant to this Section 4.3, and such obligations shall survive, remain to be performed after, any expiration or earlier termination of this Sublease.

In the event that Sublandlord audits the books and records, or any of them, of the Master Landlord with respect to any payment of Master Landlord's Operating Expenses and/or Taxes with respect to the Subleased Premises, subject to Master Landlord's prior written consent in each instance, Sublandlord agrees to provide Subtenant with copies of any such books and records, provided that Subtenant in all cases agrees to sign any confidentiality agreement ("NDA") required by Master Landlord and Sublandlord; and provided further, that, subject to Master Landlord's prior written consent in each instance, Sublandlord shall, upon the reasonable written request of Subtenant and consistent with any express rights accorded to Sublandlord under the Master Lease, at Subtenant's sole cost and expense, request an audit of Master Landlord's books and records in which Subtenant may participate, so long as Subtenant first signs any NDA required by Master Landlord and Sublandlord. If Sublandlord obtains a refund allocable to Master Landlord's Operating Expenses and/or Master Landlord Operating Expenses and/or Master Landlord's Taxes (as applicable), Sublandlord shall, based upon Sublandlord's equitable determination, refund Subtenant an amount corresponding to Subtenant's proportionate share of such refund.

4.4. Throughout the Sublease Term, Subtenant also shall pay within thirty (30) days after written notice from Sublandlord (i) any other fees, charges or sums due under the Master Lease in connection with Subtenant's use and/or occupancy of the Sublease Premises, (ii) costs related to Utilities (defined in Section 6.1 below), and (iii) any gross receipts and/or rent tax respecting this Sublease and/or imposed on Sublandlord based upon the Rent payable hereunder, and any taxes assessed upon or incurred with respect to the possession, leasing, operating, management, maintenance, alteration, repair, use or occupancy by Subtenant of the Sublease Premises or any portion of the Building (collectively, "Other Charges"). By way of illustration and not limitation, Other Charges include: (a) excess or after hours electrical service or heating, ventilating or air conditioning service supplied to the Sublease Premises; (b) services or benefits supplied to the Sublease Premises for which Master Landlord reserves any right to impose a fee or charge separate from Direct Expenses; (c) to reimburse Master Landlord for taxes on personal property, equipment and fixtures located in or about the Sublease Premises during the Sublease Term; (d) to pay for any damage to the Building resulting from the gross negligence or willful misconduct of Subtenant or Subtenant's officers, employees, architects, engineers, contractors or other licensees, guests, visitors or other invitees, subsubtenants, successors or assigns (collectively, the "Subtenant Parties"), but only to the extent not covered by insurance maintained or required to be maintained by Master Landlord under the Master Lease; and (e) for damages or other sums recoverable under the Master Lease which are the result of any acts, omissions, or negligence by Subtenant, its agents, employees, or contractors, or failure of performance or Default by Subtenant under this Sublease.

4.5. All Rent shall be paid to Sublandlord at the address set forth in Section 1.11, or to such other person or such other place as Sublandlord may from time to time designate in writing. If any Rent is not paid within three (3) business days after its due date, Subtenant acknowledges that Sublandlord will incur additional administrative expenses and costs which are difficult or economically impractical to ascertain. Subtenant shall pay an administrative charge to Sublandlord equal to five percent (5%) of the delinquent amount plus any attorneys' fees incurred by Sublandlord by reason of Subtenant's failure to pay Rent and/or Other Charges when due hereunder. However, Subtenant shall be entitled to notice of nonpayment and a three (3) business day cure period prior to the imposition of such late charge on the first occasion in any twelve (12) consecutive month period in which any installment of Rent is not timely paid. Neither demand for nor receipt of any late charge called for under this Sublease shall (i) operate to waive any default by Subtenant or provide a substitute for Subtenant's full and timely performance of the obligation to pay Rent, or (ii) limit the exercise of any other right or remedy Sublandlord may have under this Sublease in case of Subtenant's default.

## 5. POSSESSION AND USE

- Subject to the Relocation Improvements being Substantially Completed in accordance with the requirements of the First Amendment, Sublandlord subleases the Sublease Premises to Subtenant, and Subtenant accepts the Sublease Premises, otherwise in their present "as is" and "with all faults" condition. Sublandlord has no obligation to prepare, modify or alter the Sublease Premises, except that Sublandlord shall deliver the Sublease Premises to Subtenant professionally cleaned, vacant and with the Relocation Improvements Substantially Completed. Subtenant acknowledges that it has had full opportunity to inspect the condition of the Sublease Premises and Building and all laws, rules, regulations, and restrictions statutes, codes, regulations, ordinances, and restrictions of any municipal or governmental entity or insurance body and its fire prevention engineers whether in effect now or later (collectively, "Laws") relating to its use and condition. Except to the extent expressly set forth in this Sublease, Subtenant is not relying on any statement, representation or warranty made by or for Sublandlord with respect to the Sublease Premises or such Laws. Subtenant, by acceptance of possession of the Sublease Premises, conclusively acknowledges the Sublease Premises to be in good order and repair (but subject to any claims of latent defects) and in a tenantable condition and acceptable for Subtenant's intended use. Sublandlord hereby assigns to Subtenant, on a non-exclusive basis, all rights and interests, if any, Sublandlord has or receives in all warranties and guaranties by Contractor (as defined in the Relocation Space Work Letter), subcontractors, suppliers or other persons or entities related to the Relocation Improvements, such that the warranties and guarantees may be enforced by Master Landlord, Sublandlord and/or Subtenant. Sublandlord also hereby assigns to Subtenant on a non-exclusive basis the warranties given by Master Landlord to Sublandlord referred to in Section 58.1.5 of the First Amendment. If Sublandlord is prohibited under the Master Lease from assigning to Subtenant on a nonexclusive basis any warranties and/or guarantees received by Sublandlord related to the Relocation Improvements, of if Sublandlord is prohibited under the Master Lease from assigning to Subtenant any of the warranties referred to in Section 58.1.5 of the First Amendment, then, if reasonably requested by Subtenant in writing, Sublandlord agrees to promptly notify Master Landlord in writing of any malfunction, defect or non-compliance covered under the applicable warranty or guarantee given by Master Landlord or its Contractor and reasonably enforce such applicable warranty(ies) and/or guarantee(s) against Master Landlord on behalf and for the benefit of Subtenant. Sublandlord covenants to enforce any warranties Sublandlord receives from the supplier and installer/construction manager with respect to the replacement of the lab HVAC.
- 5.2. The Sublease Premises shall be used and occupied solely for Subtenant's Use as specified in Section 1.9 and for no other use or purpose. Subtenant's use of the Sublease Premises shall at all times comply with the relevant provisions of the Master Lease and all applicable Laws. Sublandlord makes no representation, express or implied, that Subtenant's Use is permitted in the Sublease Premises under applicable Laws.

# 6. SUBTENANT'S UTILITY, MAINTENANCE AND REPAIR OBLIGATIONS

6.1. To the extent any utility or service provided to the Sublease Premises is not included in Direct Expenses, Sublandlord will, on a periodic basis, invoice Subtenant for Subtenant's Share of such

consumption. Subtenant shall be responsible for obtaining and paying directly all telecommunications, including phone and internet services, through direct contract with commercial providers of such services, as well as any security services or other services Subtenant elects to obtain as part of its business.

- 6.2. Subtenant shall be responsible for and shall pay before delinquency all maintenance, repairs and replacements to the Sublease Premises and its systems and equipment, to the extent Sublandlord, as "Tenant", is obligated to perform the same with respect to the Master Premises under the Master Lease. Subtenant shall be responsible for providing, or causing to be provided, its own janitorial services with respect to the Sublease Premises.
- 6.3. Subtenant shall comply with all Laws, including, without limitation, the American's with Disabilities Act of 1990, 42 U.S.C. § 12101 et seq. (the "ADA") and other state and local laws governing access by the disabled, and all orders, rules and regulations of all governmental authorities and of all insurance bodies and their fire prevention engineers at any time in force, applicable to the Sublease Premises or to Subtenant's particular use or manner of use thereof, solely to the extent Sublandlord, as "Tenant" under the Master Lease, is obligated to comply with the same with respect to the Master Premises under the Master Lease.

## 7. INSURANCE & INDEMNIFICATION

- 7.1. Throughout the Sublease Term, and beginning on the earlier of the Early Access Date and the Sublease Commencement Date, Subtenant shall procure and maintain, at its own cost and expense, such insurance as is required to be carried by Sublandlord under the Master Lease to the extent it pertains to the Sublease Premises, naming Sublandlord, Master Landlord and any additional entities required under the Master Lease or reasonably requested by Sublandlord as additional insureds in the manner required therein. If the Master Lease requires Sublandlord to insure leasehold improvements or alterations, then Subtenant shall insure such leasehold improvements which are located in the Sublease Premises, as well as alterations in the Sublease Premises made by Subtenant. Subtenant shall furnish to Sublandlord a certificate of Subtenant's insurance required under this Section 7.1 prior to the earlier of the Early Access Date and Sublease Commencement Date.
- 7.2. Each party hereto waives claims against the other for damage to property owned by the other party where such damage is covered under any policy of property damage insurance maintained (or required by this Sublease or the Master Lease to be maintained) by such party. Subtenant hereby waives claims against the Master Landlord and Sublandlord for injury, loss or damage to or at the Sublease Premises or the Project or any personal property of such party therein or thereon of every kind and nature, if and to the extent that Sublandlord waives or releases such claims against Master Landlord under the Master Lease. Subtenant agrees to obtain, for the benefit of Master Landlord and Sublandlord, such waivers of subrogation rights from its insurer as are required of Sublandlord under the Master Lease. Subtenant agrees to request of Master Landlord that Master Landlord waive claims against Subtenant for loss or damage to property owned by Master Landlord, including the Premises, Building and Project and personal property of Master Landlord therein or thereon where such damage or loss is covered under any policy of property damage insurance maintained by Master Landlord.
- 7.3. Subtenant shall indemnify, defend and hold Sublandlord, its officers, directors, shareholders, agents and employees (collectively, "Sublandlord Parties") harmless from and against all third-party loss, cost, damage, expense and liability, including, without limitation, reasonable attorneys' fees and disbursements, to the extent incurred as a result of or arising from: (i) any accident, damage or injury to any person or property occurring in, on or about the Sublease Premises from and after the earlier of the Sublease Commencement Date and the Early Access Date until the expiration or earlier termination of this Sublease; (ii) Subtenant's breach or default of any of its obligations under this Sublease (or under the Master Lease to the extent applicable and the obligation of Subtenant hereunder); (iii) any work done in or to the Sublease Premises, either by or on behalf of Subtenant; or (iv) any negligence or willful misconduct by Subtenant or any of its officers, employees, agents, customers, licensees or invitees, or any person claiming through or under Subtenant; provided, however, and notwithstanding anything to the contrary contained in this Section, Subtenant shall not be obligated to indemnify Sublandlord against any such loss,

cost, damage, expense or liability to the extent caused by the negligence or willful misconduct of Sublandlord or Sublandlord Parties or of Master Landlord or any of its members, managers, officers, directors, shareholders, partners, agents, employees, contractors or other representatives.

#### 8. ASSIGNMENT AND SUBLETTING

- Except with the prior written consent of Master Landlord and Sublandlord. Subtenant shall not (a) assign, convey or mortgage this Sublease or any interest under it; (b) allow any transfer of this Sublease or any interest thereunder or any lien upon Subtenant's interest therein by operation of law; (c) further sublet the Sublease Premises or any part thereof; or (d) permit the occupancy of the Sublease Premises or any part thereof by anyone other than Subtenant and its employees (other than occupancy merely by Subtenant's use of the Sublease Premises). Sublandlord's consent to an assignment of this Sublease or sub-sublease of all or any portion of the Sublease Premises shall not be unreasonably withheld, conditioned or delayed; provided, however it shall not be unreasonable for Sublandlord to withhold consent if: (i) the transferee intends to use the Sublease Premises for a purpose which is not permitted by the Master Lease or this Sublease; (ii) the transferee is not a party of reasonable financial worth and/or financial stability in light of the obligations to be undertaken with respect to the proposed transfer; (iii) the Master Landlord withholds consent to the transfer. In connection with Subtenant's request for consent to any proposed assignment or sublease, Subtenant shall deliver to Sublandlord at least three (3) years of financial statements for the proposed transferee, which shall include cashflows, income statements and balance sheets, provided Sublandlord shall deliver to Subtenant a non-disclosure agreement on Sublandlord's commercially reasonable form. If Sublandlord consents to any assignment of this Sublease or further sub-subletting of the Sublease Premises, or applicable part thereof, Sublandlord shall use reasonable efforts to obtain the consent of Master Landlord. Subtenant shall pay all costs and fees payable to Master Landlord under the Master Lease with respect to the proposed assignment or further subletting, as and when payable under the Master Lease, whether or not consent is granted by Master Landlord or Sublandlord. In addition thereto, Subtenant shall also reimburse Sublandlord for all out-of-pocket costs and expenses (including, without limitation, legal fees) reasonably incurred by Sublandlord with respect to any proposed assignment or sub-subletting (whether or not Sublandlord's consent is granted with respect thereto) within thirty (30) days following Subtenant's receipt of written request therefor and reasonable back- up documentation evidencing the out-of-pocket costs and expenses and legal fees, if any, reasonably incurred by Sublandlord as provided above.
- 8.2. No permitted assignment shall be effective and no permitted sub-sublease shall commence unless and until any Default by Subtenant hereunder has been cured. No permitted assignment or sub- subletting shall relieve Subtenant from Subtenant's obligations and agreements under this Sublease and Subtenant shall continue to be liable under this Sublease as a principal and not as a guarantor or surety, to the same extent as though no assignment or sub-subletting had been made.
- 8.3. Any Bonus Rent realized by Subtenant in connection with any Transfer shall be shared by Sublandlord and Subtenant as follows: fifty percent (50%) to Sublandlord and fifty percent (50%) to Subtenant, after payment to Master Landlord of any amount required to be paid under the Master Lease. As used herein, "Bonus Rent" shall mean the excess of (i) all consideration received by Subtenant on account of a sub-sublease or assignment over (ii) the sum of the Base Rent and Additional Rent payable by Subtenant to Sublandlord under this Sublease (prorated, in the case of a sub-sublease of less than all of the Sublease Premises, to reflect obligations allocable to only the portion of the Sublease Premises so sublet), after deducting any design and construction costs incurred on account of changes, alterations and improvements to the Premises in connection with the Transfer, any free base rent and tenant improvements allowances reasonably provided to the Transferee in connection with the Transfer (provided that such free rent and tenant improvement allowances shall be deducted only to the extent the same is to be credited, applied or payable to such Transferee), any brokerage commissions in connection with the Transfer, and legal fees and disbursements reasonably incurred in connection with the Transfer.
- 8.4. In the event Subtenant seeks to assign the Sublease or further sublease more than fifty percent (50%) of the Sublease Premises for substantially all of the Sublease Term, Sublandlord shall have the option, in lieu of consenting to such transfer, to terminate the Sublease of the Sublease Premises as of

the proposed effective date of the proposed assignment or subletting set forth in Subtenant's notice. Such option to terminate shall be exercised, if at all, by Sublandlord giving Subtenant written notice thereof within fifteen (15) days following Sublandlord's receipt of Subtenant's written request. Time is of the essence with respect to such notice of exercise of Sublandlord's option to terminate. In the event of such termination by Sublandlord, from and after the effective date of such termination, Sublandlord and Subtenant shall have no further obligations or liabilities to each other with respect to the affected portion of the Sublease Premises, except with respect to obligations or liabilities which have accrued as of, or survive, such termination (in the same manner as if such termination date were the date originally fixed for the expiration of the Sublease Term). Without in any manner limiting the rights of Sublandlord, following any such termination by Sublandlord, Sublandlord may sublease or assign the affected portion of the Sublease Premises to the prospective assignee or sublessee proposed by Subtenant, without liability to the Subtenant. In the event Sublandlord terminates the Sublease as to a portion of the Sublease Premises, as opposed to the entire Sublease Premises, Rent under the Sublease shall be proportionately abated on the per rentable square foot basis. Sublandlord's failure to exercise such termination right as herein provided shall not be construed as Sublandlord's consent to the proposed assignment or subletting.

8.5. Subtenant may assign this Sublease to a Permitted Transferee (as defined in the Master Lease) without the written consent of Sublandlord, subject to the terms of the Master Lease. For avoidance of doubt, notwithstanding anything to the contrary in this Sublease, as between Sublandlord and Subtenant only (and without limiting any rights of Master Landlord under the Master Lease), (i) Subtenant may, without Sublandlord's prior written consent and without payment of any amount to Sublandlord, sub-sublet the Sublease Premises or assign this Sublease to (a) an entity controlling, controlled by or under common control with Subtenant, (b) a successor to Subtenant by merger, consolidation or reorganization, or (c) a purchaser of all or substantially all of Subtenant's assets, and (ii) the sale or transfer of Subtenant's stock or equity interests in connection with a bona fide financing for the benefit of Subtenant shall not be deemed an assignment, subletting or other transfer of this Sublease or of the Sublease Premises provided Subtenant's net worth is not decreased by such sale or transfer.

#### 9. ALTERATIONS

- 9.1. Except as expressly provided in this Sublease, Subtenant shall not make any alterations, improvements or additions in or to the Sublease Premises ("Alterations") without the prior written consent of the Sublandlord, which consent shall not be unreasonably withheld, conditioned or delayed. Subtenant desires to construct or install in the Sublease Premises the leasehold improvements referred to on <a href="Exhibit E">Exhibit E</a> attached hereto and, subject to Master Landlord and Sublandlord first consenting to the same in writing (which may be via email or facsimile), Subtenant shall have the right to construct or install, or cause to be constructed or installed, any or all of the leasehold improvements referred to on such <a href="Exhibit E">Exhibit E</a> attached to this Sublease.
- 9.2. Notwithstanding any other provisions in this Sublease, no Alterations shall be made that would constitute a Default or event of default under the Master Lease. If Sublandlord consents to any Alterations, Sublandlord shall use reasonable efforts to obtain the consent of Master Landlord, if required under the Master Lease, and Subtenant shall pay all costs reasonably incurred by Sublandlord in seeking or obtaining Master Landlord's consent (regardless of whether Master Landlord's consent is granted). If Alterations by Subtenant are consented to by Sublandlord and consented to by Master Landlord (if required under the Master Lease), Subtenant shall comply with all of the covenants of Sublandlord, as "Tenant" under the Master Lease, contained in the Master Lease pertaining to the performance of such Alterations.
- 9.3. Subject to Section 7.2 above, Subtenant shall indemnify, defend and hold harmless Sublandlord against liability, loss, cost, damage, liens and expense imposed upon Sublandlord to the extent arising from any Alterations constructed or made by Subtenant, including those Alterations permitted under the terms of this Sublease.
- 9.4. Any permitted Alterations by Subtenant shall be made at Subtenant's sole cost and expense, including any cost to comply with applicable Laws (including any code compliance with respect to any improvements required to be performed outside of the Sublease Premises), any management or

supervision fee charged by Master Landlord pursuant to the terms of the Master Lease, and any removal or restoration costs necessary or incurred pursuant to the provisions of the Master Lease. In addition to any fees payable to Master Landlord with respect to Alterations under the Master Lease, Subtenant shall reimburse Sublandlord for the reasonable review fees, if any, incurred by Sublandlord by third-party consultants and for the review of plans or any inspections that Sublandlord reasonably deems necessary with regards to the requested Alterations.

## 10. SURRENDER

- 10.1. On the Expiration Date, or upon the earlier termination of this Sublease or of Subtenant's right to possession of the Sublease Premises, Subtenant shall at once surrender and deliver up the Sublease Premises to Sublandlord in materially the same condition as existed on the earlier of the Early Access Date and Sublease Commencement Date, excepting reasonable wear and tear, damage and/or destruction from casualty or condemnation, Hazardous Materials (other than those released by or brought into the Sublease Premises by Subtenant or any of Subtenant's employees, agents, contractors or invitees), repairs not Subtenant's responsibility under this Sublease, and approved or permitted Alterations which are not required to be removed pursuant to the Master Lease or the express terms and provisions of this Sublease; provided, however, conditions existing because of Subtenant's failure to perform maintenance, repairs or replacements as required of Subtenant under this Sublease shall not be deemed "reasonable wear and tear." At the expiration or earlier termination of this Sublease, Subtenant shall surrender to Sublandlord all keys to the Sublease Premises.
- 10.2. As between Sublandlord and Subtenant, Subtenant shall not be required to remove any alterations, additions or improvements performed by or at the request of Sublandlord or Master Landlord prior to the earlier of the Sublease Commencement Date and Early Access Date or to restore the Sublease Premises to their condition prior to Sublandlord's or Master Landlord's making of such alterations, additions or improvements.
- 10.3. If Sublandlord is required under the Master Lease to remove any alterations performed by Sublandlord prior to the Expiration Date, Subtenant shall permit Sublandlord to enter the Sublease Premises for a reasonable period of time, subject to such conditions as Subtenant may reasonably impose, for the purpose of removing such alterations and restoring the Sublease Premises as required by the Master Lease. However, if either Sublandlord or Subtenant reasonably determines that Sublandlord's entry prior to the Expiration Date is not compatible with Subtenant's continued use of the Sublease Premises, then at any time during the last forty-five (45) days of the Sublease Term, either party may terminate this Sublease upon not less than ten (10) days written notice to the other, with such termination to be effective on the date of Sublandlord's re-entry into the Sublease Premises for the purpose of removing such alterations and restoring the Sublease Premises. In the event Sublandlord enters the Sublease Premises pursuant to the terms of this Paragraph 10.3, Sublandlord shall, during the period of such entry, take all reasonable steps to minimize, to the extent practicable under the circumstances, any disturbance of and/or interference with Subtenant's business operations in the Sublease Premises.
- 10.4. At the expiration or earlier termination of this Sublease, Subtenant shall have the right (subject to Master Landlord's prior written approval, to the extent removal is not expressly permitted under the Master Lease), to remove from the Sublease Premises any specialized tenant improvements and/or equipment installed by and paid for by Subtenant so long as Subtenant repairs any damage resulting from such removal.

## 11. CASUALTY AND EMINENT DOMAIN

In the event of any damage, destruction, casualty or condemnation affecting the Sublease Premises, Rent payable hereunder shall be abated but only to the extent that Rent is abated under the Master Lease with respect to the Sublease Premises. Subtenant shall have no right to terminate this Sublease in connection with any damage, destruction, casualty, condemnation or threat of condemnation except to the extent the Master Lease is also terminated as to the Master Premises or any material portion thereof.

### 12. HOLDING OVER

Holding over by Subtenant is specifically prohibited, and Subtenant shall have no right to retain possession of the Sublease Premises following the expiration or earlier termination of the Sublease Term ("Holding Over"). If Subtenant fails to vacate the Sublease Premises or any portion thereof and deliver the Sublease Premises to Sublandlord in the condition required by this Sublease on or prior to the expiration or earlier termination of this Sublease, then, in addition to any other right or remedy of Sublandlord under this Sublease, at law or in equity, Subtenant shall pay to Sublandlord, in addition to Additional Rent and Other Charges, an amount equal to the greater of (a) [\*\*\*] percent ([\*\*\*]%) of the monthly Base Rent in effect immediately prior to the expiration or earlier termination of this Sublease for each month (or portion thereof) that such failure(s) continue(s), and (b) the holdover rent Sublandlord is required to pay to Master Landlord under the Master Lease due to Subtenant's Holding Over. In addition, Subtenant shall be liable to Sublandlord for all damages incurred by Sublandlord as a result of such Holding Over (including, but not limited to, attorneys' fees and expenses and any rent payable by Sublandlord to Master Landlord under the Master Lease) (including consequential damages) incurred by Sublandlord as a result of such holding over. Notwithstanding the foregoing, Subtenant shall not be liable to Sublandlord for any consequential damages suffered or incurred by Sublandlord as a result of Subtenant Holding Over (other than consequential damages due from Sublandlord to Master Landlord under the Master Lease as a result of Subtenant's holding over) unless Sublandlord gives Subtenant written notice that Sublandlord has entered into a written lease with a third party covering the Sublease Premises, such written notice states the date that such third party is entitled to take possession of the Sublease Premises following the expiration or earlier termination of this Sublease and Subtenant fails to vacate the Sublease Premises within thirty (30) days following the date of Subtenant's receipt of Sublandlord's written notice: however, in no event shall Subtenant be obligated to vacate the Sublease Premises prior to the expiration or earlier termination of this Sublease. No Holding Over by Subtenant or payment by Subtenant after the expiration or earlier termination of this Sublease shall be construed to extend the Sublease Term or prevent Sublandlord from immediately recovering possession of the Sublease Premises by summary proceedings or otherwise.

## 13. ENCUMBERING TITLE

- 13.1. Subtenant shall not do any act which in any way encumbers the title of Master Landlord in and to the Building nor shall the interest or estate of Master Landlord or Sublandlord be in any way subject to any claim by way of lien or encumbrance, whether by operation of law or by virtue of any express or implied contract by Subtenant, or by reason of any other act or omission of Subtenant. Any claim to, or lien upon, the Sublease Premises or Building arising from any act or omission of Subtenant shall accrue only against the subleasehold estate of Subtenant therein and shall be subject and subordinate to the paramount title and rights of Master Landlord in and to the Building and the interest of Sublandlord in the Master Premises.
- 13.2. Without limiting the generality of the foregoing, Subtenant shall not permit the Sublease Premises or Building to become subject to any mechanics', laborers' or materialmen's lien on account of labor or material furnished to Subtenant or claimed to have been furnished to Subtenant in connection with work of any character performed or claimed to have been performed on the Sublease Premises or anywhere in the Building by, or at the direction or sufferance of, Subtenant. In the event any such lien is imposed or recorded, Subtenant shall cause the same to be released of record by payment or recording of a lien release bond as provided by Law within fifteen (15) days after Subtenant receives notice or becomes aware of such imposition or recording. If Subtenant shall fail to cause any such lien to be released within such fifteen (15) day period, then Sublandlord shall have, in addition to all other rights and remedies provided in this Sublease and at law, the right, but not the obligation, to cause any such lien to be released by such means as Sublandlord shall deem proper, including payment of the claim giving rise to such lien.

## 14. SUBTENANT'S DEFAULT

14.1. Any one or more of following events shall be considered a "**Default**" by Subtenant, as such term is used in this Sublease:

a. Subtenant fails to make any payment of Rent required to be made by Subtenant within three (3) business days following written notice from Sublandlord that the same is past due; or
b. Subtenant fails to fulfill, keep, observe or perform any of the other covenants and obligations herein contained to be fulfilled, kept, observed and performed by Subtenant, and such failure continues for more than twenty-five (25) days after notice thereof in writing to Subtenant, or for such longer period as may be reasonably required to cure such failure, provided Subtenant is continuously and diligently prosecuting such cure at all times to completion and such cure period does not cause Sublandlord to be in an event of default under the Master Lease; provided, such notice shall be in lieu of, and not in addition to, any notice required under Section 1161 et seq. of the California Code of Civil Procedure; or
c. Subtenant shall be adjudged an involuntary bankrupt, or a decree or order approving a petition or answer filed against Subtenant seeking reorganization of Subtenant under the Federal bankruptcy laws as now or hereafter amended, or under the laws of any State, shall be entered, and any such decree or judgment or order shall not have been vacated or stayed or set aside within sixty  (60) days from the date of the entry or granting thereof; or
d. Subtenant shall file, or admit the jurisdiction of the court and the material allegations contained in, any petition in bankruptcy, or any petition pursuant or purporting to be pursuant to the Federal Bankruptcy laws now or hereafter amended, or Subtenant shall institute any proceedings for relief of Subtenant under any bankruptcy or insolvency laws or any laws relating to the relief of debtors, readjustment of indebtedness, re-organization, arrangements, composition or extension; or

- e. Subtenant shall (i) abandon the Sublease Premises during the Term for a continuous period in excess of five (5) consecutive business days and Subtenant is during that time in default of its other obligations under this Sublease (Subtenant waives any right to notice Subtenant may have under Section 1951.3 of the Civil Code of the State of California, the terms of this Section 14.1 being deemed such notice to Subtenant as required by said Section 1951.3) or (ii) assign this Sublease or further sublet the Sublease Premises other than in strict accordance with Section 8 of this Sublease; or
- f. Subtenant fails to secure insurance or to provide proper evidence of insurance as set forth in Section 7 of this Sublease and does not cure such failure within three (3) business days: following Subtenant's receipt of notice from Sublandlord or fails to keep the Sublease Premises or the Building free of lien claims as set forth in Section 13 of this Sublease where such failure is not cured within fifteen (15) days following receipt of notice or actual knowledge of the imposition of any such lien; or
- g. Subtenant causes an event or condition under the Master Lease which either is a default thereunder or, subject only to the delivery of any required notice or passage of any cure or grace period, would constitute a default thereunder, and such default is not cured within two (2) business days less than any period allowed under the Master Lease for cure. Where notice of default from Master Landlord is required and given under the Master Lease, Sublandlord agrees to use good faith efforts to provide as quickly as reasonably practicable a copy of any such notice to Subtenant.
- 14.2. Upon the occurrence of any one or more Default(s), Sublandlord may exercise any remedy against Subtenant which Master Landlord may exercise for default by Sublandlord under the Master Lease in addition to any remedy available at law and/or in equity, and Sublandlord may resort to its remedies cumulatively or in the alternative. Without limiting the generality of the foregoing, Sublandlord may exercise the damage remedies available under any applicable law, including without limiting the foregoing, California Civil Code Sections 1951.2 and 1951.4 or any similar or successor statute which provides that a lessor may continue a lease in effect and recover damages as they become due. Subtenant expressly acknowledges and agrees that the restrictions on assignment and subsubletting imposed by this Sublease are reasonable for purposes of California Civil Code Section 1951.4 and any successor or similar statute.
  - 14.3. Intentionally Omitted.

14.4. If Subtenant shall default in the observance or performance of any term or covenant of this Sublease on Subtenant's part to be observed or performed, and if such default has not been cured following twenty (20) days' written notice to Subtenant (or such shorter time in the event of an emergency), then Sublandlord may (but shall not be obligated to), after giving Subtenant an additional five (5) business day prior written notice of Sublandlord's intention to cure Subtenant's Default, immediately or at any time thereafter, perform the same for the account of Subtenant. If Sublandlord makes any expenditure or incurs any obligation for the payment of money in connection therewith (including, without limitation, reasonable attorneys' fees and disbursements), then such sums paid, or obligations incurred, together with interest thereon at the lesser of (i) [\*\*\*] percent ([\*\*\*]%) per month or (ii) the maximum rate allowable under Law from the date of the expenditure until repaid, shall be deemed to be Other Charges under this Sublease and shall be paid by Subtenant to Sublandlord within five (5) days after Sublandlord's demand therefor. Subtenant hereby expressly waives its rights under any statute to make repairs at the expense of Sublandlord.

## 15. PROVISIONS REGARDING MASTER LEASE

- 15.1. This Sublease and all rights of the parties hereunder, are subject and subordinate to all of the terms, covenants and conditions of the Master Lease, except as otherwise expressly provided to the contrary in this Sublease. Subtenant (and Sublandlord to the extent of its obligations under the Master Lease that are not assumed by Subtenant under this Sublease) each agree that it will not, by its act or omission to act, cause a default under the Master Lease. In furtherance of the foregoing, the parties hereby acknowledge, each to the other, that it is not practical in this Sublease to enumerate all of the rights and obligations of the various parties under the Master Lease and specifically to allocate those rights and obligations in this Sublease. Accordingly, in order to afford to Subtenant the benefits of this Sublease and of those provisions of the Master Lease which by their nature are intended to benefit the party in possession of the Sublease Premises, and in order to protect Sublandlord against a Default by Subtenant which might cause an event of default by Sublandlord under the Master Lease, Sublandlord and Subtenant covenant and agree as set forth in this Article 15.
- Except as otherwise expressly provided in this Sublease, Sublandlord shall fully, and within any time period expressly prescribed in the Master Lease, perform its covenants and obligations under the Master Lease which do not require for their performance possession of the Sublease Premises and/or which are not otherwise to be performed hereunder by Subtenant on behalf of Sublandlord, unless Sublandlord is prevented from performing such due to Subtenant's actions or inactions, including a Default by Subtenant. Except as otherwise expressly set forth in this Sublease, in case of any breach of this Sublease by Sublandlord, Subtenant shall have all of the rights and remedies against Sublandlord as would be available to Sublandlord, as Tenant, against Master Landlord under the Master Lease (to the extent the provisions thereof have been incorporated by reference into this Sublease without modification) if such breach were made by Master Landlord thereunder (but only to the extent such actions by Subtenant do not constitute a breach of the Master Lease). Except as otherwise expressly provided in this Sublease (i.e., to the extent not the retained obligation of Sublandlord under this Sublease), Subtenant shall perform all affirmative covenants, and shall refrain from performing any act which is prohibited by the negative covenants, of the Master Lease, where the obligation to perform or refrain from performing is by its nature imposed upon the party in possession of the Sublease Premises. In furtherance of the foregoing, Subtenant shall assume and perform for the benefit of Sublandlord all of the obligations of "Tenant" under the Master Lease provisions as incorporated herein to the extent that the provisions are applicable to the Subleased Premises. In addition, whenever any period for notice from "Tenant" to "Landlord" is specified under the Master Lease, or any period within which "Tenant" is required to do anything under the Master Lease, the period applicable to Subtenant's obligation to give such notice to Sublandlord or to perform under this Sublease shall be two (2) business days shorter than the corresponding period applicable to "Tenant" or "Lessee" under the Master Lease (so that Sublandlord shall always have at least two (2) business days within which to give its own notice or performance to Master Landlord); further, wherever any period for notice from "Landlord" or "Lessor" to "Tenant" or "Lessee" is specified under the Master Lease, Sublandlord shall similarly have an additional period of at least two (2) business days within which to give notice to Subtenant under this Sublease.

- 15.3. Sublandlord shall not agree to an amendment to the Master Lease which materially adversely affects Subtenant's access to, use or occupancy of the Sublease Premises and/or Common Areas or that increases the monetary obligations of Subtenant under this Sublease, unless Sublandlord shall first obtain Subtenant's prior written approval to such amendment (which approval may be given or withheld by Subtenant in its sole and absolute discretion). However, it is expressly agreed that: (a) if, without the fault of Sublandlord, the Master Lease should terminate prior to the Expiration Date, Sublandlord shall have no liability to Subtenant; and (b) to the extent the Master Lease grants Sublandlord any discretionary right to terminate the Master Lease due to casualty or condemnation, Sublandlord shall be entitled to exercise or not exercise such right in its reasonable discretion and without liability to Subtenant. Except as provided in clause (b) immediately above, Sublandlord agrees that it will not voluntarily agree with Master Landlord to terminate the Master Lease prior to its natural expiration unless Sublandlord shall first obtain Subtenant's prior written approval (which approval may be given or withheld in Subtenant's sole and absolute discretion). Sublandlord shall not waive any provisions under the Master Lease or make any elections, exercise any right or remedy or give any consent or approval under the Master Lease which will adversely affect Subtenant's access to, use or occupancy of the Sublease Premises and/or Common Areas or that increases the monetary obligations of Subtenant under this Sublease without, in each instance, Subtenant's prior written consent, which consent shall not be unreasonably conditioned, delayed or withheld.
- So long as Subtenant is not in Default, Subtenant shall be entitled to all of the services and benefits with respect to the Sublease Premises which are to be provided by Master Landlord under the Master Lease. Except to the extent inconsistent with or contrary to the terms of this Sublease, the terms and conditions of this Sublease shall include all of the terms of the Master Lease and such terms are incorporated into this Sublease as if fully set forth herein, except that: (i) each reference in such incorporated sections to "Lease" shall be deemed a reference to "Sublease"; (ii) each reference to the "Premises" and "Relocation Space" shall be deemed a reference to the "Sublease Premises"; and (iii) each reference to "Landlord" and "Tenant" shall be deemed a reference to "Sublandlord" and "Subtenant", respectively. Notwithstanding the foregoing and anything herein to the contrary, Sublandlord shall have no duty to perform any obligations of Master Landlord which are, by their nature, the obligation of an owner or manager of real property. By way of illustration, Sublandlord shall not be obligated: (a) to provide any of the services or utilities that Master Landlord has agreed in the Master Lease to provide, (b) to make any of the repairs or restorations that Master Landlord has agreed in the Master Lease to make, (c) to comply with any laws with which Master Landlord has agreed in the Master Lease to comply, if any, (d) to comply with any insurance provisions of the Master Lease with which Master Landlord has agreed in the Master Lease to comply, or (e) to take any action with respect to the operation, administration or control of the Project or any of the Common Areas that Master Landlord has agreed in the Master Lease to take. Sublandlord shall have no responsibility for or be liable to Subtenant for any default, failure or delay on the part of Master Landlord in the performance or observance by Master Landlord of any of its obligations under the Master Lease, nor shall such default by Master Landlord affect this Sublease or waive or defer the performance of any of Subtenant's obligations under this Sublease, including without limitation the obligation to pay Rent; and Subtenant hereby expressly waives the provisions of any statute, ordinance or judicial decision, now or hereafter in effect, which would give Subtenant the right to make repairs at the expense of Sublandlord, or to claim any actual or constructive eviction by virtue of any interruption in access, services or utilities to, or any failure to make repairs in or to, the Sublease Premises or the Building. Notwithstanding the foregoing, the parties do contemplate that Master Landlord will, in fact, perform its obligations under the Master Lease, that Sublandlord shall use good faith and diligent efforts to enforce the rights of the Tenant" under the Master Lease on behalf of Subtenant, and that in the event of any default or failure of such performance by Master Landlord, Sublandlord agrees that it will, upon notice from Subtenant, promptly make demand upon Master Landlord to perform its obligations under the Master Lease and, provided that Subtenant specifically agrees to pay all reasonable costs and expenses of Sublandlord and pays the estimated amount of such costs and expenses in advance based upon Sublandlord's commercially reasonable projections from time to time, Sublandlord will take appropriate action to enforce the Master Lease, including, taking legal action against Master Landlord for its failure to perform; provided, however, that to the extent any such costs and expenses paid in advance by Subtenant are later recovered by Sublandlord from Master Landlord pursuant to the terms of the Master Lease, Sublandlord shall promptly pay any such recovered amounts to Subtenant. Any non-liability, release, waiver, indemnity or hold

harmless provision in the Master Lease for the benefit of Master Landlord that is incorporated herein by reference shall be deemed to apply under this Sublease and inure to the benefit of both Sublandlord and Master Landlord; provided, however, that Sublandlord acknowledges and agrees that despite the provisions of Section 29.1 of the Master Lease, Sublandlord's liability under this Sublease shall not be limited to Sublandlord's interest in the Premises, Building or Project.

- 15.5. If Subtenant desires to take any action which requires the consent of Master Landlord under the terms of the Master Lease, then, notwithstanding anything to the contrary herein: (a) Sublandlord, independently, shall have the same rights of approval or disapproval as Master Landlord has under the Master Lease (however, Sublandlord's approval shall not be unreasonably withheld, conditioned or delayed); (b) Subtenant shall not take any such action until it obtains the consent of both Sublandlord and Master Landlord; and (c) Subtenant shall request that Sublandlord obtain Master Landlord's consent on Subtenant's behalf and Sublandlord shall use commercially reasonable and diligent efforts to obtain such consent. Subtenant shall pay all costs reasonably incurred by Sublandlord in seeking or procuring Master Landlord's consent. Any approval or consent required of Sublandlord conclusively shall be deemed reasonably withheld if approval or consent also is required of the Master Landlord, and Master Landlord fails to give Master Landlord's approval or consent. In all provisions of the Master Lease requiring Tenant to submit, exhibit to, supply or provide, as the case may be, the same to both Landlord and Sublandlord.
- 15.6. Notwithstanding any other provision of this Sublease, Subtenant shall not have any rights hereunder that are personal to Sublandlord or its affiliates as expressly provided in the Master Lease. Furthermore, (i) all representations and warranties made by Master Landlord in the Master Lease are made solely by Master Landlord and not by Sublandlord, (ii) any rights of Sublandlord to extend, renewal, expand, contract, cancel or terminate the Master Lease shall not apply to or benefit Subtenant in any manner (however, the foregoing shall not limit or restrict Subtenant from canceling or terminating this Sublease to the extent such cancellation or termination rights are available to Sublandlord under the Master Lease and such Master Lease cancellation or termination provisions are incorporated into this Sublease), and (iii) Subtenant shall not have any right to require that Sublandlord otherwise exercise any option for Subtenant's benefit.
- 15.7. In addition to the obligations of Subtenant under the terms of this Sublease as set forth in this Sublease (and except as otherwise expressly provided to the contrary in this Sublease), Subtenant shall also have and perform for the benefit of Sublandlord all obligations of the "Tenant" as are set forth in the Master Lease, which are hereby incorporated into this Sublease as though set forth herein in full, substituting "Subtenant" wherever the term "Tenant" appears, "Sublandlord" wherever the term "Landlord" appears, and "Sublease Premises" wherever the term "Premises" and/or "Relocation Space" appears (except for the definition of Premises, Tenant's Address and Landlord's Address in the Basic Lease Information) Notwithstanding the foregoing, the following provisions of the Master Lease are hereby expressly excluded from this Sublease and not incorporated herein, except as expressly set forth or referenced elsewhere in this Sublease, and then only to the extent expressly set forth or referenced: (A) any redacted portions of the Master Lease; (B) The following provisions of the Original Lease: all of the Basic Lease Information, Sections 2.1 (excepting therefrom the second and third sentences), 2.2, 2.4, 2.5, 2.6, 4.3, 5.4, 6.8, 15.6, 28.2 (first sentence only), 32.2 (except that Sublandlord agrees to ask Master Landlord to include Subtenant's name on the Monument Signage in place of Sublandlord's name pursuant to Section 23.1), 33.3 (clause (ii), except that at the expiration or earlier termination of the Sublease Term, Subtenant, at its sole cost, shall cause all Hazardous Materials brought into or about the Sublease Premises by Subtenant to be removed from the Sublease Premises and disposed of in accordance with all Environmental Laws,42.1, 51, 56, Exhibit B (and all references thereto in the Master Lease); Exhibit C (and all references thereto in the Master Lease); Exhibit C (and all references thereto in the Master Lease);
- (B) the entire First Amendment, <u>except</u> Sections 1 (as to the definitions of Relocation Amendment and Relocation Space), 2, 3 (as to Sections 58.1.5 (this Section is incorporated to the extent that Sublandlord agrees only to use commercially reasonable efforts to enforce any rights that Sublandlord has against Master Landlord under this Section of the First Amendment), 58.1.6 (this this Section is incorporated to the extent only that Sublandlord agrees to use commercially reasonable efforts to enforce any obligations that

Master Landlord has to Sublandlord under this Section of the First Amendment), 58.1.8 (except that such Section 58.1.8 shall be deemed modified to provide that all other terms and conditions of the Master Lease incorporated into this Sublease shall, except to the extent inconsistent with Article 58 of the First Amendment, apply to the Sublease Premises, and further provided that Subtenant shall not be entitled to any allowance)), 4 (only as to 4.1 and 4.4), 7 (and Sublandlord acknowledges and agrees that Subtenant shall not be obligated to remove from the Sublease Premises any of the Relocation Improvements), 8, 13, 14, 16.1, 16.2, 16.3, 16.5, 16.6, 16.7, 16.10, 16.11, Exhibit B-1 and Exhibit C (Sections 1.1 (second sentence to the extent only that Sublandlord agrees to use commercially reasonable efforts to enforce any obligations that Master Landlord has to Sublandlord under this Section of the First Amendment), 4.3.2 (from the beginning of the first sentence and ending with the words ""Landlord shall supervise the construction by Contractor", to the extent only that Sublandlord agrees to use commercially reasonable efforts to enforce any obligations that Master Landlord has to Sublandlord under this Section of the First Amendment), and

4.3.3. Furthermore, notwithstanding the foregoing, in the following provisions on the Master Lease which are incorporated herein, all references to "Landlord" shall refer only to "Master Landlord": Original Lease in the following Sections: Section 1.3 (fifth and sixth sentences only), 6.1, 6.3, 6.5, 6.6, 6.7, 6.8, 7.1, 13.1

(except the second sentence), 13.3, the second and third sentence of Section 29.1, 30.2, 30.4, 30.5,32.1 (last sentence), 32.3 (subject to the express signage rights granted to Subtenant in this Sublease), 34.2, 34.3, 40.2, 44.2, and 57.4; and First Amendment: Sections 58.1.5 (provided that Sublandlord shall similarly have no liability for repairs or replacements necessitated by the negligent acts or omissions of Tenant and/or Tenant's representatives, agents, contractors and/or employees), 58.1.6 and Exhibit C (Sections 1.1 (second sentence), 4.1 (first sentence), 4.3.2 (from the beginning of the first sentence and ending with the words "Landlord shall supervise the construction by Contractor"), 4.3.3.

- 15.8. Sublandlord shall have the right to enter the Sublease Premises at reasonable times and upon reasonable advance notice, and subject to Subtenant's reasonable security requirements, to cure any default by Subtenant under this Sublease, which is also, or would be, with the passage of time or the giving of notice, an Event of Default under the Master Lease. Any sums paid and all reasonable costs and expenses of performing any such cure shall be deemed Rent payable by Subtenant to Sublandlord upon demand, together with interest thereon at the rate of eight percent (8%) per annum, from the date of expenditure and written demand made by Sublandlord to Subtenant until paid.
- 15.9. As between the parties hereto only, in the event of a conflict between the terms of the Master Lease and the terms of this Sublease, the terms of this Sublease shall control only to the extent they are inconsistent with the terms of the Master Lease and their respective counterpart provisions in the Master Lease shall be excluded only to such extent.
- 15.10. In all provisions of the Master Lease requiring Tenant to designate Landlord as an additional or named insured on its insurance policy, Subtenant shall be required to so designate Landlord and Sublandlord on its insurance policy. Sublandlord shall have no obligation to maintain the insurance to be maintained by Landlord under the Master Lease.
- 15.11. Sublandlord shall have no obligation to restore or rebuild any portion of the Sublease Premises after any destruction or taking by eminent domain. Subtenant shall be entitled to receive any abatement of Rent as to the Sublease Premises during the Sublease Term resulting from any casualty, condemnation or interruption of services that Sublandlord has actually received under the Master Lease, including, without limitation, the rights granted to Sublandlord under Section 6.8 of the Original Lease, less any expenses reasonably incurred by Sublandlord in obtaining such abatement. Sublandlord shall use commercially reasonable efforts to enforce its abatement rights under the Master Lease and shall keep Subtenant reasonably apprised of all such efforts on request of Subtenant.
- 15.12. The provisions of this Sublease and/or Master Lease to the contrary notwithstanding, Subtenant shall have no obligation to remove, clean-up, remediate or abate any Hazardous Materials from the Premises, Building or Project unless such Hazardous Materials have been Released or discharged by Subtenant or any of its agents, employees, contractors, licensees or subsublessees in violation of any

Environmental Laws.

- 15.13. Sublandlord acknowledges and agrees that Subtenant shall not be obligated to remove from the Sublease Premises any of the Relocation Improvements.
- 15.14. Subtenant shall have no obligation to pay for any costs related to the design, permitting or construction of the Relocation Improvements or Tenant Improvements referred to in Relocation Space Work Letter referred to in the First Amendment.
- 15.15. If Sublandlord is entitled to and receives rent abatement under the terms of the Master Lease, Subtenant shall be entitled to a proportionate and equitable abatement of rent due under this Sublease (to the extent allocable to the Sublease Premises) as reasonably determined by Sublandlord and Subtenant.

## 16. MASTER LANDLORD'S CONSENT

- 16.1. This Sublease and the obligations of the parties hereunder are expressly conditioned upon Sublandlord's obtaining the prior written consent of Master Landlord to this Sublease (the "Consent"). Subtenant shall promptly deliver to Sublandlord any information reasonably requested by Master Landlord in connection with the Consent with respect to the nature and operation of Subtenant's business, the financial condition of Subtenant, and any other information reasonably requested by Master Landlord.
- 16.2. Sublandlord shall use commercially reasonable efforts to obtain Master Landlord's consent to this Sublease as soon as reasonably practicable following the execution of this Sublease by Sublandlord and Subtenant. Subject to the immediately-preceding sentence, Sublandlord shall submit to Master Landlord a copy of this Sublease, and all other information required by the Master Landlord (to the extent required to be delivered to Master Landlord under the Master Lease and in Sublandlord's possession or control), within five (5) business days of the mutual execution and delivery of this Sublease (or as soon thereafter as is reasonably practicable) and all other information reasonably requested by Master Landlord (to the extent in Sublandlord's possession or control) within five (5) business days of request of Master Landlord (or as soon thereafter as is reasonably practicable). If Master Landlord fails to consent to this Sublease within sixty (60) days after the Execution Date, either party shall have the right to terminate this Sublease by giving written notice thereof to the other at any time thereafter, but before, Master Landlord grants such consent.
- 16.3. Sublandlord and Subtenant hereby agree, for the benefit of Master Landlord, that this Sublease and Master Landlord's consent hereto shall not (a) create privity of contract between Master Landlord and Subtenant; (b) be deemed to have amended the Master Lease in any regard (unless Master Landlord shall have expressly agreed writing to such amendment); or (c) be construed as a waiver of Master Landlord's right to consent to any assignment of the Master Lease by Sublandlord or any further subletting of the Sublease Premises, or as a waiver of Master Landlord's right to consent to any assignment by Subtenant of this Sublease or any further subletting of the Sublease Premises or any part thereof.

### 17. LETTER OF CREDIT

17.1. Not later than five (5) days following receipt of the Master Landlord Consent, Subtenant shall deliver to Sublandlord, as collateral for the full performance by Subtenant of all of its obligations under this Sublease and for all losses and damages Sublandlord may suffer (or which Sublandlord reasonably estimates it may suffer) as a result of Subtenant's failure to comply with one or more provisions of this Sublease, including, but not limited to, any post lease termination damages under Section 1951.2 of the California Civil Code, a standby, unconditional, irrevocable, transferable (with Subtenant responsible for the payment of any transfer fee or charge imposed by the Issuing Bank, as defined below, in connection with only the first transfer, if applicable of the Letter of Credit) letter of credit (the "Letter of Credit") in a form reasonably acceptable to Sublandlord and containing the terms required herein, in the amount specified in Section 1.12 (the "Letter of Credit Amount"), naming Sublandlord as beneficiary, issued (or

confirmed) by a financial institution reasonably acceptable to Sublandlord (the "Issuing Bank"), permitting multiple and partial draws thereon from a location in San Francisco (or, alternatively, permitting draws via overnight courier or facsimile in a manner acceptable to Sublandlord), and otherwise in form acceptable to Sublandlord in its reasonable discretion. Sublandlord hereby pre-approves [\*\*\*] as an Issuing Bank; however, Sublandlord acknowledges and agrees that Subtenant shall not be required to use [\*\*\*] as the Issuing Bank; it being understood and agreed that if [\*\*\*] is not the Issuing Bank selected by Subtenant, then the Issuing Bank shall be a financial institution reasonably acceptable to Sublandlord.

17.2. The Letter of Credit shall be "callable" at sight, permit partial draws and multiple presentations and drawings, and be otherwise subject to the Uniform Customs and Practices for Documentary Credits (1993-Rev), International Chamber of Commerce Publication #500, or the International Standby Practices-ISP 98, International Chamber of Commerce Publication #590. In the event of an assignment by Subtenant of its interest in this Sublease (and irrespective of whether Sublandlord's consent is required for such assignment), the acceptance of any replacement or substitute letter of credit by Sublandlord from the assignee shall be subject to Sublandlord's prior written approval, in Sublandlord's reasonable discretion, and the attorney's fees incurred by Sublandlord in connection with such determination shall be payable by Subtenant to Sublandlord within thirty (30) days of billing. Subtenant shall cause the Letter of Credit to be continuously maintained in effect (whether through replacement, amendment, renewal or extension) in the Letter of Credit Amount through the date (the "Final LC Expiration Date") that is the later to occur of (x) the date that is ninety-five (95) days after the scheduled expiration of the Sublease Term and (y) the date that is ninety-five (95) days after Subtenant vacates the Sublease Premises and completes any restoration or repair obligations of Subtenant hereunder. In furtherance of the foregoing, Sublandlord and Subtenant agree that the Letter of Credit shall contain a so- called "evergreen provision," whereby the Letter of Credit will automatically be renewed unless at least sixty

(60) days' prior written notice of non-renewal is provided by the Issuing Bank to Sublandlord; provided, however, that the final expiration date identified in the Letter of Credit, beyond which the Letter of Credit shall not automatically renew, shall not be earlier than the Final LC Expiration Date. Subtenant shall neither assign nor encumber the Letter of Credit or any part thereof. Neither Sublandlord nor its successors or assigns will be bound by any assignment, encumbrance, attempted assignment or attempted encumbrance by Subtenant in violation of this Article 17. If the Letter of Credit held by Sublandlord expires earlier than the Final LC Expiration Date (whether by reason of a stated expiration date or a notice of termination or non-renewal given by the Issuing Bank), Subtenant shall deliver a new or amended Letter of Credit or certificate of renewal or extension to Sublandlord not later than thirty (30) days prior to the expiration or termination of the Letter of Credit then held by Sublandlord. Any renewal, amended or replacement Letter of Credit shall comply with all of the provisions of this Sublease.

17.3 Sublandlord without prejudice to any other remedy provided in this Sublease or by law, shall have the right to draw down an amount up to the face amount of the Letter of Credit if any of the following shall have occurred or be applicable (each, a "Draw Event"): (i) Subtenant breaches or defaults in its obligations under this Sublease beyond applicable notice and cure periods; provided however if Sublandlord is prevented from delivering a notice of default to Subtenant for any reason, including without limitation, because Subtenant has filed a voluntary petition or an involuntary petition has been filed against Subtenant under the Bankruptcy Code (as defined below) then no notice or cure period shall be applicable or (ii) Subtenant has filed a voluntary petition under the U. S. Bankruptcy Code or any State bankruptcy code (collectively, "Bankruptcy Code"), or (iii) an involuntary petition has been filed against Subtenant under the Bankruptcy Code, and such involuntary petition has not been dismissed within ninety (90) days of such filing, or (iv) Subtenant executes an assignment for the benefit of creditors, or (v) Subtenant is placed into receivership or conservatorship, or becomes subject to similar proceedings under Federal or State law, and Subtenant's assets or substantially all of its assets are not restored to Subtenant within sixty

(60) days or (vi) the Issuing Bank has notified Sublandlord that the Letter of Credit will not be renewed or extended through the Final LC Expiration Date <u>and</u> Subtenant fails to provide Sublandlord with a new or amended Letter of Credit or certificate of renewal or extension on or before the date thirty (30) days prior to the expiration or termination of the Letter of Credit then held by Sublandlord or (vii) Subtenant fails to timely provide a replacement Letter of Credit as required by the terms of this Article 17 (the events described in clauses (ii), (iii), (iv), and (v) above, collectively, being referred to herein as an "**Insolvency** 

Event"). Upon any such draw, Sublandlord may use all or any part of the proceeds only (a) to cure any Event of Default by Subtenant; (b) to pay any other sum to which Sublandlord becomes obligated by reason of an Event of Default by Subtenant; or (c) to compensate Sublandlord for any monetary loss or damage which Sublandlord suffers thereby arising from an Event of Default by Subtenant. In addition, if the Draw Event is the failure of Subtenant to renew the Letter of Credit as required hereunder, then Sublandlord shall be entitled to draw the entire Letter of Credit as a cash security deposit, held as a pledge under the California Uniform Commercial Code to secure Subtenant's obligations under the Sublease. Among other things, it is expressly understood that the draw proceeds will not be considered an advance payment of Base Rent or Additional Rent or a measure of Sublandlord's damages resulting from any Event of Default by Subtenant hereunder (past, present or future). Further, immediately upon the occurrence and during the continuance of any one or more Draw Events, Sublandlord may, from time to time and without prejudice to any other remedy, use the draw proceeds (whether from a contemporaneous or prior draw on the Letter of Credit) to the extent necessary to make good any arrearages of Base Rent or Additional Rent which Subtenant has failed to pay within any applicable notice and cure periods, to pay to Sublandlord any and all amounts to which Sublandlord is entitled in connection with the pursuit of any one or more of its remedies hereunder due to an Event of Default by Subtenant, and to compensate Sublandlord for any and all other damage, injury, expense or liability caused to Sublandlord by any and all such Events of Default by Subtenant.

The proceeds of any draw upon the Letter of Credit which are not used to pay for damages suffered by Sublandlord (or which Sublandlord reasonably estimates it will suffer) (the "Unused Proceeds") as described above shall be held in Sublandlord's own name and for its own account and need not be segregated from any other funds of Sublandlord. Subtenant (i) agrees that (A) Subtenant has no property interest whatsoever in the proceeds from any such draw, and (B) such proceeds shall not be deemed to be or treated as a "security deposit" under the Security Deposit Laws (defined below), and (ii) waives all rights, duties and obligations either party may now or, in the future, will have relating to or arising from the Security Deposit Laws. Any Unused Proceeds shall be paid by Sublandlord to Subtenant (x) upon receipt by Sublandlord of a replacement Letter of Credit in the full Letter of Credit Amount, which replacement Letter of Credit shall comply in all respects with the requirements of this Sublease, or (y) within thirty (30) days after the Final LC Expiration Date; provided, however, that if prior to the Final LC Expiration Date a voluntary petition is filed by Subtenant, or an involuntary petition is filed against Subtenant by any of Subtenant's creditors, under the Bankruptcy Code, then Sublandlord shall not be obligated to make such payment in the amount of the Unused Proceeds until either all preference issues relating to payments under this Sublease have been resolved in such bankruptcy or reorganization case or such bankruptcy or reorganization case has been dismissed, in any case pursuant to a final court order not subject to appeal or any stay pending appeal.

## 17.5 Additional Covenants of Subtenant:

a. Replacement of Letter of Credit if Issuing Bank No Longer Satisfactory to Sublandlord. If, at any time during the Sublease Term, Sublandlord reasonably determines in good faith that (A) the Issuing Bank fails to meet any of the following three ratings standards as to its unsecured and senior, long-term debt obligations (not supported by third party credit enhancement) (the "Credit Rating Threshold"): (x) "A2" or better by Moody's Investors Service, or its successor, (y) "A" or better by Standard & Poor's Rating Service, or its successor; or (z) "A" or better by Fitch Ratings, or its successor, or (B) the Issuing Bank has been placed into receivership by the Federal Deposit Insurance Corporation ("FDIC"), or has entered into any other form of regulatory or governmental receivership, conservatorship or other similar regulatory or governmental proceeding, or is otherwise declared insolvent or downgraded by the FDIC or other governmental authority (any of the foregoing, an "Issuing Bank Credit Event"), then, within ten (10) business days following Sublandlord's notice to Subtenant, Subtenant shall deliver to Sublandlord a new Letter of Credit meeting the terms of this Sublease issued by an Issuing Bank meeting the Credit Rating Threshold and otherwise reasonably acceptable to Sublandlord, in which event, Sublandlord shall return to Subtenant the previously held Letter of Credit. If Subtenant fails to timely deliver such replacement Letter of Credit to Sublandlord, such failure shall be deemed a Default by Subtenant under this Sublease, without the necessity of additional notice or the passage of additional grace periods, entitling Sublandlord to draw upon the Letter of Credit.

- b. Replacement of Letter of Credit Upon Draw. If, as result of any application or use by Sublandlord of all or any part of the Letter of Credit, the amount of the Letter of Credit plus any cash proceeds previously drawn by Sublandlord and not applied pursuant to Section 17.3 above shall be less than the Letter of Credit Amount, Subtenant shall, within ten (10) business days thereafter, provide Sublandlord with additional Letter(s) of Credit or cash proceeds in an amount equal to the deficiency (or a replacement or amended Letter of Credit in the total Letter of Credit Amount), and any such additional (or replacement or amended) Letter of Credit shall comply with all of the provisions of this Sublease; notwithstanding anything to the contrary contained in this Sublease, if Subtenant fails to timely comply with the foregoing, the same shall constitute a Default by Subtenant under this Sublease, without the necessity of additional notice or the passage of additional grace periods.
- c. Nature of Letter of Credit. Sublandlord and Subtenant (i) acknowledge and agree that in no event or circumstance shall the Letter of Credit or any renewal thereof or substitute therefor or any proceeds thereof be deemed to be or treated as a "security deposit" under any law applicable to security deposits in the commercial context, including, but not limited to, Section 1950.7 of the California Civil Code, as such Section now exists or as it may be hereafter amended or succeeded (the "Security Deposit Laws"), (ii) acknowledge and agree that the Letter of Credit (including any renewal thereof or substitute therefor or any proceeds thereof) is not intended to serve as a security deposit, and the Security Deposit Laws shall have no applicability or relevancy thereto, and (iii) waive any and all rights, duties and obligations that any such party may now, or in the future will, have relating to or arising from the Security Deposit Laws. Without limiting the generality of the foregoing, Subtenant hereby agrees that Sublandlord may claim those sums specified in Section 17.2 above and/or those sums reasonably necessary to compensate Sublandlord for any loss or damage caused by the acts or omissions of Subtenant or Subtenant's breach of this Sublease, including any damages Sublandlord suffers following termination of this Sublease, and/or to compensate Sublandlord for any and all damages arising out of, or incurred in connection with, the termination of this Sublease, including, without limitation, those specifically identified in Section 1951.2 of the California Civil Code.
- d. Return of Unused Proceeds and Letter of Credit. Notwithstanding the foregoing provisions of this Sublease, upon the Final LC Expiration Date, and so long as there then exist no Draw Events or Default by Subtenant under this Sublease, Sublandlord agrees to return any remaining unapplied balance of the Unused Proceeds then held by Sublandlord to Subtenant, and the Letter of Credit itself (if and to the extent not previously drawn in full) to the Issuing Bank; provided that if, prior to the Final LC Expiration Date, a voluntary petition is filed by Subtenant or an involuntary petition is filed against Subtenant by any of Subtenant's creditors, under the Federal Bankruptcy Code, then Sublandlord shall not be obligated to make such payment in the amount of the Unused Proceeds until either all preference issues relating to payments under this Sublease have been resolved in such bankruptcy or reorganization case or such bankruptcy or reorganization case has been dismissed, in each case pursuant to a final court order not subject to appeal or any stay pending appeal.

## 18 NOTICES

All notices which may or are required to be given by either party to the other shall be in writing and shall be deemed given when received or refused if personally delivered, or if sent by United States registered or certified mail, postage prepaid, return receipt requested, or if sent by a nationally recognized overnight commercial courier service providing receipted delivery, in any such case (a) if to Subtenant, addressed to Subtenant at the addresses specified in the Basic Sublease Provisions or at such other place as Subtenant may from time to time designate by notice in writing to Sublandlord (provided, however, if Subtenant has abandoned the Sublease Premises, any such notice may be properly sent to Subtenant's agent for service of process), or (b) if for Sublandlord, addressed to Sublandlord at the address specified in the Basic Sublease Provisions or at such other place as Sublandlord may from time to time designate by notice in writing to Subtenant. Each party agrees promptly to deliver a copy of any notice, demand, request, consent or approval received from Master Landlord. Any notice delivered by Sublandlord in connection with, or as a precondition to, a Default by Subtenant shall be in lieu of and not in addition to any notice to pay rent or notice to perform any covenant required under law.

#### 19 CASp

- 19.1 Pursuant to Section 1938 of the California Civil Code, Sublandlord hereby advises Subtenant that (i) the Sublease Premises, as delivered to Subtenant, have not undergone an inspection by a Certified Access Specialist ("CASp"), and (ii) to Sublandlord's actual knowledge, the Building has not undergone an inspection by a CASp. Sublandlord makes no representations or warranties with respect to the Sublease Premises or Building complying with any applicable federal, state and local standards, codes, rules and regulations governing physical access for persons with disabilities at places of public accommodation, including, but not limited to, the ADA, California Building Standards Code, or California Health and Safety Code.
- 19.2 The following disclosure is made pursuant to §1938 of the California Civil Code, which provides: "A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the Sublease Premises." Notwithstanding the foregoing, if Subtenant elects to cause a CASp inspection, then the same will be performed at Subtenant's sole cost and expense, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the Sublease Premises will be at Subtenant's cost and expense.

### 20 MISCELLANEOUS

- 20.1 Signage. Subject to terms and restrictions of the Master Lease, the Building rules and regulations, and further subject to the prior written consent of the Master Landlord, Subtenant shall, at Subtenant's sole cost and expense, be permitted to install Building standard lobby and suite entrance signage, provided that at the expiration of this Sublease, Subtenant removes same at its cost and expense and repairs any damage to the Sublease Premises and Building caused by such installation and/or removal. Subtenant may be entitled to install Monument Signage as defined in the Master Lease, subject to the prior written consent of the Master Landlord. Subtenant acknowledges that Sublandlord's Monument Signage rights are personal to Sublandlord; however, Sublandlord agrees to ask Master Landlord to include Subtenant's name on the Monument Signage in place of Sublandlord's name. Notwithstanding the foregoing, failure of Master Landlord to consent to the inclusion of Subtenant's name on the Monument Signage in place of Sublandlord's name for any reason whatsoever shall not affect the validity of this Sublease or Subtenant's obligations hereunder, nor subject Sublandlord to any liability on account thereof. All Subtenant signage must be consistent with any signage program implemented by the Master Landlord and subject to the approval and consent requirements of the Master Lease.
- **20.2 Sublandlord Representations**. Sublandlord, as the tenant under the Master Lease identified in Section 1.3 above, represents and warrants to Subtenant that: (a) **Exhibit B** to this Sublease is a full and complete copy of the Master Lease, as redacted; (b) the Master Lease, as of the Execution Date, is in full force and effect and constitutes the entire agreement of Master Landlord and Sublandlord relating to the lease of the Sublease Premises, and (c) the person or persons executing this Sublease for Sublandlord are fully authorized to so act and no other action is required to bind Sublandlord to this Sublease; and (d) Sublandlord has the right and power to execute and deliver this Sublease and to perform its obligations hereunder, subject only to Master Landlord's consent; and (e) to Sublandlord's knowledge, neither the Master Landlord nor Sublandlord, as Tenant, is in default under the Master Lease.
- **20.3** Subtenant Representations. Subtenant represents and warrants to Sublandlord that: (a) Subtenant has reviewed and is familiar with all of the terms, agreements, covenants and conditions of the Master Lease and understands how such provisions pertain to the Sublease Premises and Subtenant's use and occupation thereof under this Sublease; (b) Subtenant has the right and power to execute and

deliver this Sublease and to perform its obligations hereunder; (c) the person or persons executing this Sublease for Subtenant are fully authorized to so act and no other action is required to bind Subtenant to this Sublease; and (d) Subtenant is duly organized and in good standing in its state of formation and is authorized to conduct business in the state where the Sublease Premises are located.

- **20.4 Brokers**. Each party warrants to the other that it has had no dealings with any broker or agent in connection with this Sublease, except those Brokers specified in the Basic Sublease Provisions. [\*\*\*] Each party covenants to protect, defend, indemnify and hold harmless the other party from and against any and all costs (including reasonable attorneys' fees), expense or liability for any compensation, commission and charges claimed by any broker or other agent, other than the Brokers, with respect to this Sublease or the negotiation thereof on behalf of such party.
- **20.5** Entire Agreement. There are no representations, warranties, agreements, arrangements or understandings, oral or written, between the parties or their representatives relating to the subject matter of this Sublease which are not fully expressed in this Sublease. This Sublease is subject to amendment only by a writing that makes reference to this Sublease and is signed by all parties hereto.
- **20.6 Waiver**. No waiver of any provision of this Sublease or consent to any action shall constitute a waiver of any other provision of this Sublease or consent to any other action. No waiver or consent shall constitute a continuing waiver or consent, or commit a party to provide a future waiver, unless such provision is expressly set forth in writing. Any waiver given by a party shall be void if the party requesting such waiver has not provided a full and complete disclosure of all material facts relevant to the waiver requested.
- **20.7 Interpretation; Headings.** The terms of this Sublease have been negotiated by the parties hereto and the language used in this Sublease shall be deemed to be the language chosen by the parties hereto to express their mutual intent. The parties acknowledge and agree that each party and its counsel have reviewed and revised this Sublease and that no rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall be employed in the interpretation of this Sublease. The captions, headings and titles, if any, in this Sublease are solely for convenience of reference and shall not affect its interpretation.
- **20.8** Prevailing Party Rights. If there is any legal or arbitration action or proceeding between Sublandlord and Subtenant to enforce any provision of this Sublease or to protect or establish any right or remedy of either Sublandlord or Subtenant hereunder, the unsuccessful party to such action or proceeding shall pay to the prevailing party all costs and expenses, including reasonable attorneys' fees incurred by such prevailing party in such action or proceeding and in any appearance in connection therewith, and if such prevailing party recovers a judgment in any such action, proceeding or appeal, such costs, expenses and attorneys' fees shall be determined by the court or arbitration panel handling the proceeding and shall be included in and as part of such judgment.

## 20.9 Sublandlord Liability.

a. Notwithstanding anything to the contrary set forth in this Sublease, (a) Sublandlord's liability to Subtenant for any default in Sublandlord's obligations under this Sublease shall be limited to actual, direct damages, and under no circumstances shall Subtenant, its partners, members, shareholders, directors, agents, officers, employees, contractors, sublessees, successors and/or assigns be entitled to recover from Sublandlord (or otherwise be indemnified by Sublandlord) for (i) any losses, costs, claims, causes of action, damages or other liability incurred in connection with a failure of Master Landlord, its partners, members, shareholders, directors, agents, officers, employees, contractors, successors and/or assigns to perform or cause to be performed Master Landlord's obligations under the Master Lease, unless and to the extent Sublandlord or any of its agents, employees, affiliates, members, managers, officers, directors, partners, contractors or other representatives causes or contributes to such failure, (ii) lost revenues, lost profits or other consequential, special or punitive damages arising in connection with this Sublease for any reason, or (iii) any damages or other liability arising from or incurred

in connection with the condition of the Sublease Premises or suitability of the Sublease Premises for Subtenant's intended use, and (b) no personal liability shall at any time be asserted or enforceable against Sublandlord's partners, members, shareholders, directors, officers or agents or any of their assets on account of any action or inaction by Sublandlord or Sublandlord's partners, members, shareholders, directors, agents, officers, employees or contractors under this Sublease.

- b. In the event of any assignment or transfer of the Sublandlord's interest under this Sublease, provided the assignee or transferee assumes in writing the Sublandlord's obligations under this Agreement accruing from and after the effective date of such assignment or transfer, Sublandlord shall be and is hereby relieved of all of the covenants and obligations of Sublandlord under this Sublease accruing subsequent to the date of the transfer. Sublandlord may transfer and deliver any then-existing Security Deposit to the transferee of Sublandlord's interest in this Sublease, and thereupon Sublandlord shall be discharged from any further liability with respect thereto.
- **20.10** Confidentiality. Subtenant acknowledges that the terms of this Sublease are confidential between Sublandlord and Subtenant. Subtenant shall not disclose the economic terms of this Sublease, including the rental rates, to any third party other than Master Landlord, Subtenant's attorneys, accountants, brokers. Letter of Credit issuer and other financial, legal and space planning consultants on a 'need to know' basis who are assisting Subtenant in the consummation of this transaction or in the enforcement or interpretation of Subtenant's rights hereunder, or except as otherwise required by Law, including disclosure to regulators governing Subtenant's business.
- **20.11** No Offer. The submission of this Sublease to Subtenant does not constitute an offer to lease or otherwise create any right or interest of Subtenant in, the Sublease Premises. This Sublease shall become effective only upon the execution and delivery thereof by both Sublandlord and Subtenant and upon Master Landlord consenting to the subletting pursuant to this Sublease. Sublandlord shall have no liability or obligation to Subtenant by reason of Sublandlord's rejection of this Sublease or a failure to execute, acknowledge and deliver same to Subtenant.
  - **20.12 Exhibits.** All Exhibits attached to this Sublease and incorporated herein by this reference.
- 20.13 USA Patriot Act Disclosures. Neither Subtenant nor any of its constituent partners, managers, members or shareholders, nor any beneficial owner of Subtenant or of any such partner, manager, member or shareholder (a) to Subtenant's knowledge, is listed on the Specially Designated Nationals and Blocked Persons List maintained by the Office of Foreign Asset Control, Department of the Treasury ("OFAC") pursuant to the Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) ("Order"); (b) to Subtenant's knowledge, is listed on any other list of terrorists or terrorist organizations maintained pursuant to the Order, the rules and regulations of OFAC or any other applicable requirements contained in any enabling legislation or other Executive Orders in respect of the Order (the Order and such other rules, regulations, legislation or orders are collectively called the "Orders"); (c) to Subtenant's knowledge, is engaged in activities prohibited in the Orders; or (d) has been convicted, pleaded nolo contendere, indicted, arraigned or custodially detained on charges involving money laundering or predicate crimes to money laundering.
- **20.14** Governing Law. Irrespective of the place of execution or performance, this Sublease shall be governed by and construed in accordance with the laws of the State in which the Sublease Premises are located.
- **20.15 Invalidity**. If any provision of this Sublease or the application thereof to any person or circumstance shall, for any reason and to any extent, be invalid or unenforceable, the remainder of this Sublease and the application of that provision to other persons or circumstances shall not be affected but rather shall be enforced to the extent permitted by Law.
- **20.16** Counterparts; Electronic Signature. This Sublease may be executed in multiple counterparts, each of which shall constitute an original, and all of which when taken together shall constitute one instrument. Delivery via facsimile or PDF transmission of a counterpart of this Sublease executed by

the party(ies) making such delivery shall constitute a valid execution and delivery of this Sublease for all purposes as if such party had delivered an original counterpart. Signatures may also be transmitted using electronic signature technology. The party's further consent and agree that (a) to the extent a party signs this document using electronic signature technology, by clicking "sign", such party is signing this Sublease electronically and (b) the electronic signatures appearing on this Sublease shall be treated, for purposes of validity, enforceability and admissibility, the same as hand-written signatures.

**20.17 Subtenant Liability**. Notwithstanding anything to the contrary set forth in this Sublease, no personal liability shall at any time be asserted or enforceable against Subtenant's officers, directors, shareholders, partners, members, managers, or agents or any of their assets on account of any action or inaction by Subtenant or any of Subtenant's officers, directors, shareholders, partners, members, managers, employees, agents or contractors under this Sublease.

# [SIGNATURES ON FOLLOWING PAGE]

**IN WITNESS WHEREOF**, Sublandlord and Subtenant have executed this Sublease as of the Execution Date.

SUBLANDLORD: KRIYA THERAPEUTICS, INC., a Delaware corporation SUBTENANT: TALIS BIOMEDICAL CORPORATION, a Delaware corporation

Ву	/s/ Curt Herberts	Ву	/s/ Roger Moody
Name	Curt Herberts	Name	Roger Moody
Title	President & COO	Title	CFO

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

## **CONSENT TO SUBLEASE**

This Consent to Sublease (the "Consent") is entered into as of March 16, 2023 ("Effective Date"), by and among WESTPORT OFFICE PARK, LLC, a Delaware limited liability company (formerly a California limited liability company) ("Landlord"), KRIYA THERAPEUTICS, INC., a Delaware corporation ("Tenant"), and TALIS BIOMEDICAL CORPORATION, a Delaware corporation ("Subtenant"), with respect to the following facts and circumstances:

- A. Landlord and Tenant are parties to that certain Lease Agreement dated as of July 24, 2020 ("Original Lease"), as amended by that certain First Amendment dated as of April 8, 2022 ("First Amendment" and collectively with the Original Lease, the "Lease") pursuant to which Landlord leases to Tenant certain premises (the "Premises") in the building known as 1100 Island Drive, Redwood City, California 94065 ("Building"), as more particularly described in the Lease.
- B. Tenant and Subtenant have entered into (or are about to enter into) a sublease agreement dated March 16, 2023 (the "Sublease"), pursuant to which Tenant has agreed to sublease to Subtenant the entire Premises containing approximately 13,165 rentable square feet, located in Suite 101 on the first (1st) floor of the Building (the "Sublet Premises") for a term expiring no later than the stated expiration date of the term of the Lease.
  - C. Tenant and Subtenant have requested Landlord's consent to the Sublease.
- D. Landlord is willing to consent to the Sublease on the terms and conditions contained in this Consent.

Now, therefore, in consideration of the mutual covenants contained in this Consent, and for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord hereby consents to the Sublease subject to the following terms and conditions, all of which are hereby acknowledged and agreed to by Landlord, Tenant and Subtenant:

1. Tenant shall be and remain liable and responsible for the due keeping, performance and observance, throughout the term of the Lease, of all of the covenants and agreements therein set forth on the part of Tenant to be kept, performed and observed and for the payment of the fixed rent, additional rent and all other sums and any other charges whatsoever now and/or hereafter becoming payable thereunder, expressly including as such additional rent, any and all charges for any property, material, labor, utility or other services furnished or rendered by Landlord in or in connection with the premises demised by the Lease, whether for, or at the request of, Tenant or Subtenant.

- 2. The Sublease shall be subject and subordinate at all times to the Lease, and to all of the covenants and agreements of the Lease and of this Consent, and Subtenant shall not do, permit or suffer anything to be done in or in connection with Subtenant's use or occupancy of the Sublet Premises which would violate any of such covenants and agreements. All acts and omissions of Subtenant or anyone claiming under Subtenant which shall be in violation of the Lease shall be deemed a violation by Tenant. If there is a conflict between this Consent and the Sublease, the terms, conditions, and obligations of this Consent shall control.
- Neither the Sublease nor this Consent thereto shall: (a) release or discharge Tenant from any liability whether past, present or future, under the Lease; (b) operate as a consent to or approval by Landlord of any of the terms, covenants, conditions, provisions or agreements of the Sublease and Landlord shall not be bound thereby; (c) be construed to modify, waive or affect any of the terms, covenants, conditions, provisions or agreements of the Lease or to waive any breach thereof, or any of Landlord's rights thereunder, or enlarge or increase Landlord's duties or obligations thereunder; (d) be construed as a consent by Landlord to any further subletting by Tenant or Subtenant or to any assignment by Tenant of the Lease or assignment by Subtenant of the Sublease, whether or not the Sublease purports to permit the same, provided the foregoing shall not preclude Tenant from exercising Tenant's rights outlined in Section 18.8 of the Original Lease with respect to Permitted Transfers (as modified by Section 16.5 of the First Amendment); (e) be construed as consent by Landlord to a term in the Sublease beyond the term of the Lease; (f) grant any rights to Subtenant greater than those rights granted to Tenant under the Lease; (g) create obligations or costs to Landlord with regard to the Sublease; (h) require Landlord to recognize Subtenant in the event of a default under the Lease by Tenant; (i) limit Landlord's right, in the event of a proposed future transfer, to recapture any portion of the Premises, including the Sublet Premises, affected by that proposed transfer, to the extent provided in the Lease; (j) require Landlord to proceed in any action under the Lease or this Consent against either Tenant or Subtenant without first exhausting Landlord's remedies against the other; (k) without limiting the effectiveness of this Consent, be construed as Landlord's agreement or acknowledgement that there does not exist a reasonable basis to withhold consent to the Sublease; or (1) be construed to waive, limit or impair Landlord's rights to withhold consent with respect to any other sublease or any assignment of lease (to the extent Landlord's consent is required under the Lease). Subtenant shall have no recourse against Landlord on account of any failure by Landlord to perform any of its obligations under the Lease. Subtenant's only recourse shall be against Tenant.
- 4. This Consent is not assignable, nor shall this Consent be a consent to any amendment, modification, extension or renewal of the Sublease, without Landlord's prior written consent, in accordance with the terms of the Lease.
- 5. Tenant and Subtenant each covenants and agrees that under no circumstances shall Landlord be liable for any brokerage commission or other charge or expense in connection with the Sublease and Tenant and Subtenant each agrees to indemnify Landlord against the same and against any cost or expense (including but not limited to reasonable attorneys' fees and expenses) incurred by Landlord in resisting any claim for any such brokerage commission. The provisions of this Section 5 shall survive the expiration or earlier termination of Sublease and this Consent.
- 6. The Sublet Premises shall (subject to all of the covenants and agreements of the Lease) be used solely for the purposes permitted by the Lease.

- A true and complete copy of the Sublease and a true and complete copy of each amendment thereto shall be delivered to Landlord within ten (10) days after the execution and delivery thereof by the parties thereto; it being understood that Landlord shall not be deemed to be a party to the Sublease or any such amendment nor bound by any of the covenants or agreements thereof and that neither the execution and delivery of this Consent nor the receipt by Landlord of a copy of the Sublease or a copy of any such amendment shall be deemed to change any provision of this Consent or to be consent to, or an approval by Landlord of, any covenant or agreement contained in the Sublease or any such amendment. Landlord and Tenant acknowledge and agree that Tenant shall pay to Landlord the Transfer Premium in accordance with Section 18.3 of the Lease.
- All of the covenants and agreements contained herein shall be binding upon and shall inure to the benefit of the parties hereto and their respective legal representatives, successors and assigns.
- This Consent shall not be effective and binding unless and until it has been fully executed and delivered by all of the parties hereto. Subtenant shall not be permitted to access the Premises until Subtenant has delivered to Landlord evidence of insurance in compliance with Section 13 of the Original Lease and this Consent. Furthermore, within thirty (30) days after the Effective Date of this Consent, Tenant shall pay to Landlord \$[\*\*\*] as reimbursement of Landlord's fees and charges in connection with this Consent in accordance with Section 18.1 of the Original Lease. Tenant's failure to deliver such reimbursement within thirty (30) days after the Effective Date and Subtenant's failure to cure Tenant's failure within ten (10) days following receipt of written notice from Landlord of such Tenant's failure shall, at Landlord's option, render this Consent and the Sublease null, void and of no effect.
- 10. Tenant assigns and transfers to Landlord Tenant's interest in the Sublease and all rentals and income arising from the Sublease, subject to the terms of this Section 10. Landlord, by consent to the Sublease, agrees that, until Tenant defaults in performing its obligations under the Lease beyond applicable notice and cure periods. Tenant may receive, collect, and enjoy the rents accruing under the Sublease. If Tenant defaults in the performance of its obligations to Landlord beyond applicable notice and cure periods, Landlord may elect to receive and collect, directly from Subtenant, all rent and any other sums owing and to be owed under the Sublease, as further set forth below. Landlord will not, as a result of the Sublease, or as a result of the collection of rents or any other sums from Subtenant under this Section 10, be liable to Subtenant for any failure of Tenant to perform any obligation of Tenant under the Sublease. Tenant irrevocably authorizes and directs Subtenant, on receipt of any written notice from Landlord stating that a default exists in the performance of Tenant's obligations under the Lease beyond applicable notice and cure periods, to pay to Landlord the rents and any other sums due and to become due under the Sublease. Tenant agrees that Subtenant has the right to rely on any such statement from Landlord, and that Subtenant will pay those rents and other sums to Landlord without any obligation or right to inquire as to whether a default exists and despite any notice or claim from Tenant to the contrary. Tenant will not have any right or claim against Subtenant for those rents or other sums paid by Subtenant to Landlord. Landlord will credit Tenant with any rent received by Landlord under this assignment, but the acceptance of any payment on account of rent from Subtenant as the result of a default by Tenant (beyond applicable notice and cure periods) will not: (a) be an attornment by Landlord to Subtenant or by Subtenant to Landlord; (b) be a waiver by Landlord of any provision of the Lease; or (c) release Tenant from any liability under the terms.
- agreements, or conditions of the Lease. Notwithstanding the foregoing,

no payment of rent from Subtenant directly to Landlord, regardless of the circumstances or reasons therefor, shall in any manner whatsoever be deemed an attornment by Landlord to Subtenant or by Subtenant to Landlord in the absence of a specific written agreement signed by Landlord to such an effect.

- Subtenant hereby assumes, with respect to Landlord, all of the indemnity, release, waiver and insurance 11. obligations of Tenant under the Lease with respect to the Sublet Premises, provided that the foregoing shall not be construed as relieving or releasing Tenant from any such obligations. Without limiting the generality of the foregoing, Subtenant shall (a) maintain in effect such liability insurance as Tenant is required by the Lease to maintain, (b) cause to be named as additional insureds under that liability insurance such persons as Tenant is required by the Lease to name as additional insureds on its liability insurance, and (c) furnish to Landlord such evidence of insurance as Tenant is required by the Lease to furnish. Subtenant shall cause to be included in each of its property insurance policies (including business interruption) a waiver of the insurer's right of subrogation against Landlord, and Subtenant hereby releases Landlord from any claim (including a claim for negligence) which Subtenant might otherwise have for loss, damage or destruction of Subtenant's property during the term of the Sublease (including business interruption) to the extent to which such loss, damage or destruction is insured by Subtenant or would have been required to be insured by Subtenant if Subtenant were the tenant under the Lease. Landlord hereby waives any and all rights of recovery, claim, action, or cause of action against the Subtenant, its agents, employees, licensees, or invitees for any loss or damage to or at the Sublet Premises or any personal property of Landlord therein or thereon by reason of fire, the elements, or any other cause to the extent the same is insured against under the terms of the property insurance policy required to be maintained by Landlord under the Lease, Landlord, Tenant, and Subtenant agree that any and all insurance policies required to be carried by a party pursuant to the Lease or Sublease (as applicable) shall be endorsed with a subrogation clause, substantially as follows: "This insurance shall not be invalidated should the insured waive, in writing prior to a loss, any and all right of recovery against any party for loss occurring to the property described therein," and shall provide that such party's insurer waives any right of recovery against the other party in connection with any such loss or damage.
- 12. Tenant and Subtenant understand and acknowledge that Landlord's consent to the Sublease is not a consent to any improvement or alteration work being performed in the Sublet Premises, and that for any improvements or alteration work that requires Landlord's consent under the terms of the Lease, Landlord's consent must be separately sought and will not necessarily be given or withheld pursuant to the terms of the Lease.
- 13. Both Tenant and Subtenant shall be and continue to be liable for the payment of (a) all bills rendered by Landlord for charges incurred by Subtenant for services and materials supplied to the Sublet Premises, including without limitation, any services and materials supplied beyond that which is required by the terms of the Lease and (b) any additional costs incurred by Landlord for maintenance and repair of the Sublet Premises as the result of Subtenant (rather than Tenant) occupying the Sublet Premises (including but not limited to any excess cost to Landlord of services furnished to or for the Sublet Premises resulting from the extent to which Subtenant uses them for purposes other than as set forth in the Lease).

- 14. If the Lease or Tenant's right to possession thereunder terminates for any reason prior to expiration of the Sublease, Subtenant agrees, at the written election of Landlord, to attorn to Landlord upon the then executory terms and conditions of the Sublease for the remainder of the term of the Sublease. In the event of any such election by Landlord, Landlord will not be (a) liable for any rent paid by Subtenant to Tenant more than one month in advance, or any security deposit paid by Subtenant to Tenant, unless same has been transferred or credited to Landlord by Tenant; (b) liable for any act or omission of Tenant under the Lease, Sublease or any other agreement between Tenant and Subtenant or for any default of Tenant under any such documents which occurred prior to the effective date of the attornment, provided that Landlord shall be obligated to perform all of its obligations under the Lease; (c) subject to any defenses or offsets that Subtenant may have against Tenant which arose prior to the effective date of the attornment, provided that Landlord shall be obligated to perform all of its obligations under the Lease; (d) bound by any changes or modifications made to the Sublease without the written consent of Landlord;
- (e) obligated in any manner with respect to the transfer, delivery, use or condition of any furniture, equipment or other personal property in the Sublet Premises which Tenant agreed would be transferred to Subtenant or which Tenant agreed could be used by Subtenant during the term of the Sublease; or (f) liable for the payment of any improvement allowance, or any other payment, credit, offset or amount due from Tenant to Subtenant under the Sublease. If Landlord does not elect to have Subtenant attorn to Landlord as described above, the term of the Sublease, and the estate thereby granted, shall expire and come to an end, regardless of any provision of the Sublease to the contrary, upon the earlier of (i) its natural expiration date or (ii) concurrently with any premature termination or earlier expiration of the Lease (whether by consent, agreement or other right, now or hereafter agreed to by Landlord or Tenant, or both, or by operation of law or, at Landlord's option, in the event of default by Tenant). Any failure of Subtenant to vacate the Sublet Premises by that date shall be deemed a failure of Tenant to vacate the Premises and a continuing occupancy of the Premises by Tenant. The terms of this Section 14 supersede any contrary provisions in the Sublease.
- 15. It is hereby acknowledged and agreed that any provisions in the Sublease which limit the manner in which Tenant may amend the Lease are binding only upon Tenant and Subtenant as between such parties. Landlord shall not be bound in any manner by such provisions and may rely upon Tenant's execution of any agreements amending or terminating the Lease subsequent to the date hereof notwithstanding any contrary provisions in the Sublease.
- 16. Subtenant shall not further sublease the Sublet Premises, assign its interest as the Subtenant under the Sublease or otherwise transfer its interest in the Sublet Premises or the Sublease to any person or entity without the written consent of Landlord, which Landlord shall grant or withhold in accordance with the standards and procedures set forth in the Lease. Landlord may consent to subsequent subleases and assignments of the Sublease or any amendments or modifications to the Sublease without notifying Tenant or anyone else liable under the Lease, including any guarantor of the Lease, and without obtaining their consent. No such action by Landlord will relieve those persons from any liability to Landlord or otherwise with regard to the Sublet Premises.

- 17. As additional consideration for this Consent, Tenant hereby certifies that:
  - (a) The Lease is in full force and effect.
- (b) To Tenant's knowledge, there are no uncured defaults on the part of Landlord or Tenant under the Lease.
- (c) There are no existing offsets or defenses which Tenant has against the enforcement of the Lease by Landlord.
- 18. Tenant and Subtenant represent and warrant that there are no additional payments of rent or any other consideration of any type which has been paid or is payable by Subtenant to Tenant in connection with the Sublease, other than as disclosed in the Sublease.
- 19. If Landlord is entitled, pursuant to the terms of the Lease, to receive any portion of the rent to be paid by Subtenant to Tenant under the Sublease, then, in addition to all rent otherwise payable by Tenant to Landlord under the Lease, Tenant shall pay to Landlord such portion of such rent as required under the Lease. Landlord's failure to bill Tenant for, or to otherwise collect, such sums shall not be deemed a waiver by Landlord of its right to collect such sums in accordance with the Lease.
  - 20. Tenant's new address for notices under the Lease shall be as follows: Kriya Therapeutics, Inc.

3790 El Camino Real, Unit #614 Palo Alto, CA

94306

With an email copy to: legal@kriyatx.com

Notices shall otherwise be sent in accordance with the terms of, the Lease. Any notice from Landlord to Subtenant may be given to the Sublet Premises in the manner provided for in the Lease with a copy of such notice also given to Subtenant at 1375 West Fulton Market, Suite 700, Chicago, Illinois 60607 in the manner provided for in the Lease.

- 21. Each party of this Consent represents hereby that its respective signatories below have the authority to execute and deliver the same on behalf of the party hereto for which such signatory is acting.
  - 22. Intentionally Deleted.
- 23. By executing this Consent, Subtenant acknowledges that it has received a copy of the Lease from Tenant. Landlord shall not have any obligation to disclose the status of the Lease to Subtenant or to inform Subtenant as to any changes in the status of the Lease or the financial condition of Tenant.
- 24. Tenant hereby represents and warrants that Tenant (i) has full power and authority to sublease the Sublet Premises to Subtenant, (ii) has not transferred or conveyed its interest in

the Lease to any person or entity collaterally or otherwise, and (iii) has full power and authority to enter into the Sublease and this Consent. Subtenant hereby represents and warrants that Subtenant has full power and authority to enter into the Sublease and this Consent. This Consent constitutes the final, complete and exclusive statement between the parties to this Consent pertaining to the terms of Landlord's consent to the Sublease, supersedes all prior and contemporaneous understandings or agreements of the parties, and is binding on and inures to

the benefit of their respective heirs, representatives, successors and assigns. The terms and provisions of this Consent will be construed in accordance with, and will be governed by, the laws of the State of California. If any party commences litigation against any other party for the specific performance of this Consent, for damages for the breach hereof or otherwise for enforcement of any remedy hereunder, the parties waive any right to a trial by jury and, in the event of any commencement of litigation or arbitration, the prevailing party or parties shall be entitled to recover from the non-prevailing party or parties such costs and reasonable attorneys' fees as may have been incurred. This Consent may be executed in counterparts and shall constitute an agreement binding on all parties notwithstanding that all parties are not signatories to the original or the same counterpart provided that all parties are furnished a copy or copies thereof reflecting the signature of all parties. Delivery via facsimile or PDF transmission of a counterpart of this Consent executed by the party(ies) making such delivery shall constitute a valid execution and delivery of this Consent for all purposes as if such party had delivered an original counterpart. Signatures may also be transmitted using electronic signature technology. The party's further consent and agree that (a) to the extent a party signs this document using electronic signature technology, by clicking "sign", such party is signing this Consent electronically and (b) the electronic signatures appearing on this Consent shall be treated, for purposes of validity, enforceability and admissibility, the same as hand-written signatures.

[Signatures are on following pages]

IN WITNESS WHEREOF, this Consent is executed as of the date first-above written.

# "LANDLORD"

WESTPORT OFFICE PARK, LLC, a Delaware limited liability company (formerly a California limited liability company)

By: /s/ Jessica Brock
Its: Authorized Signatory

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## "TENANT"

# KRIYA THERAPEUTICS, INC., a Delaware corporation

By: /s/ Curt Herberts
Its: President & COO

By: /s/ Dana B. Johnson
Its: Secretary & CLO

If this entity is a corporation, this instrument must be executed by BOTH the chairman of the board, the president or any vice president AND the secretary, any assistant secretary, the chief financial officer or any assistant financial officer or any assistant treasurer of such corporation, unless the bylaws or a resolution of the board of directors shall otherwise provide, in which case the bylaws or a certified copy of the resolution, as the case may be, must be attached to this instrument.

## "SUBTENANT"

# TALIS BIOMEDICAL CORPORATION, a Delaware corporation

By: /s/ J. Roger Moody

Its: CFO

By: /s/ Gillian Green

Its: SVP Legal, Corporate Secretary

If this entity is a corporation, this instrument must be executed by BOTH the chairman of the board, the president or any vice president AND the secretary, any assistant secretary, the chief financial officer or any assistant financial officer or any assistant treasurer of such corporation, unless the bylaws or a resolution of the board of directors shall otherwise provide, in which case the bylaws or a certified copy of the resolution, as the case may be, must be attached to this instrument.

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

## TERMINATON AND RELEASE AGREEMENT

**THIS TERMINATION AND RELEASE AGREEMENT** (the "<u>Agreement</u>") is made effective as of March 21, 2023 (the "<u>Effective Date</u>") between Talis Biomedical Corporation ("<u>Talis</u>") and thinXXS Microtechnology GmbH ("<u>thX</u>"). Talis and thX may hereafter be referred to collectively as the "<u>Parties</u>" or each individually, a "<u>Party</u>."

**WHEREAS**, the Parties entered into a Supply Agreement dated as of 22 May 2020, as subsequently amended (the "Supply Agreement");

**WHEREAS**, the Parties now desire to terminate the Supply Agreement, enter into a mutual release of any potential claims or actions, as further described below, and end their business relationship.

**NOW, THEREFORE,** in consideration of the promises, covenants and undertakings herein contained, the receipt and adequacy of which the Parties hereto confess and acknowledge, the Parties agree as follows:

**1. Termination**. The Parties acknowledge and agree that the Supply Agreement is hereby terminated effective as of the Effective Date. Except as otherwise expressly provided in this Agreement or the License Agreement (as hereafter defined), neither Party shall have any further rights or obligations under the Supply Agreement.

## 2. License.

- A. Concurrent with this Agreement, the Parties shall enter into the License Agreement attached hereto as **Exhibit A** (the "License Agreement"). The License Agreement shall not become effective until thX has received the License Payment (as defined in Section 3 of the License Agreement) and is subject to Talis' compliance with its obligations under this Agreement.
- B. The Parties agree to execute the next steps outlined in the attached Termination Execution List (attached and incorporated herein as Exhibit D) within ten (10) days following the Effective Date.
- **3. Payment of Invoices**. Talis shall pay in full and on time, without setoff or deduction, all invoices owed to thX, or any of its affiliates, for product ordered prior to the Effective Date and delivered to Talis prior to or after the Effective Date and any payments due hereunder.

# 4. Transfer of [\*\*\*] and Raw Materials.

A. [\*\*\*]. In consideration of the terms of this Agreement, thX shall sell, transfer and assign ownership of the [\*\*\*] listed in **Exhibit B** (the "<u>Transferred Equipment</u>") to Talis for a purchase price of [\*\*\*]. Prior to completing the transfer, thX or its agent shall have the right to remove the parts identified in Exhibit B from the Transferred Equipment, and thX shall [\*\*\*]. All other equipment or infrastructure purchased under the Supply Agreement and not listed in **Exhibit B** (including, without limitation, [\*\*\*]) shall remain the property of thX, regardless of which Party may have paid

- for such equipment or infrastructure initially, and thX and its affiliates shall have a freedom to use the equipment and infrastructure as they see fit. In addition, Talis agrees to use reasonable efforts to [\*\*\*].
- B. <u>Raw Material</u>. In consideration of the terms of this Agreement, thX shall sell, transfer and assign ownership of the raw material listed in **Exhibit C** (the "<u>Raw Material</u>") to Talis for a purchase price of [\*\*\*].
- C. <u>Costs.</u> thX shall be responsible to prepare certain of the Transferred Equipment, molds, and Raw Material for shipment and shall make the Transferred Equipment and Raw Material available to Talis for pickup at thX's Zweibrücken facility. Talis shall be solely responsible to arrange for, and pay the cost of, shipping the Transferred Equipment, molds and Raw Material. In addition, Talis will reimburse thX for the time and expenses incurred by thX (or its applicable affiliate) (for clarity, [\*\*\*]) to prepare the transferred Equipment, molds and Raw Material, including removal of any thX intellectual property in accordance with Subsection A ("<u>Equipment Prep</u>"), up to a maximum of [\$\*\*\*]. The Parties acknowledge and agree that thX shall quote, and require a PO from Talis prior to the commencement of any Equipment Prep.
- D. <u>No Warranty.</u> TALIS ACKNOWLEDGES THAT THE TRANSFERRED EQUIPMENT AND THE RAW MATERIAL ARE BEING PROVIDED ON AN "AS-IS-WHERE-IS" BASIS WITHOUT ANY WARRANTIES, REPRESENTATIONS OR GUARANTEES. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, THX EXPRESSLY DISCLAIMS ANY AND ALL EXPRESS OR IMPLIED WARRANTIES INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PURPOSE UNDER THE UNIFORM COMMERCIAL CODE.
- **5. Indemnification**. Talis shall indemnify and hold harmless thX and its affiliates, their directors, officers, employees, invitees, agents and customers ("<u>Indemnitees</u>") from and against all liability, demands, claims, losses, costs, actions, judgments, fines, penalties, damages and expenses pursued by any third party, including attorney's fees incurred by Indemnitees related to or arising in connection with: (i) any breach of this Agreement or the License Agreement; (ii) the manufacture, sale, shipment and distribution of any product manufactured by Talis (or its affiliates, contract manufacturer or successors in interest) utilizing the Transferred Equipment, the Raw Materials, or the License Agreement. The Parties shall be subject to the Indemnification Procedures set forth in Section 5.3 of the License Agreement, which provision is hereby incorporated by reference.
- **6. Mutual Release.** Except for their respective obligations under this Agreement and the License Agreement and subject to California Civil Code § 1542, each Party, for itself, its successors, predecessors, assigns, subsidiaries, parents, affiliates and/or related entities, as well as their officers, directors, employees, partners, and agents, and/or any other successor in interest, hereby releases, acquits and forever discharges the other Party, its successors, predecessors, assigns, subsidiaries, parents, affiliates and/or related entities, as well as their officers, directors, employees, partners, and agents, and/or any other successor in interest from any and all claims,

demands, actions, causes of action, damages, costs, expenses, fees, suits, debts, dues, sums of money, accounts, bonds, bills, contracts, covenants, controversies, variances, judgments, obligations and other liabilities whatsoever, whether known or unknown, whether foreseen or unforeseen, whether in law or in equity, whether compulsory or permissive, whether sounding in tort, contract, fraud, statutory or regulatory violation, from the beginning of time through the date of this Agreement.

## 7. Confidentiality and Non-Disparagement.

- A. <u>Confidentiality</u>. Absent the prior written consent of the other Party, each Party shall keep confidential and shall not disclose or announce to any member of the media or any other third party the fact, terms or conditions of this Agreement except to assist the Parties with respect to the implementation of, compliance with or accounting for the transactions contemplated by this Agreement. Notwithstanding any of the foregoing, the Parties may make required public filings regarding the required fact, terms or conditions of this Agreement that are disclosed to the other Party prior to such public filings.
- B. <u>Non-Disparagement</u>. Each Party shall not: (i) disparage, criticize or make negative or derogatory statements or comments about; or (ii) take any action or attempt to communicate in any way information or opinions intended to or which is likely to have the effect of damaging, discrediting, or otherwise call into disrepute, the other Party, its successors, predecessors, assigns, subsidiaries, parents, affiliates and/or related entities, as well as their officers, directors, employees, partners, and agents, and/or any other successor in interest. This provision applies to all such disparaging acts without regard for the truth or falsehood of the statement and regardless of whether the statement(s) would constitute a claim for defamation.
- C. <u>Permitted Statements</u>. Each Party may make general statements to the effect that the Parties have reached an agreement to end their business relationship on mutually agreeable terms. Nothing in this Agreement shall be construed to prevent either Party from making any disclosure required by law, regulation, or court rule.
- **8. Binding Nature**. This Agreement shall be binding upon and inure solely to the benefit of the Parties, their heirs, successors and assigns.
- **9. Choice of Law/Forum Selection**. This Agreement shall be governed by and construed in accordance with the laws of the State of Illinois, excluding any of its conflict of laws principles that would require the application of the laws of another jurisdiction. Exclusive jurisdiction for any disputes arising from this Agreement shall be in the state or federal courts located in Chicago, Illinois and both Parties submit to the jurisdiction and venue of such courts.
- **10. Interpretation**. Whenever possible, each provision of this Agreement shall be interpreted in such a manner as to be effective and valid under applicable law, and the Parties agree to take any and all steps that are necessary in order to enforce the provisions hereof.

- **11. Entire Agreement**. This Agreement constitutes the entire agreement between the Parties hereto, superseding all prior oral or written representations, negotiations, understandings and agreements, on the subject matter hereof.
- **12. Copies/Counterparts**. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which shall be considered one instrument and shall become binding when one or more counterparts have been signed by each of the Parties and delivered to the other. Electronic or facsimile copies of signatures hereon shall be treated as originals.
- **13. Authority/Proper Party**. The Parties do hereby declare that this Agreement has been duly authorized by each of the Parties after consultation with counsel, and that the undersigned do fully understand the terms of this Agreement and have the express authority to enter into this Agreement.
- **14. No Rescission on Grounds of Mistake**. The Parties acknowledge that they have made their own investigations of the matters covered by this Agreement to the extent they deemed it necessary to do so. Therefore, the Parties agree that they will not seek to set aside any part of this Agreement on the grounds of mistake. Furthermore, the Parties understand, agree, and expressly assume the risk that any fact not recited, contained or embodied in the Agreement may turn out hereinafter to be other than, different from, or contrary to the facts now known to them, or believed by them to be true, and further agree that the Agreement shall be effective in all respects notwithstanding, and shall not be subject to termination, modification, or rescission by reason of any such mistake with regard to the facts.
- **15. Construction of this Agreement.** The Parties acknowledge that all Parties, through their legal counsel, played an equal role in drafting and/or had an equal opportunity to review and modify the provisions set forth in this Agreement. Thus, in the event of any misunderstanding, ambiguity, or dispute concerning this Agreement's provisions or interpretations, no rule of construction shall be applied that would result in having this Agreement interpreted against any Party.

**IN WITNESS WHEREOF**, the Parties have executed this Agreement as of the date set forth below.

## **Talis Biomedical Corporation**

## thinXXS Microtechnology GmbH

By:	/s/ Roger Moody	By:	/s/ Joseph Rytell
Print Name:	Roger Moody	Print Name:	Joseph Rytell
Title:	CFO	Title:	President
Dated:	3/22/2023	Dated:	3/22/2023
_	_	_	

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

## ATTACHMENT 1 TO THE TERMINATION AGREEMENT LICENSE AGREEMENT

This License Agreement ("License Agreement") is entered into as of March 22, 2023 (the "Effective Date"), by and between thinXXS Microtechnology GmbH, a German corporation ("thX"); and Talis Biomedical Corporation, a Delaware corporation ("Talis"). thX and Talis are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

## RECITALS

**W**HEREAS, thX and Talis have entered into a certain Termination and Release Agreement concurrently herewith to terminate a prior relationship of the Parties; and

**W**HEREAS, in connection with such termination, thX is willing to license certain patent rights to Talis, and Talis desires to obtain from thX a license under such patent rights, in each case under the terms and conditions of this License Agreement.

**Now,** THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this License Agreement, the Parties agree as follows:

- **1. Definitions.** Capitalized terms shall have the meanings given them in this Section 1 or as defined elsewhere in the body of this License Agreement.
  - 1.1. "**Confidential Information**" of a Party means any and all proprietary information of such Party that is disclosed to the other Party under this License Agreement.
  - 1.2. **"Licensed Patents"** means (i) the patents and patent applications listed in <u>Attachment 1</u> to this License Agreement, (ii) [\*\*\*], and (iii) [\*\*\*].
  - 1.3. **"Licensed Products"** means products for incorporation into, or otherwise for sale in conjunction with, Talis' products, that are (i) [\*\*\*] and (ii) [\*\*\*], in each case whether [\*\*\*].
  - 1.4. **"Person"** means an individual, corporation, partnership, limited liability company, limited partnership, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.
  - 1.5. "Third Party" means any Person other than a Party.
  - 1.6. "thX Competitors" shall mean Third Parties that are direct competitors of thX listed on Attachment 2, and [\*\*\*].

## 2. License Grant.

- 2.1. **License Grant.** Subject to the terms and conditions of this License Agreement, thX hereby grants to Talis a non-exclusive, worldwide, [\*\*\*] (subject to Talis' compliance with Section 3), non-transferable license, without the right to sublicense, to the Licensed Patents to make, have made [\*\*\*], use, sell, have sold, offer for sale and import Licensed Products for incorporation into, or otherwise for sale in conjunction with, Talis' products.
- 2.2. **Have Made Rights.** The license granted to Talis in Section 2.1 above shall include the right to have contract manufacturers, [\*\*\*], whether directly or indirectly. Talis shall be responsible for such contract manufacturers, and Talis [\*\*\*]. If Talis exercises its have made rights (under this Section 2.2) with a [\*\*\*], and such Third Party either (a) [\*\*\*] or (b) [\*\*\*], notwithstanding the restriction set forth in this Section, Talis may nevertheless continue to exercise its rights and obligations under this License Agreement with such Third Party, provided that Talis's agreement with such Third Party contract manufacturer requires such Third Party contract manufacturer to: (i) [\*\*\*]; (ii) put in place [\*\*\*]; and (iii) use commercially reasonable efforts to [\*\*\*].
- 2.3. **No Implied Licenses.** Except as explicitly set forth in this License Agreement, thX shall not be deemed by estoppel, implication, or otherwise to have granted Talis any license or other right to any intellectual property of thX. For the avoidance of doubt, thX grants no rights to Talis with respect to [\*\*\*].
- 2.4. **No Technology Transfer.** thX shall have no obligation to conduct any transfer of technology to Talis.
- 2.5. **Marking.** Talis will place on any Licensed Product made or sold that is covered by a Licensed Patent, a patent notice in accordance with 35 U.S.C. 287 and/or similar laws of applicable foreign countries.
- **3. Compensation.** In consideration of the license granted to Talis herein, upon execution of this Agreement, Talis shall pay thX a [\*\*\*], non-refundable, non-creditable payment of (US\$2,000,000).

### 4. Patent Prosecution and Enforcement.

- 4.1. **Definition.** For the purpose of this Section 4, "prosecution" (and all correlative forms of "prosecution") of patents and patent applications shall include, without limitation, all communication and other interaction with any patent office or patent authority having jurisdiction over a patent or patent application throughout the world in connection with any pregrant proceedings and post-grant proceeding, including opposition proceedings.
- 4.2. **Prosecution.** As between the Parties, thX shall have the sole right, but not obligation, at its cost, to prepare, file, prosecute and maintain or abandon the Licensed Patents on a worldwide basis. thX does not represent or warrant that any patent will issue or be granted based on patent applications contained in the Licensed Patents, or that the claims in any such patents or patent applications will not later be held unpatentable or invalid.

4.3. **Enforcement.** thX shall have the sole right, but not the obligation, at its cost, to bring a suit or other action against any Person engaged in the infringement of any Licensed Patent on a worldwide basis, and shall be entitled to retain all recovery associated therewith.

# 5. Indemnification; Limitation of Liability.

- 5.1. **Indemnification by thX**. thX shall defend, indemnify, and hold Talis and its affiliates and their respective officers, directors, employees, and agents (the "**Talis Indemnitees**") harmless from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees ("**Losses**") to which any Talis Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (collectively, "**Claims**") arising out of, based on, or resulting from, directly or indirectly: (a) [\*\*\*], or (b) the willful misconduct or negligent acts of or violation of applicable law by any thX Indemnitee in connection with this License Agreement. The foregoing indemnity obligation shall not apply to the extent that (i) the Talis Indemnitees fail to comply with the indemnification procedures set forth in Section 5.3 and thX' defense of the relevant Claim is materially prejudiced by such failure, or (ii) any Claim arises from, is based on, or results from any activity or occurrence for which Talis is obligated to indemnify the thX Indemnitees under Section 5.2.
- 5.2. **Indemnification by Talis**. Talis shall defend, indemnify, and hold thX and its affiliates and their respective officers, directors, employees, and agents (the "**thX Indemnitees**") harmless from and against any and all Losses to which any thX Indemnitee may become subject as a result of any Claims arising out of, based on, or resulting from, directly or indirectly: (a) [\*\*\*], (b) the willful misconduct or negligent acts of or violation of applicable law by any Talis Indemnitee in connection with this License Agreement, or (c) the development, manufacture, or commercialization of Licensed Products by or on behalf of Talis or its agents on or after the Effective Date. The foregoing indemnity obligation shall not apply to the extent that (i) the thX Indemnitees fail to comply with the indemnification procedures set forth in Section 5.3 and Talis' defense of the relevant Claim is materially prejudiced by such failure, or (ii) any Claim arises from, is based on, or results from any activity or occurrence for which thX is obligated to indemnify the Talis Indemnitees under Section 5.1.
- 5.3. **Indemnification Procedures**. The Party claiming indemnity under this Section 5 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim and shall offer control of the defense of such Claim to the Indemnifying Party. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; *provided*, *however*, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle or compromise any such Claim without

the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Section 5.

5.4. Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY INDIRECT, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR OTHER SPECIAL DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS LICENSE AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 5.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 5.1 OR 5.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS IN SECTION 6.

# 6. Confidentiality.

- 6.1. **Confidentiality**. Each Party agrees that, during the Term and for a period of seven (7) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this License Agreement (which includes the exercise of any rights or the performance of any obligations hereunder or thereunder) any Confidential Information of the other Party, except to the extent expressly agreed in writing by the Parties. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent written proof:
  - 6.1.1. was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party;
  - 6.1.2. was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
  - 6.1.3. became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this License Agreement;
  - 6.1.4. was disclosed to the receiving Party by a Third Party without any confidentiality obligations being imposed on the receiving Party by the Third Party, who, to the knowledge of the receiving Party, had a legal right to make such disclosure; or
  - 6.1.5. was independently discovered or developed by the receiving Party without use of or reference to the other Party's Confidential Information, as evidenced by a contemporaneous writing.

For purposes of this Section 6.1, Confidential Information disclosed under this License Agreement shall not be deemed to be within such exceptions unless such information is readily accessible to the public in a written publication, and such exceptions shall not include information the substance of which must be pieced together from any number of different publications or other sources.

Each disclosing Party represents and warrants that as of the time of disclosure (i) it has all rights, title and ownership interest in and to the Confidential Information, and/or it has all the right and power to disclose the Confidential Information to the receiving Party; and (ii) to the best of its knowledge, such disclosure will not violate the terms of any agreement with, or any other obligation to, any Third Party.

- 6.2. **Authorized Disclosure**. Notwithstanding the obligations set forth in Section 6.1, a Party may disclose the other Party's Confidential Information or the terms of this License Agreement to the extent:
  - 6.2.1. such disclosure is reasonably necessary (i) for the filing or prosecuting of patent rights as contemplated herein, subject to the prior consent of the Party owning the Confidential Information, which consent shall not be unreasonably withheld, conditioned, or delayed; or (ii) for prosecuting or defending litigation as contemplated herein;
  - 6.2.2. such disclosure is reasonably necessary to its shareholders, directors, officers, managers, employees, agents, consultants, contractors, licensees or sublicensees on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights hereunder; *provided* that in each case, the disclosees are bound by written obligations of confidentiality consistent with those contained in this License Agreement;
  - 6.2.3. such disclosure is reasonably necessary to any bona fide potential or actual investor, advisor, lender, acquiror, merger partner, or other financial or commercial partner or research collaborator for the sole purpose of evaluating or carrying out an actual or potential investment, acquisition or other business relationship; *provided* that in connection with such disclosure, such Party shall inform each disclosee of the confidential nature of such Confidential Information and shall be bound by commercially reasonable obligations of confidentiality substantially similar to those contained in this License Agreement; or
  - 6.2.4. such disclosure is reasonably necessary to comply with applicable laws, including regulations or rules promulgated by applicable securities commissions (or other securities regulatory authorities), security exchanges, court order, administrative subpoena or order.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 6.2.1 or 6.2.4, such Party shall promptly notify the other Party of such required disclosure, to the extent that it is legally authorized or permitted to so, and shall use reasonable efforts to

obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

### 6.3. Publicity; Terms of Agreement.

- 6.3.1. The Parties agree that the terms of this License Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 6.3 (or otherwise subject to Section 6.2).
- 6.3.2. The Parties acknowledge that either or both Parties may be obligated to file under applicable laws a copy of this License Agreement with governmental authorities, including the U.S. Securities and Exchange Commission. Each Party shall be entitled to make such a required filing, *provided* that it requests confidential treatment of the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available. In the event of any such filing, each Party will provide the other Party with a copy of this License Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider in good faith and incorporate the other Party's comments thereon to the extent consistent with the legal requirements, with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed. The non-filing Party agrees to promptly (and in any event, no less than seven (7) days after receipt of such proposed redactions) provide its comments on such proposed redactions. The Party seeking such disclosure shall exercise commercially reasonable efforts to obtain confidential treatment of this License Agreement from the applicable governmental authority as represented by the redacted version reviewed by the other Party.
- 6.4. **Equitable Relief**. Each Party acknowledges and agrees, for the purpose of the disclosing Party obtaining equitable relief only, that its breach of this Section 6 will cause irreparable harm to the disclosing Party, which cannot be reasonably or adequately compensated in damages in an action at law. Each Party agrees that the disclosing Party shall be entitled, in addition to any other remedies it may have under this License Agreement or otherwise, to obtain preliminary and permanent injunctive and other equitable relief for any breach of this License Agreement, including to prevent or curtail any actual or threatened breach of the obligations relating to Confidential Information set forth in this Section 6, without the necessity of posting any bond or security.

#### 7. Term and Termination.

- 7.1. **Term**. The term of this License Agreement (the "**Term**") shall commence upon the Effective Date and, unless earlier terminated pursuant to this Section 7, shall remain in effect until the expiration of the last to expire of the Licensed Patents.
- 7.2. **Termination by thX for Cause.** thX may terminate this License Agreement in its entirety upon sixty (60) days' prior written notice to Talis if Talis [\*\*\*], unless during such sixty (60)-day period the subject [\*\*\*].

- 7.3. **Termination for Material Breach**. Each Party shall have the right to terminate this License Agreement in its entirety immediately upon written notice to the other Party if the other Party materially breaches its obligations under this License Agreement and, after receiving written notice identifying such material breach in reasonable detail, fails to cure such material breach within sixty (60) days from the date of such notice. Such notice shall (a) expressly reference this Section 7.3, (b) reasonably describe the alleged breach which is the basis of such termination, and (c) clearly state the non-breaching Party's intent to terminate this License Agreement if the alleged breach is not cured within the applicable cure period. The License Agreement shall terminate effective at the end of the notice period unless the breaching Party cures such breach during such notice period, *provided* that, such cure period shall be extended for up to an additional sixty (60) days upon the breaching Party providing a written plan that reasonably demonstrates the need for such additional time and continuing to use commercially reasonable efforts to cure such breach.
- 7.4. **Termination Due to Bankruptcy**. Either Party may terminate this License Agreement if, at any time, the other Party files in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition is not dismissed within sixty (60) days after the filing thereof, or if the other Party proposes or becomes a Party to any dissolution or liquidation, or if the other Party makes an assignment for the benefit of its creditors.
- 7.5. **Effect of Early Termination**. Upon any early termination of this License Agreement by either Party, all licenses and other rights granted by thX to Talis under this License Agreement shall terminate.
- 7.6. **Survival.** Any expiration or termination of this License Agreement shall not affect rights or obligations of the Parties under this License Agreement that have accrued prior to the date of expiration or termination. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this License Agreement: Sections 1 (Definitions), 2.3 (No Implied Licenses), 5 (Indemnification), 6 (Confidentiality) 8.3 (No Other Representations or Warranties), 7.1 (Term), 7.5 (Effect of Early Termination), 7.6 (Survival), 7.7 (Termination Not Sole Remedy), 8.3 (Disclaimers), and 9 (Miscellaneous).
- 7.7. **Termination Not Sole Remedy**. Termination is not the sole remedy under this License Agreement and, whether or not termination is effected and notwithstanding anything contained in this License Agreement to the contrary, all other remedies shall remain available except as agreed to otherwise herein.
- 8. Representations and Warranties; Covenants; Disclaimers.
  - 8.1. **General.** Each Party hereby represents and warrants to the other Party, as follows:

- 8.1.1. As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated;
- 8.1.2. As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this License Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this License Agreement and the performance of its obligations hereunder; and (iii) this License Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and similar laws affecting creditors' rights and remedies generally;
- 8.1.3. The execution and delivery of this License Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of applicable law existing as of the Effective Date; (ii) do not conflict with or violate the certificate of incorporation or by-laws (or other constating documents) of such Party; and (iii) do not conflict with, violate, breach or constitute a material default under any contractual obligations of such Party existing as of the Effective Date;
- 8.1.4. Neither Party is under any obligation to any Person, contractual or otherwise, that is in violation of the terms of this License Agreement or that would impede the fulfillment of such Party's obligations hereunder; and
- 8.1.5. No authorization, consent, approval of a Third Party, nor to such Party's knowledge, any license, permit, exemption of or filing or registration with or notification to any court or governmental authority is or will be necessary for the (i) valid execution and delivery of this License Agreement by such Party; or (ii) the consummation by such Party of the transactions contemplated hereby.
- 8.2. **Covenant by Talis.** Talis covenants that it will not, and will not permit any of its agents or contractors to, [\*\*\*].
- LICENSE 8.3. **DISCLAIMERS. EXCEPT** AS EXPRESSLY STATED IN THIS AGREEMENT, REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED. FOR CLARITY AND WITHOUT LIMITING THE FOREGOING, THX MAKES NO REPRESENTATION OR WARRANTY CONCERNING THE LICENSED PATENTS OR THE LICENSED PRODUCTS EXCEPT AS EXPRESSLY SET FORTH IN THIS LICENSE AGREEMENT. THE LICENSED PATENTS LICENSED TO TALIS HEREUNDER ARE LICENSED "AS

IS" WITHOUT WARRANTY OF ANY KIND, AND ALL WARRANTIES WITH RESPECT THERETO (EXPRESS, IMPLIED OR STATUTORY) ARE DISCLAIMED.

#### 9. Miscellaneous.

- 9.1. **Injunctive Relief.** Talis acknowledges and agrees that, for the purpose of thX obtaining equitable relief only, due to the unique and valuable nature of the thX's proprietary rights licensed hereunder, any breach of provisions of this License Agreement with respect to such proprietary rights will cause irreparable harm to thX, which cannot be reasonably or adequately compensated in damages in an action at law. Talis agrees that thX shall be entitled, in addition to any other remedies it may have under this License Agreement or otherwise, to obtain from any court of competent jurisdiction preliminary and permanent injunctive relief and other equitable relief to restrain any breach or threatened breach of, or otherwise to specifically enforce, any covenant or obligation of Talis under such provisions, without the necessity of posting any bond or security.
- 9.2. **Assignment; Delegation.** This License Agreement may not be assigned by either Party without the prior written consent of the other Party, which shall not be unreasonably withheld. In the event of any such assignment, the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all duties and obligations. This License Agreement shall inure to the benefit of and be binding upon each Party signatory hereto, its successors and permitted assigns. No assignment shall relieve either Party of the performance of any accrued obligation that such Party may then have under this License Agreement. Any assignment or attempted assignment by either Party in violation of the terms of this Section 9.2 shall be null, void and of no legal effect.
- 9.3. **Publicity**. Subject to Section 7 of the Termination Agreement, no Party shall issue a press release or public announcement or otherwise make any public disclosure concerning the subject matter of this License Agreement, without the prior written approval of the other Party.
- 9.4. **Relationship of Parties.** The Parties' relationship, as established by this License Agreement, is solely that of independent contractors. This License Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Except as expressly provided herein, neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.
- 9.5. **Entire Agreement; Amendment.** This License Agreement and its attachments, together with the Termination and Release Agreement and all exhibits attached thereto, is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This License Agreement supersedes all prior and contemporaneous agreements and communications between the Parties, whether oral, written or otherwise, concerning any and all matters contained herein, with the exception of the Settlement and Termination Agreement and attached exhibits. No amendment, modification or addition to this License Agreement shall be binding upon the Parties

hereto unless reduced to writing and signed by the respective authorized officers of the Parties.

- 9.6. **Severability.** If any provision of this License Agreement shall be deemed void in whole or in part for any reason whatsoever, the remaining provisions shall remain in full force and effect. The Parties shall make a good faith effort to replace any such provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this License Agreement may be realized.
- 9.7. **Non-Waiver.** The failure of a Party to insist upon strict performance of any provision of this License Agreement or to exercise any right arising out of this License Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time, and shall be signed by such Party.
- 9.8. **Governing Law.** This License Agreement shall be governed by and construed under the laws of the State of Illinois, without reference to its conflicts of law principles that would require the application of the laws of another jurisdiction. The United Nations Conventions on Contracts for the International Sale of Goods shall not be applicable to this License Agreement.
- 9.9. **Venue.** Any dispute, controversy or claim arising out of or relating to this License Agreement, will be made exclusively in the state or federal courts located in Chicago, Illinois and both Parties submit to the jurisdiction and venue of such courts.
- 9.10. **Force Majeure.** A Party shall be excused from performing its obligations under this License Agreement if its performance is delayed or prevented by any event beyond such Party's reasonable control, including but not limited to, acts of God, fire, explosion, weather, disease, war, insurrection, civil strife, riots, government action, power failure, earthquake, tsunami or terrorism (each a "**Force Majeure Event**"), provided that such performance shall be excused only to the extent of and during such Force Majeure Event. The affected Party shall notify the other Party of such Force Majeure Event as soon as reasonably practical and shall take reasonable efforts to remove the Force Majeure Event or to avoid its affects so as to resume performance as soon as practicable.
- 9.11. **Notices.** Any notice required or permitted to be given under this License Agreement shall be in writing, shall specifically refer to this License Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section, and shall be deemed to have been given for all purposes: (i) upon personal delivery to the Party to be notified; (ii) when sent by confirmed electronic mail if sent during normal business hours of the recipient, if not, then on the next Business Day; (iii) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (iv) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt.

If to thX: thinXXS Microtechnology AG

c/o IDEX Corporation Legal Department 3100 Sanders Road, Suite 301

Northbrook, IL 60062

If to Talis: Talis Biomedical Corp.

3400 Bridge Parkway Redwood City, CA 94065 Attention: Legal Dept.

- 9.12. **Interpretation.** The following rules of interpretation apply to this License Agreement: (i) the headings of clauses contained in this License Agreement are inserted solely for convenience and ease of reference only and shall not constitute any part of this License Agreement, or have any effect on its interpretation or construction; (ii) ambiguities and uncertainties in this License Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist; (iii) definitions contained in this License Agreement are applicable to the singular as well as the plural forms of such term; and (iv) references to an agreement or instrument mean agreement or instrument as from time to time amended, modified or supplemented. References to a Person are also to its permitted successors and assigns.
- 9.13. **Counterparts.** This License Agreement may be executed in counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument. This License Agreement may be executed by facsimile or PDF signatures, which signatures shall have the same force and effect as original signatures.

[SIGNATURE PAGE FOLLOWS]

In Witness Whereof, the Parties hereto have duly executed this License Agreement as of the Effective Date.

## THINXXS MICROTECHNOLOGY GMBH

## TALIS BIOMEDICAL CORPORATION

By:	/s/ Joseph Rytell	By:	/s/ Roger Moody
Name:	Joseph Rytell	Name:	Roger Moody
Title:	President	Title:	CFO

Attachment 1 — Licensed Patents

Attachment 2 — thX Competitors

Attachment 1 (Licensed Patents)

[\*\*\*]

[\*\*\*]

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#### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

- Registration Statement (Form S-3 No. 333-264839) on Form S-3,
- Registration Statement (Form S-8 No. 333-266470) pertaining to the 2021 Equity Incentive Plan and the 2021 Employee Stock Purchase Plan of Talis Biomedical Corporation,
- Registration Statement (Form S-8 No. 333-253218) pertaining to the 2013 Equity Incentive Plan, the 2021 Equity Incentive Plan and the 2021 Employee Stock Purchase Plan of Talis Biomedical Corporation, and
- Registration Statement (Form S-8 No. 333-261267) pertaining to the 2021 Inducement Plan of Talis Biomedical Corporation;

of our report dated March 22, 2023, with respect to the financial statements of Talis Biomedical Corporation included in this Annual Report (Form 10-K) of Talis Biomedical Corporation for the year ended December 31, 2022.

/s/ Ernst & Young LLP

Chicago, Illinois March 22, 2023

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

#### I, Robert J. Kelley, certify that:

- 1. I have reviewed this Annual Report on Form 10-K of Talis Biomedical Corporation;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 22, 2023

/s/ Robert J. Kelley

Robert J. Kelley Chief Executive Officer (Principal Executive Officer)

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

- I, J. Roger Moody, Jr., certify that:
- 1. I have reviewed this Annual Report on Form 10-K of Talis Biomedical Corporation;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 22, 2023

/s/ J. Roger Moody, Jr.

**J. Roger Moody, Jr.** Chief Financial Officer (Principal Financial Officer)

# 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, 2022 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 22, 2023

/s/ Robert J. Kelley

Robert J. Kelley
Chief Executive Officer
(Principal Executive Officer)

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

#### 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, 2022 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 22, 2023

/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.