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, 2023

OR

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

FOR THE TRANSITION PERIOD FROM TO

Commission File Number: 001-40047

Talis Biomedical Corporation

(Exact name of Registrant as specified in its Charter)

Delaware	**46-3122255**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1375 West Fulton Market, Suite 700 Chicago, Illinois	**60607**
(Address of principal executive offices)	(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**
Common Stock, $0.0001 par value per share	TLIS	The Nasdaq Stock Market LLC

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

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

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

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

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

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

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

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

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

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

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. ☐

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, 2023 (the last business day of its most recently completed second quarter), was $8,151,667, restated for the 1-for-15 Reverse Stock Split effective July 5, 2023. 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 19, 2024, there were 31,685,660 shares of the Registrant's common stock and preferred stock outstanding, consisting of 1,821,986 shares of common stock and 29,863,674 shares of Series 1 convertible preferred stock which is convertible into 1,990,914 shares of common stock, as adjusted for the 1-for-15 Reverse Stock Split effective July 5, 2023. The conversion ratio of the outstanding Series 1 convertible preferred stock increased and the number of shares of common stock issuable upon conversion of such Series 1 convertible preferred stock decreased in proportion to the 1-for-15 ratio of the Reverse Stock Split. Our Series 1 convertible preferred stock is a voting common stock equivalent, subject to certain limitations.

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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:

- the timing and availability of strategic alternatives being reviewed by our Board of Directors and our ongoing efforts to significantly reduce our expenditures on research and development activities and taking other cost cutting measures;
- our decision to cease operations in our Redwood City, CA laboratory and office facility and consolidate our operations to our Chicago facility due to unforeseen operational challenges, setbacks in product development timelines and volatile market conditions;
- our expectations regarding our ability to complete a strategic transaction within estimated timeframes or at all;
- our ability to retain key personnel;
- regulatory clearance pathways for our products;
- clinical trials and studies necessary to develop and commercialize our products and services;
- 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;
- impact from future regulatory, judicial, and legislative changes or developments in the United States and foreign countries;
- the costs and success of our research and development efforts, including the potential effects of inflation; and
- the impact on our business and the completion of any possible strategic transaction of economic or political events or trends.

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 ceased substantially all of our research and development and manufacturing activities while our Board of Directors considers strategic alternatives. If we are unable to complete a strategic transaction within a reasonable timeframe or at all, then we may cease all operations and seek stockholder approval to voluntarily dissolve and liquidate the Company. There is no set timetable for the overall process given the anticipated timelines for different strategic alternatives may vary, and there can be no assurance that this process will result in us pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms or at all.
- Commercialization of the Talis One system, if continued, 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 would 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, and there can be no assurance that we can raise additional capital given current market volatility.
- We have no products approved for commercial sale. We have no or limited experience in developing, marketing and commercializing diagnostic systems and tests.
- It may not be possible to validate manufacturing for the Talis One instrument and cartridges at scale, which may have a material adverse effect on any efforts to commercialize our products..
- 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.
- The commercial success of the Talis One system and products could be compromised if 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.

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 aimed to transform diagnostic testing by developing and commercializing innovative products that were 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 developed the Talis One system, a sample-to-answer, cloud-enabled molecular diagnostic system to 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 was designed to provide central laboratory levels of accuracy and to be operated by an untrained user.

In November 2023, due to unforeseen operational challenges, setbacks in product development timelines and volatile market conditions, the Company decided to cease operations in its Redwood City, CA laboratory and office facility and consolidate operations to its Chicago facility and to consider strategic alternatives. In addition, on November 14, 2023, we announced that we retained TD Cowen, an investment bank, to lead a comprehensive review of strategic alternatives focusing on maximizing stockholder value, including but not limited to, an acquisition, merger, reverse merger, divestiture of assets, licensing or other strategic transactions and a voluntary dissolution or liquidation of the Company. However, there is no set timetable for the overall process given the anticipated timelines for different strategic alternatives may vary, and there can be no assurance that this process will result in us pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have ceased substantially all of our research and development and manufacturing activities while our Board of Directors considers strategic alternatives. If we are unable to complete a strategic transaction within a reasonable timeframe or at all, then we may cease all operations and seek stockholder approval to voluntarily dissolve and liquidate the Company.

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 1375 West Fulton Market, Suite 700, Chicago, IL 60607, and our telephone number is (650) 433-3000. Our corporate website address is http://talisbio.com.

This Annual Report contains references to our trademarks, including Talis, Talis One®, and Sia Dx™ 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

Previous surveys of women's and sexual health providers that we conducted confirmed the continued and strong interest in adoption of point-of-care systems, such as the Talis One system. We believe the Talis One system was 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 developed 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 leveraged progress made to-date and directed 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 planned 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 believed would create a competitive advantage over other commercially available point-of-care technologies:

- *Highly accurate*—The Talis One system incorporates a shelf-stable, single-use test cartridge 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 and 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

Prior to the announcement in November 2023 to consider strategic alternatives, our strategy was to transform diagnostic testing by developing and commercializing innovative products that were designed to enable accurate, reliable, low cost and rapid molecular testing for infectious diseases and other conditions at the point of care.

Since November 2023, while we have maintained limited manufacturing capabilities to have the ability to support minimal research and development functions, our primary business strategy consists of:

- Considering strategic alternatives focusing on maximizing stockholder value, including but not limited to, equity or debt financing alternatives, an acquisition, merger, reverse merger, divestiture of assets, licensing or other strategic transactions and a voluntary dissolution or liquidation of the Company; and
- If we are unable to complete a strategic transaction within a reasonable timeframe or at all, then our Board of Directors intends to cease all operations and seek stockholder approval to voluntarily dissolve and liquidate the Company. There is no set timetable for the overall process given the anticipated timelines for different strategic alternatives may vary, and there can be no assurance that this process will result in us pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms or at all.

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 a menu of tests would create a competitive barrier to entry for other systems.

The Talis One system

We developed 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 was designed to handle a wide range of sample types, including nasal swab, vaginal swab, saliva, urine, whole blood, plasma, serum and sputum. It was also designed 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 was sufficient to meet our 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, would facilitate automated assembly and low-cost manufacturing. The compact size, approximately 7 x 10 x 14 inches, is designed to enable portability and use in various front-line locations. The instrument incorporates a touchpad interface for easily communicating instructions, information and results to the user. An integrated camera that reads and enables registration of a label on the cartridge facilitates sample custody by linking an image of the cartridge label with test results. The instruments are designed for multi-instrument deployments to satisfy different testing volume requirements and can be stacked three-by-three 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 several instrument placements in multiple exam rooms, 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 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.

Infectious Diseases

We developed our Talis One system to be used for infections related to women's health, STIs and respiratory infections. We intended 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 intended 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 planned 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 planned to 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 believed 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 were developing for our Talis One system would have had 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 did not plan a broad commercial launch for the stand-alone COVID-19 test, we intended to seek marketing authorization for the Respiratory Panel through a 510(k) clearance process.

Commercialization and Manufacturing

We developed relevant in-vitro diagnostic tests for a variety of respiratory infections and infections related to women's health and STIs. We estimated that the total potential annualized addressable global market opportunity for molecular testing of infectious diseases to be over $5.4 billion for 2022 and expected to grow to over $7.1 billion by 2026.

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 the commercial team supporting our product development and marketing needs. Leveraging progress made at that time with our stand-alone COVID test, we conducted 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 were intended to 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 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 believed would be attractive gross margins in the future. In order to drive further efficiency and cost reduction in the manufacturing process, we restructured relationships with our contract manufacturing partners in 2023. Our commercialization and manufacturing strategies are uncertain at this time pending completion of a review of strategic alternatives by our Board of Directors.

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

depended 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.

Operations

Our products have been manufactured by several third parties. The instrument assembly is largely manual with some automation in testing. We had 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 focused on developing more internal expertise in manufacturing and have developed internal pilot manufacturing lines.

Supply chain management

We utilized 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.

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).

Patents

As of March 1, 2024, we solely own 17 issued U.S. patents, 22 pending U.S. patent applications, 41 issued foreign patents, and 124 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 applicable fraud and abuse laws.

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

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

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

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

Coverage and reimbursement

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

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

The potential end-users of our Talis One system and diagnostic tests include large elder care chains where vulnerable residents have unmet needs for millions of high sensitivity 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 at-home COVID-19 diagnostic tests authorized, cleared, or approved by the FDA per covered individual per month.

Data Privacy

In the ordinary course of our business, we may process personal data and, accordingly, we are, or may become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection. Such obligations may include, without limitation, the Federal Trade Commission Act, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the California 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, 2023, we had a total of 99 full-time employees. Our employees are located in 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, maintaining adequate staffing to support the completion of a strategic transaction or the voluntary dissolution and liquidation of the Company.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (Exchange Act), are filed with the SEC. Such reports and other information filed by us with the SEC are

available free of charge on our website at http://investors.talisbio.com when such reports are available on the SEC's website. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. The information contained on the websites referenced in this Annual Report on Form 10-K is not incorporated by reference into this filing. Further, our references to website URLs are intended to be inactive textual references only.

Item 1A. Risk Factors.

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

Risks related to our business and strategy

We may not be successful in completing a strategic transaction within a reasonable timeframe, on attractive terms or at all. If we are unable to complete a strategic transaction, then we may cease all operations and seek stockholder approval to voluntarily dissolve and liquidate the Company.

Since November 2023, we have ceased substantially all of our research and development and manufacturing activities while our Board of Directors considers strategic alternatives. We may be unable to complete a strategic transaction within a reasonable timeframe, on attractive terms or at all, and market conditions, including the historical volatility in our common stock will likely limit our ability to raise capital on favorable terms, or at all, and the terms of any public or private offerings of debt or equity securities likely would be significantly dilutive to existing stockholders. There is no set timetable for the overall process given the anticipated timelines for different strategic alternatives may vary, and there can be no assurance that this process will result in us pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms or at all. Given these challenges, if we are unable to complete a strategic transaction, then we may cease all operations and seek stockholder approval to voluntarily dissolve and liquidate the Company. The completion of a strategic transaction or the voluntary dissolution and liquidation of the Company each would have a material adverse effect on our growth strategy and our results of operations and financial condition.

Commercialization of the Talis One system 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.

Our historical research and development efforts focused 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 pursuant to 510(k) submissions to the FDA.

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 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.

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.

Commercial success of the Talis One system 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 the Talis One system 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.

Also, there may be research and development, regulatory, marketing and other difficulties that could delay or prevent the 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.

It may not be possible to validate manufacturing for the Talis One instrument and cartridges at scale, which may have a material adverse effect on any efforts to commercialize our products.

In order to commercialize our products, if approved, it is necessary 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.

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 the FDA. We may initiate voluntary recalls involving our commercialized products. The FDA or other agency could take enforcement action for failing to report the recalls when they were conducted. In addition, if we are required to make changes to our products to redress the deficiencies leading to the recall, we may be required to seek marketing authorization for the modified device prior to commercializing it. Any recall announcement by us or a governmental authority, or any changes that we make to our products as a result of such recall, could harm our reputation with customers and negatively affect our business, financial condition, and results of operations.

If we initiate a recall, including a correction or removal, for one of our commercialized products, 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 cost-effective basis and to pursue new market opportunities that develop as a result of scientific and technological advances. We must continuously enhance our Talis One system and develop new tests to keep pace with evolving standards of care. If we do not update our products to reflect new scientific knowledge our products could become obsolete and sales of our current products and any new products we develop could decline or fail to grow as expected.

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.

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 we may encounter difficulties in managing our operations, completing a strategic transaction or keeping current and timely with our Exchange Act reporting obligations with our reduced staffing and limited resources.

Due to our limited resources, we may not be able to effectively manage our operations, complete any possible strategic transaction or remain current and timely with our Exchange Act reporting obligations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, errors in disclosure, loss of additional business opportunities, loss of employees and reduced productivity among remaining employees. The loss of members of our senior management, research and development, science and engineering, manufacturing and marketing teams could delay our completion of any possible strategic transaction or the achievement of our research, product development and commercialization objectives and harm our business.

We also do not maintain fixed-term employment contracts or key man life insurance with any of our employees.

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 must obtain marketing authorizations for our products for point-of-care clinical diagnostic use 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.

Our 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, marketing authorization is required 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 to obtain or comply with such marketing authorizations could have a material adverse effect on the ability to commercialize our products.

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.

The commercial success of the Talis One system 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 at-home 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.

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 could have a material adverse effect on our business.

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

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

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

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

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

Data privacy and information security have become significant issues in the United States, countries in Europe, and in other countries in which we operate. The legal and regulatory framework for privacy and security issues is rapidly evolving, and is expected to increase our compliance costs and exposure to liability. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, 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 personal data.

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 jurisdiction.

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 treble damages and civil penalties.

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

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

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

Our manufacturers are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally

prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

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

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

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, the legislation enacted on December 22, 2017, informally known as the Tax Cuts and Jobs Act (TCJA) repealed the tax-based shared responsibility payment imposed by the ACA, on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." Additionally, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. 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 ACA or our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers and suppliers of 2% per fiscal year, starting in 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 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, 2023, 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 $258.2 million of U.S. federal NOLs that can be carried forward indefinitely under current law. As of December 31, 2023, we also had aggregate U.S. federal research and development (R&D) credits of approximately $11.4 million and U.S. state research and development (R&D) credits of approximately $8.7 million. Our NOL carryforwards and R&D credits are subject to review and possible adjustment by the U.S. and state tax authorities.

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

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

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

Risks related to our intellectual property

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

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

lawsuits, interferences, oppositions, and *inter-partes* review, post-grant review and *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 in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technology. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers 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 patents or patent applications or those of our licensors.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur 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 in-licenses of intellectual property rights of others, for our products, as well as our ability to preserve our trade secrets, to prevent third parties from infringing, misappropriating, 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 or 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 any of our obligations related to such prosecution, we may incur significant liability to our licensing partners.

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

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

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

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

Obtaining and maintaining a patent portfolio entails significant expense, including periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications. These expenditures can be at numerous stages of prosecuting patent applications and over the lifetime of maintaining and enforcing issued patents. We may or may not choose to pursue or maintain protection for particular intellectual property in our portfolio. If we choose to forgo patent protection or to allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. Furthermore, we employ reputable law firms and other professionals to help us comply with the various procedural, documentary, fee payment and other similar provisions we are subject to and, in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with 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 license. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business.

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

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

In addition to seeking patent protection for certain aspects of our technology, we also consider trade secrets, including 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 rights in or diminish the goodwill associated with our trademarks and trade names.

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

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

Intellectual property rights do not necessarily address all potential threats.

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

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

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

Risks related to our financial condition and capital requirements

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

We have historically incurred substantial net losses, including net losses of $62.0 million and $113.0 million for the twelve months ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $540.0 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 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. 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.

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 718,230 shares of common stock issuable upon the exercise of options outstanding and 14,484 shares of common stock issuable upon vesting of restricted stock units as of December 31, 2023. 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, 2023, holders of approximately 2,499,285 shares (adjusted for the 1-for-15 reverse stock split and activity during the twelve months ended December 31, 2023), or 66% of our capital stock have certain registration rights with respect to the resale of such shares. In March 2024, we terminated a previously filed registration statement on Form S-3 as the Company was no longer eligible to register securities on Form S-3 and obtained a waiver of the registration rights relating to these 2,499,285 shares. This waiver of the registration rights is effective for a period of thirty (30) days from the filing of this Form 10-K.

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 19, 2024, our executive officers, directors and five percent or greater stockholders and their respective affiliates, beneficially own, in the aggregate, approximately 74% 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 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 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

The Company maintains a cybersecurity program designed to detect, identify, classify and mitigate cyber security and other data security threats, as part of its efforts to protect and maintain the confidentiality and security of customer, employee and vendor information, and non-public information about the Company. Our cyber security program is led by the Company's SVP, Head of Legal and Compliance.

The Company and its third-party service providers conduct periodic risk assessments to identify significant cybersecurity threats that may affect information systems that are vulnerable to such cyber security threats and regularly review these risk assessments for changes in our business practices and the external cybersecurity landscape as well as the impact of our security processes. These risk assessments include physical, administrative and technical safeguards and involves identification of reasonably foreseeable internal and external risks and evaluation of the likelihood and potential damage that could result from the realization of such risks.

Following our risk assessments, we evaluate when and how to design, implement, and maintain reasonable safeguards to minimize the identified risks and address any identified gaps in existing safeguards, and proceed with such design, implementation, and maintenance as deemed appropriate. We also engage third-party service providers in connection with our risk assessment process and certain risk management processes. Our collaboration with these third-party service providers includes threat assessments and consultation on security enhancements, 24/7 monitoring and incident response support.

Based on the information we have as of the date of this Form 10-K, we do not believe any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition. See “Item 1A. Risk Factors” for further information about these risks.

Cybersecurity Governance

Our Board of Directors is focused on cyber security. Specific responsibility for cybersecurity oversight is managed by the Audit Committee. The SVP, Head of Legal and Compliance is responsible for the management and mitigation of identified risks and the presentation of any changes in risk factors, identified risks, overall cybersecurity efforts and upcoming improvements to the Audit Committee. The SVP, Head of Legal and Compliance is also responsible for the response to and the remediation and resolution of a security incident involving a potential or actual compromise of our proprietary information and/or personal information. The SVP,

Head of Legal and Compliance reports to the Audit Committee quarterly with respect to the Company's cybersecurity infrastructure and risk assessment and reports any security incidents to the Audit Committee. The Audit Committee will report the Company's cybersecurity infrastructure and risk assessment and any findings and recommendations to the full Board of Directors for consideration if and when the Audit Committee deems it necessary or appropriate.

In the event of a cybersecurity incident, the Company's SVP, Head of Legal and Compliance is equipped with a well-defined Incident Response and Reporting Policy (IRRP) to guide response, reporting, and recovery actions. This IRRP includes immediate actions to mitigate the impact of the incident, long-term strategies for remediation and prevention of future incidents, and provides for internal notification of the incident to functional areas as well as senior leadership and the Board of Directors, as appropriate.

Item 2. Properties.

Our corporate headquarters are currently located in Chicago, IL (Chicago office), where we occupy approximately 26,400 square feet of office and laboratory space under a lease that ends in July 2032.

The Company also has 13,165 square feet of office and laboratory space in Redwood City, California under a sublease that ends on May 31, 2030. While the sublease is still in effect, in November 2023, we decided to cease operations in our Redwood City laboratory and office facility and have consolidated all of our operations to our Chicago office during 2024.

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 the Company, certain of its officers and directors, and J.P. Morgan Securities LLC, BofA Securities, Inc., Piper Sandler & Co., and BTIG, LLC, underwriters of the Company's 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 the Company's stock that were registered in the Company's 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 the Company, and the same officers and directors as the Modrak lawsuit. These two cases were consolidated and co-lead plaintiffs were appointed as mandated by the applicable federal securities laws. On December 9, 2022, the Court granted the Company's motion to dismiss and gave 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 of 1933 ("Securities Act") against all defendants and Section 15 of the Securities Act against the individual defendants. The amended complaint alleges that the Company's registration statement and prospectus issued in connection with the Company's IPO was false and misleading, and omitted to state material adverse facts, related to (1) instrument manufacturing, (2) the reliability and accuracy of the Company's Talis One COVID-19 test, and (3) the comparator test used in the Company's primary study in support of its EUA application for the Talis One COVID-19 Test System. The amended complaint seeks unspecified damages under Sections 11 and 15 of the Securities Act, reasonable attorneys' fees, and other costs. The amended complaint does not assert claims against the above referenced underwriters. On April 28, 2023, the Court denied our motion to dismiss. On February 9, 2024, the Court certified the class and appointed plaintiff Martin Dugan as class representative. Discovery is ongoing. Trial is currently set for February 24, 2025.

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 was 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 had not regained compliance with the Bid Price Requirement, Nasdaq determined that the Company was eligible for an additional 180-day period, and extended the Company until July 24, 2023 to regain compliance. We committed to effectuate a reverse stock split by the end of the second compliance period, if necessary, to regain compliance with the Bid Price Requirement. The Notice had no other immediate effect on the listing of the Company's common stock, which trades on the Capital Market under the symbol "TLIS."

On July 5, 2023, we effected our 1-for-15 Reverse Stock Split. The common stock began trading on a post-split as-adjusted basis on July 6, 2023. On July 20, 2023, we received notice from Nasdaq that we had regained compliance with the Minimum Bid Price Requirement. There can be no assurance that the Company will be able to maintain compliance with the Minimum Bid Price Requirement, even after the implementation of the Reverse Stock Split.

Holders

As of March 19, 2024, we had approximately 69 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, 2023, 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.

Recent Developments

In November 2023, due to unforeseen operational challenges, setbacks in product development timelines and volatile market conditions, the Company decided to cease operations in its Redwood City, CA laboratory and office facility and consolidate operations to its Chicago facility and to consider strategic alternatives. In addition, on November 14, 2023, we announced that we have retained TD Cowen, an investment bank, to lead a comprehensive review of strategic alternatives focusing on maximizing stockholder value, including but not limited to, an acquisition, merger, reverse merger, divestiture of assets, licensing or other strategic transactions and a voluntary dissolution or liquidation of the Company. However, there is no set timetable for the overall process given the anticipated timelines for different strategic alternatives may vary, and there can be no assurance that this process will result in us pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms or at all. If we are unable to complete a strategic transaction within a reasonable timeframe or at all, then we may cease all operations and seek stockholder approval to voluntarily dissolve and liquidate the Company. We do not expect to disclose developments with respect to this process unless and until the evaluation of strategic alternatives has been completed or we have concluded that disclosure is appropriate or legally required.

In connection with the evaluation of strategic alternatives and in order to extend our cash, we implemented a cost-savings plan that includes a reduction in force of approximately 90% of our positions, with the remaining employees focusing primarily on supporting the exploration and potential completion of strategic alternatives as well as preserving limited manufacturing capabilities to have the ability to support minimal research and development functions throughout this process.

Overview

Prior to the November 2023 announcement to consider strategic alternatives, Talis aimed 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, currently, 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 were 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 in less than 30 minutes.

Previous surveys of women's and sexual health providers that we conducted confirmed continued and strong interest in adoption of point-of-care systems. We believe that the Talis One system was 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.

On July 19, 2023, we paused our COVID-19 clinical trials due to an increase in invalid rates and decided to terminate these clinical trials. We have also suspended all other planned clinical trials intended to support regulatory clearance and commercialization of our other tests.

We had been developing Talis One tests to address some of the most critical infectious diseases in women's and sexual health with a targeted product menu and disciplined regulatory strategy to minimize risk and accelerate time to first commercial launch. However, on November 10, 2023, our Board of Directors decided to pursue strategic alternatives and cease continued development of our test menu, consisting of a respiratory panel for influenza A, influenza B and COVID-19; Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis (CT/NG/TV); herpes simplex virus (HSV); and vaginal infections including bacterial vaginosis (Vaginal Infections Panel) and are focused primarily on pursuing strategic alternatives.

We invested in and increased the flexibility of our manufacturing capabilities to support the development and commercialization of the Talis One system. We automated cartridge manufacturing lines, currently located and operated by our contract manufacturing partners, to enable production advantages with quality, speed, and cost at full scale. We also established internal manufacturing lines to enable flexibility and stability in our ability to support our strategic efforts around research and development, clinical trials and commercialization. These internal 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. We intended to perform a cartridge stability study of cartridges from our internal manufacturing line to confirm the performance of our COVID-19 test on this manufacturing line. In order to drive further efficiency and cost reduction in the manufacturing process, we restructured our relationships with our contract manufacturing partners and streamlined our supply chain. Additionally, we have built several hundred instruments to date and invested in, and received, the raw materials to build thousands more to help ensure that we were positioned to support completion of any possible strategic transactions.

We outsourced a substantial portion of our manufacturing. Design work, prototyping and pilot manufacturing were performed in-house before outsourcing to third-party contract manufacturers. Our outsourced production strategy was intended to drive rapid scalability. Certain of our suppliers of components and materials were single source suppliers. During the twelve months ended December 31, 2023 we had one supplier that individually provided 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 $62.0 million and $113.0 million for the twelve months ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $540.0 million. We expect to continue to generate operating losses and negative operating cash flows for the foreseeable future if and as we:

- consider strategic alternatives;
- obtain, maintain, protect and enforce our intellectual property portfolio;
- defend the stockholder litigation and any other litigation that may arise in the future; and
- experience delays or encounter issues with any of the above.

As of December 31, 2023, we had unrestricted cash and cash equivalents of $76.7 million. Based on our planned operations, we expect that our unrestricted cash and cash equivalents of $76.7 million as of December 31, 2023 will be sufficient to fund our operations through at least the next 12 months from the date our financial statements are issued. We expect to finance our future operations with our existing cash and cash equivalents and through one or more possible strategic alternatives. However, there is no guarantee that any of these strategic opportunities will be executed or realized on favorable terms, if at all, and some could be dilutive to existing stockholders.

In March 2023, in order to support our long-term financial objectives, we terminated our former lease for laboratory and office space in Redwood City, CA and entered into a sublease for new laboratory and office space in Redwood City, CA. This move reduced our facilities footprint by two-thirds, and we expected approximately $9.0 million of cash savings on a discounted basis over the life of the lease. While the sublease is still in effect, in November 2023, we have decided to cease operations in our Redwood City laboratory and office facility and have consolidated all of our operations to our Chicago facility in 2024.

In November 2023, due to unforeseen operational challenges, setbacks in product development timelines and volatile market conditions, we decided to cease operations in our Redwood City, CA laboratory and office facility and consolidate operations to our Chicago facility in 2024 and to consider strategic alternatives. In order to further reduce costs and extend our remaining cash, we announced a reduction in force of approximately 90% of our work force on November 14, 2023 ("November 2023 RIF"). As part of these actions, we provided notices to the impacted employees under the Worker Adjustment and Retraining Act ("WARN Act") for job eliminations to occur through March 2024.

During the twelve months ended December 31, 2023, we incurred $3.4 million of expenses related to the November 2023 RIF which included payroll costs for salaries, wages and benefits paid or to be paid to employees during the minimum WARN act retention period and other costs. Expenses related to the November 2023 RIF are included in Selling, general and administrative and Research and development expenses in the statement of operations and comprehensive loss.

Depending on the outcome of our plans to consider strategic alternatives, we expect to incur approximately $0.5 million of additional expenses related to the November 2023 RIF, substantially all of which will consist of charges related to the staff reduction.

In 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.

Reverse Stock Split

On June 30, 2023, we filed a certificate of amendment to the our Amended and Restated Certificate of Incorporation (the “Certificate of Amendment”), with the Secretary of State of the State of Delaware to effect a 1-for-15 reverse stock split of the shares of the our common stock, par value $0.0001 per share, effective as of 5:00 p.m., Eastern

Time, on July 5, 2023 (the “Reverse Stock Split”). On this date, every 15 issued and outstanding shares of common stock were converted into one share of common stock, with any fractional shares resulting from the Reverse Stock Split rounded up to the nearest whole share. The number of outstanding shares of common stock was reduced from approximately 26.9 million shares to approximately 1.8 million shares.

The Reverse Stock Split did not change our authorized shares of common stock or Series 1 convertible preferred stock, which remained at 200,000,000 and 60,000,000 shares, respectively. The Reverse Stock Split did not change the par value of the common stock. Proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise of stock options and the settlement of restricted stock units and the number of shares authorized and reserved for issuance pursuant to the our equity incentive plans. Additionally, the Reverse Stock Split had no impact on the number of shares of our Series 1 convertible preferred stock issued and outstanding. However, the conversion ratio of the outstanding Series 1 convertible preferred stock increased and the number of shares of common stock issuable upon conversion of such preferred stock decreased in proportion to the 1-for-15 split ratio.

All share and per share amounts for common stock in this Annual Report on Form 10-K for the twelve months ended December 31, 2023 have been retroactively adjusted for all periods presented to give effect to the Reverse Stock Split, including reclassifying an amount equal to the reduction in the number of shares of common stock at par value to additional paid-in capital.

Components of our results of operations

Revenue

To date, we have not generated any revenue from sales of our Talis One system. As a result of the announcement in November 2023 to consider strategic alternatives, we no longer plan to commercialize the Talis One system.

Product revenue, net

In January 2022, we began distributing third party antigen tests (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 the test kits to the customer. This program concluded as of December 31, 2022, as the majority of sales of Antigen Tests occurred during 2022. However, during the twelve months ended December 31, 2023, we earned $0.4 million of revenue from the remaining sales of Antigen Tests from existing inventory.

Grant revenue

For the twelve months ended December 31, 2023 and 2022, 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 sub-award 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).

Under the NIH grant, we recognized $1.7 million and $0.5 million during the twelve months ended December 31, 2023 and 2022. In April 2023, the Company exercised a one-year option under the grant, extending the term through April 2024. As of December 31, 2023 there is $0.4 million in additional funding available under the grant, which we do not expect to fully utilize.

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 for the RADx initiative.

These grants are not in the scope of ASC 606 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;
- cost of performing clinical trials 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 were central to our historical operations. We previously focused our research and development efforts on the stand-alone Talis One COVID-19 test and developing tests for women's and sexual health infections, including a respiratory panel consisting of tests for influenza A, influenza B and COVID-19; Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis (CT/NG/TV); herpes simplex virus (HSV); and the Vaginal Infections Panel.

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.

Other income, net

Other income, 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, 2023 and 2022

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

(in thousands)	Twelve Months Ended December 31, 2023	2022	Change
Revenue			
Grant revenue	$ 1,722	$ 1,160	$ 562
Product revenue, net	412	3,652	(3,240)
Total revenue, net	$ 2,134	$ 4,812	$ (2,678)
Operating expenses:			
Cost of goods sold	41	8,391	(8,350)
Research and development	40,694	70,831	(30,137)
Selling, general and administrative	28,214	40,729	(12,515)
Total operating expenses	$ 68,949	$ 119,951	$ (51,002)
Loss from operations	(66,815)	(115,139)	48,324
Other income, net	4,808	2,127	2,681
Net loss and comprehensive loss	$ (62,007)	$ (113,012)	$ 51,005

Grant revenue and product revenue, net

Grant revenue for the twelve months ended December 31, 2023, primarily relates to the NIH grant. During the twelve months ended December 31, 2023 and 2022, $1.7 million and $0.5 million of revenue was recognized related to NIH grant, respectively.

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.

We began to generate product sales during January 2022 after we entered into a distribution agreement to sell the Antigen Tests. The change in product revenue, net is driven by the conclusion of the program at the end of 2022.
During the twelve months ended December 31, 2023 we earned $0.4 million of revenue from the remaining sales of Antigen Tests from existing inventory.

Cost of products sold

The decrease in cost of product sold during the twelve months ended December 31, 2023 is due to higher volume in units sold during the twelve months ended December 31, 2022 whereas we did not conduct significant product revenue generating activities during the same period in 2023.

During the twelve months ended December 31, 2022, the Company also 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, 2023 and 2022 were $40.7 million and $70.8 million, respectively, a decrease of $30.1 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 decline of $30.1 million was driven by a reduction of $13.0 million in pre-launch inventory costs, a decrease of $8.0 million in depreciation expense as certain manufacturing equipment was fully depreciated by December 31, 2022, and a decrease of $5.0 million related to lower manufacturing costs and the costs related to the automation of consumables manufacturing as we completed our scale-up investments in 2022. Payroll and related expenses decreased by $5.0 million during the twelve months ended December 31, 2023 as a result of our March 2022 and August 2022 reductions in force which was partially offset by expenses of $2.4 million incurred during the fourth quarter of fiscal year 2023 related to the November 2023 RIF. Partially offsetting these declines was $2.0 million of expense

incurred in 2023 to purchase a license for patents, cartridge raw materials and components in connection with the termination of our supply agreement with a contract manufacturer.

Selling, general and administrative expenses

Selling, general and administrative expenses were $28.2 million for twelve months ended December 31, 2023, compared to $40.7 million for the twelve months ended December 31, 2022, a decrease of $12.5 million. The decline was primarily due to decreases in 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, which was partially offset by expenses of $1.0 million incurred during the fourth quarter of 2023 related to the November 2023 RIF. Lower insurance costs also contributed to the decrease in selling, general and administrative expenses for the twelve months ended December 31, 2023. Selling, general and administrative expenses also include an impairment expense related to our right-of-use assets of $2.8 million for the twelve months ended December 31, 2023 compared to $3.6 million for the twelve months ended December 31, 2022.

Liquidity and capital resources

Sources of liquidity

As of December 31, 2023, we had unrestricted cash and cash equivalents of $76.7 million. We have funded our operations primarily through public equity offerings, private placements of equity securities and through government grants. We believe our unrestricted cash and cash equivalents balance as of December 31, 2023 is sufficient to fund our operations for at least the next 12 months from the date our financial statements are issued. We expect to finance our future operations with our existing unrestricted cash and cash equivalents and through one or more possible strategic alternatives. However, there is no guarantee that any of these strategic opportunities will be executed or realized on favorable terms, if at all, and some could be dilutive to existing stockholders.

On February 17, 2021, we completed our initial public offering (IPO), pursuant to which we issued and sold 1,058,000 shares (15,870,000 shares pre-Reverse Stock Split) of our common stock, at a public offering price of $240 per share ($16.00 per share pre-Reverse Stock Split). The net proceeds from the IPO were $232.5 million after deducting underwriting discounts and commissions and other offering expenses.

In 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.

On November 14, 2023, in connection with our plans to consider strategic alternatives, reduce costs and preserve cash, we terminated approximately 90% of our work force. During the twelve months ended December 31, 2023, the Company incurred $3.4 million of expenses related to the November 2023 RIF which included payroll costs for salaries, wages and benefits paid or to be paid to employees during the minimum WARN act retention period and other costs. Expenses related to the November 2023 RIF are included in Selling, general and administrative and Research and development expenses in the statement of operations and comprehensive loss. Depending on the outcome of our plans to consider strategic alternatives, the Company expects to incur approximately $0.5 million of additional expenses related to the November 2023 RIF, substantially all of which will consist of charges related to the staff reduction.

Cash flows

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

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	$ (53,240)	$ (100,136)
Net cash used in investing activities	(486)	(1,615)
Net cash provided by financing activities	33	406
Net decrease in cash, cash equivalents and restricted cash	$ (53,693)	$ (101,345)

Operating activities

During the twelve months ended December 31, 2023, net cash used in operating activities was $53.2 million, resulting from our net loss of $62.0 million, a $2.4 million decrease in accounts payable and a decrease of $3.1 million in accrued expenses and other liabilities. These outflows were partially offset by a decrease of $1.9 million in prepaid expenses and other current assets, as well as non-cash items including $4.4 million of stock-based compensation, a $2.8 million impairment of long-lived assets and $4.3 million of non-cash lease expense. The reduction in net cash used in operating activities from 2022 to 2023 was driven by the completion of our manufacturing scale-up investments in 2022 and the impact of lower employee compensation costs from the 2022 RIFs.

During the twelve months ended December 31, 2022, net cash used in operating activities was $100.1 million, resulting from our net loss of $113.0 million and a $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.

Investing activities

During the twelve months ended December 31, 2023 and 2022, we used $0.5 million and $1.6 million of cash for investing activities related to purchases of property and equipment.

Financing activities

During the twelve months ended December 31, 2023, net cash provided by financing activities related to proceeds from stock purchases pursuant to the Company's employee stock purchase plan.

During the twelve months 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.

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, 2023.

In March 2023, the Company entered into a lease termination agreement with the landlord of our former Redwood City, CA facility. The Company incurred immaterial customary termination and broker fees during the twelve months ended December 31, 2023. The lease of our former Redwood City, CA facility was terminated on May 12, 2023.

In March 2023, the Company entered into a sublease for laboratory and office space in our current 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 sublease commenced for accounting purposes on May 1, 2023 and the Company recorded a lease liability and corresponding right-of-use asset and liability of $7.3 million.

Purchase commitments

Currently, we have no material long-term purchase commitments.

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.

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.

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.

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

There are no accounting pronouncements pending at December 31, 2023 that we expect to have a material impact on our financial statements and disclosures.

Recently adopted accounting standards

We did not adopt any new accounting standards during the twelve months ended December 31, 2023.

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

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, 2023 and 2022, the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, 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 28, 2024

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

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 76,732	$ 130,191
Accounts receivable, net	50	308
Prepaid expenses and other current assets	901	2,783
Total current assets	77,683	133,282
Property and equipment, net	3,030	3,312
Operating lease right-of-use-assets	12,419	30,920
Other long-term assets	1,542	1,776
Total assets	$ 94,674	$ 169,290
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,339	$ 3,768
Accrued compensation	3,836	4,212
Accrued liabilities	715	989
Operating lease liabilities, current portion	2,882	3,703
Total current liabilities	8,772	12,672
Operating lease liabilities, long-term portion	16,786	29,879
Total liabilities	25,558	42,551
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, 2023 and December 31, 2022; 29,863,674 shares issued and outstanding as of December 31, 2023 and December 31, 2022; aggregate liquidation preference of $3 as of December 31, 2023 and December 31, 2022	3	3
Common Stock, $0.0001 par value; 200,000,000 shares authorized as of December 31, 2023 and December 31, 2022; 1,821,986 and 1,811,396 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	609,074	604,690
Accumulated deficit	(539,961)	(477,954)
Total stockholders' equity	69,116	126,739
Total liabilities and stockholders' equity	$ 94,674	$ 169,290

See accompanying notes to the financial statements

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

	Year ended December 31,	
	2023	**2022**
Revenue		
Grant revenue	$ 1,722	$ 1,160
Product revenue, net	412	3,652
Total revenue, net	$ 2,134	$ 4,812
Operating expenses:		
Cost of product sold	41	8,391
Research and development	40,694	70,831
Selling, general and administrative	28,214	40,729
Total operating expenses	68,949	119,951
Loss from operations	(66,815)	(115,139)
Other income	4,808	2,127
Net loss and comprehensive loss	$ (62,007)	$ (113,012)
Net loss per share, basic and diluted	$ (34.12)	$ (62.77)
Weighted average shares used in the calculation of net loss per share, basic and diluted:	1,817,506	1,800,447

See accompanying notes to the financial statements

Talis Biomedical Corporation
Statements of stockholders' equity
(in thousands, except for share amounts)

	Series 1 Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Stockholders'
	Shares	Value	Shares	Value	Capital	Deficit	Equity
Balance at December 31, 2021	29,863,674	$ 3	1,785,476	—	$ 598,916	$ (364,942)	$ 233,977
Issuance of common stock pursuant to equity incentive plan	—	—	8,199	—	98	—	98
Issuance of common stock pursuant to employee stock purchase plan	—	—	17,721	—	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	1,811,396	$ -	$ 604,690	$ (477,954)	$ 126,739
Issuance of Common Stock pursuant to equity incentive plan	—	—	6,030	—	—	—	—
Issuance of Common Stock pursuant to employee stock purchase plan	—	—	4,560	—	33	—	33
Stock-based compensation expense	—	—	—	—	4,351	—	4,351
Net loss	—	—	—	—	—	(62,007)	(62,007)
Balance at December 31, 2023	29,863,674	$ 3	1,821,986	$ -	$ 609,074	$ (539,961)	$ 69,116

See accompanying notes to the financial statements

Talis Biomedical Corporation
Statements of cash flows
(in thousands)

	Year ended December 31,	
	2023	**2022**
Operating activities		
Net loss	$ (62,007)	$ (113,012)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	4,351	5,368
Depreciation and amortization	770	8,830
Non-cash lease expense	4,304	2,771
Impairment of long-lived assets	2,766	3,593
Changes in operating assets and liabilities:		
Accounts receivable	259	(125)
Prepaid expenses and other current assets	1,879	604
Other long-term assets	—	741
Accounts payable	(2,429)	(1,194)
Accrued expenses and other liabilities	(3,133)	(7,712)
Net cash used in operating activities	$ (53,240)	$ (100,136)
Investing activities		
Purchase of property and equipment, net	(486)	(1,615)
Net cash used in investing activities	$ (486)	$ (1,615)
Financing activities		
Proceeds from stock option exercises	—	98
Proceeds from stock issuances pursuant to employee stock purchase plan	33	308
Net cash provided by financing activities	$ 33	$ 406
Net decrease in cash, cash equivalents and restricted cash	(53,693)	(101,345)
Cash, cash equivalents and restricted cash at beginning of year	131,967	233,312
Cash, cash equivalents and restricted cash at end of year	$ 78,274	$ 131,967
Supplemental disclosure of noncash activities		
Right-of-use assets obtained in exchange for operating lease liabilities	$ 7,265	$ 19,245
Remeasurement of operating lease right-of-use asset for lease modification	$ (18,696)	$ —

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,	
	2023	**2022**
Cash and cash equivalents	$ 76,732	$ 130,191
Restricted cash - other long-term assets	1,542	1,776
Total cash, cash equivalents and restricted cash	$ 78,274	$ 131,967

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. Prior to the announcement to consider strategic alternatives in November 2023, the Company planned 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 Chicago, Illinois (IL).

Liquidity

The Company has incurred significant losses and negative cash flows since inception, including a net loss of $62.0 million for the twelve months ended December 31, 2023.

Management expects to continue to incur additional losses in the foreseeable future while the Board of Directors considers strategic alternatives for the Company, including without limitation, equity or debt financing alternatives, an acquisition, merger, reverse merger, divestiture of assets, licensing or other strategic transactions and a voluntary dissolution or liquidation of the Company. The Company's activities are subject to significant risks and uncertainties, including failing to secure a strategic alternative or additional funding to continue to develop the Company's current technology and to achieve clinical approval of its products.

As of December 31, 2023, the Company had unrestricted cash and cash equivalents of $76.7 million and $1.5 million of restricted cash. The Company expects its existing unrestricted cash and cash equivalents 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 one or more possible strategic alternatives. However, there is no guarantee that any of these strategic opportunities will be executed or realized on favorable terms, if at all, and some could be dilutive to existing stockholders.

Reverse Stock Split

On June 30, 2023, the Company filed a certificate of amendment to the Company's Amended and Restated Certificate of Incorporation (the "Certificate of Amendment") with the Secretary of State of Delaware to effect a 1-for-15 reverse stock split of the shares of the Company's common stock, par value $0.0001 per share, effective as of 5:00 p.m., Eastern Time, on July 5, 2023 (the "Reverse Stock Split"). On this date, every 15 issued and outstanding shares of common stock were converted into one share of common stock, with any fractional shares resulting from the Reverse Stock Split rounded up to the nearest whole share. The number of outstanding shares of common stock was reduced from approximately 26.9 million shares to approximately 1.8 million shares.

The Reverse Stock Split did not change the Company's authorized shares of common stock and Series 1 convertible preferred stock, which remained at 200,000,000 and 60,000,000 shares, respectively. The Reverse Stock Split did not change the par value of the common stock and, therefore, the Company reclassified an amount equal to the reduction in the number of shares of common stock at par value to additional paid-in capital. Proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise of stock options and the settlement of restricted stock units and the number of shares authorized and reserved for issuance pursuant to the Company's equity incentive plans, see Note 8. Additionally, the Reverse Stock Split had no impact on the number of shares of the Company's Series 1 convertible preferred stock issued and outstanding. However, the conversion ratio of the outstanding Series 1 convertible preferred stock increased and the number of shares of common stock issuable upon conversion of such preferred stock decreased in proportion to the 1-for-15 split ratio, see Note 7.

All share and per share amounts for common stock in these financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to the Reverse Stock Split.

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.

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, restricted 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.

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 and restricted cash are 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, restricted cash and cash equivalents are held.

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
Furniture and fixtures	5 years
Office and computer equipment	3 years
Leasehold improvements	Shorter of life of the asset or remaining lease term

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

Impairment of long-lived assets

A long-lived asset may be impaired when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset's carrying amount. Any required impairment loss would be measured as the amount by which the asset or asset group's carrying value exceeds its fair value and would be recorded as a reduction in the carrying value of the related asset 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.

As the Company's market capitalization is below the carrying value of equity, the Company regularly assesses if its long-lived assets are impaired by comparing the estimated fair value of the long-lived assets to their respective carrying amounts. The impairment of long-lived asset charge relates solely to the operating lease right-of-use assets and 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. During the twelve months ended December 31, 2023 and 2022, the Company recorded long-lived asset impairment charges related to right-of-use assets within selling, general and administrative expenses on the statement of operations and comprehensive loss of $2.8 million and $3.6 million, respectively.

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.

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.

The Company makes estimates of its accrued research and development 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

The Company has classified its Series 1 convertible preferred stock as permanent equity within the accompanying balance sheet at December 31, 2023 and December 31, 2022 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.

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.

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, 2023 and 2022, 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

Recently issued accounting pronouncements

There are no accounting pronouncements pending at December 31, 2023 that we expect to have a material impact on our financial statements and disclosures.

Recently adopted accounting standards

We did not adopt any new accounting standards during the twelve months ended December 31, 2023

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 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents (money market funds)	$ 72,143	$ —	$ —	$ 72,143
Total assets measured at fair value	$ 72,143	$ —	$ —	$ 72,143

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents (money market funds)	$ 127,404	$ —	$ —	$ 127,404
Total assets measured at fair value	$ 127,404	$ —	$ —	$ 127,404

4. Balance sheet components

Property and equipment, net

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

	December 31,	
	2023	2022
Lab equipment	$ 13,289	$ 12,521
Office and computer equipment	562	548
Furniture and fixtures	870	828
Leasehold improvements	1,253	1,253
Total	15,974	15,150
Less accumulated depreciation	(12,944)	(12,822)
Total	3,030	2,328
Construction in progress	—	984
Property and equipment, net	$ 3,030	$ 3,312

November 2023 RIF liability

In November 2023, due to unforeseen operational challenges, setbacks in product development timelines and volatile market conditions, the Company decided to cease operations in its Redwood City, CA laboratory and office facility and consolidate operations to its Chicago facility and to consider strategic alternatives. In order to further reduce costs and extend its remaining cash, the Company announced a reduction in force of approximately 90% of its work force on November 14, 2023 ("November 2023 RIF"). As part of these actions, the Company provided notices to the impacted employees under the Worker Adjustment and Retraining Act ("WARN Act") for job eliminations to occur through March 2024.

During the twelve months ended December 31, 2023, the Company incurred $3.4 million of expenses related to the November 2023 RIF which included payroll costs for salaries, wages and benefits paid or to be paid to employees during the minimum WARN act retention period and other costs. Expenses related to the November 2023 RIF are

included in Selling, general and administrative and Research and development expenses in the statement of operations and comprehensive loss.

Depending on the outcome of our plans to consider strategic alternatives, the Company expects to incur approximately $0.5 million of additional expenses related to the November 2023 RIF, substantially all of which will consist of charges related to the staff reduction.

The following table summarizes the activity for the November 2023 RIF accrued liability (in thousands):

	Twelve Months ended December 31, 2023
Balance at December 31, 2022	$ —
Charges	3,387
Cash Payments	(1,057)
Balance at December 31, 2023	$ 2,330

The November 2023 RIF accrued liability is included in Accrued Compensation on the balance sheet.

In March 2022 and August 2022, the Company implemented two separate reductions in force (RIF) designed to reduce its operating expenses, preserve cash and align its 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 twelve months ended December 31, 2022, the Company incurred $1.0 million of expenses related to the March 2022 RIF and $1.5 million of expenses related to the August 2022 RIF.

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 twelve months ended December 31, 2023.

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 2023, the Company exercised a one-year option under the grant, extending the term through April 2024. There is $0.4 million in additional funding available under the grant as of December 31, 2023, which the Company does not expect to fully utilize.

During each of the twelve months ended December 31, 2023 and 2022, the Company recognized $1.7 million and $0.5 million of revenue related to this grant, respectively.

NIH Rapid Acceleration of Diagnostics - RADx Initiative contracts

In July 2020, the Company was awarded a sub-award 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 twelve months ended December 31, 2022, the Company recognized revenue of $0.7 million related to the RADx initiative.

6. Commitments and contingencies

Operating leases

In March 2023, the Company entered into a lease termination agreement with the landlord of its former Redwood City, CA facility. The original term of the lease commenced in June 2022 and was for an initial term of 10.5 years. As a result of this modification, the Company remeasured the lease liability and the corresponding right-of-use asset resulting in a reduction of each by $18.7 million. The Company incurred immaterial customary termination and broker fees during the twelve months ended December 31, 2023. The lease of our former Redwood City, CA facility was terminated on May 12, 2023.

In March 2023, the Company entered into a sublease for laboratory and office space in its current 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 sublease commenced for accounting purposes on May 1, 2023 and the Company recorded a lease liability and corresponding right-of-use asset and liability of $7.3 million. While the sublease is still in effect, in November 2023, the Company decided to cease operations in its Redwood City laboratory and office facility and have consolidated all of its operations to its Chicago office during 2024.

The Company recorded long-lived asset impairment charges related to right-of-use assets of $2.8 million and $3.6 million during the twelve months ended December 31, 2023 and 2022, respectively. 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	**2023**	**2022**
Operating lease costs	$ 6,635	$ 4,100
Variable lease costs	787	834
Total operating lease costs	$ 7,422	$ 4,934
Cash flows		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows used for operating leases	$ 3,965	$ 1,360

	December 31,	
	2023	**2022**
Weighted-average remaining lease term	7.8 years	9.8 years
Weighted-average discount rate	6.4%	7.0%

The undiscounted future lease payments for our Redwood City, CA and Chicago, IL operating leases as of December 31, 2023 were as follows (in thousands):

Year ending December 31,	Operating Leases
2024	$ 2,970
2025	3,055
2026	3,144
2027	3,235
2028	3,329
2029 and thereafter	9,177
Total future minimum lease payments	$ 24,910
Less: imputed interest	(5,243)
Present value of operating lease liabilities	19,667
Less: current portion of lease liabilities	(2,882)
Noncurrent portion of lease liabilities	$ 16,786

Standby letters of credit

In January 2022, in conjunction with the Company's former 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. In March 2023, the Company entered into a lease termination agreement with the landlord of its former Redwood City, CA facility, which accelerated the lease termination date to May 12, 2023. During the twelve months ended December 31, 2023 all the criteria in the termination agreement were met and the landlord released the LOC of $1.0 million, which is now classified within cash and cash equivalents on the balance sheet as of December 31, 2023.

In March 2023, the Company entered into a sublease for laboratory and office space in its current Redwood City, CA facility. The Company is required to hold a LOC in the amount of $0.7 million to secure this lease through expiration. The Company is required to maintain a cash balance of $0.7 million as collateral for the LOC, which has been classified in other long-term assets on the balance sheet as of December 31, 2023, because it is unavailable for a period longer than one year from the balance sheet date.

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, 2023, because it is unavailable for a period longer than one year from the balance sheet date.

The Company has not drawn upon any LOC through December 31, 2023.

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, 2023, 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. Circumstances change over time and actual results may vary significantly from estimates.

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 the Company, certain of its officers and directors, and J.P. Morgan Securities LLC, BofA Securities, Inc., Piper Sandler & Co., and BTIG, LLC, underwriters of the Company's 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 the Company's stock that were registered in the Company's 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 the Company, and the same officers and directors as the Modrak lawsuit. These two cases were consolidated and co-lead plaintiffs were appointed as mandated by the applicable federal securities laws. On December 9, 2022, the Court granted the Company's motion to dismiss and gave 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 of 1933 ("Securities Act") against all defendants and Section 15 of the Securities Act against the individual defendants. The amended complaint alleges that the Company's registration statement and prospectus issued in connection with the Company's IPO was false and misleading, and omitted to state material adverse facts, related to (1) instrument manufacturing, (2) the reliability and accuracy of the Company's Talis One COVID-19 test, and (3) the comparator test used in the Company's primary study in support of its EUA application for the Talis One COVID-19 Test System. The amended complaint seeks unspecified damages under Sections 11 and 15 of the Securities Act, reasonable attorneys' fees, and other costs. The amended complaint does not assert claims against the above referenced underwriters. On April 28, 2023, the Court denied our motion to dismiss. On February 9, 2024, the Court certified the class and appointed plaintiff Martin Dugan as class representative. Discovery is ongoing. Trial is currently set for February 24, 2025.

The Company has not recorded an accrual related to this matter as of December 31, 2023 as it determined that any such loss contingency was not probable or reasonably estimable.

Other than the litigation matters discussed above, 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

Common Stock

The Company's February 2021 amended and restated certificate of incorporation authorized the issuance of up to 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, 2023 and 2022.

On July 27, 2022, the Company received a notice (Notice) from the Nasdaq Stock Market (Nasdaq) that the Company was not in compliance with the $1.00 minimum bid price requirement for continued listing, as set forth in Nasdaq Listing Rule 5450(a)(1) (Minimum Bid Price Requirement), 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 had not regained compliance with the Minimum Bid Price Requirement, Nasdaq determined that the Company was eligible for an additional 180-day

period, or until July 24, 2023, to regain compliance. We committed to effectuating 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 had no other immediate effect on the listing of the Company's common stock, which trades on the Capital Market under the symbol "TLIS."

Effective July 5, 2023, the Company completed a 1-for-15 reverse stock split of its issued and outstanding shares of common stock, as further described in Note 1. As a result of the Reverse Stock Split, every 15 shares of common stock issued and outstanding were converted into one share of common stock with any fractional shares resulting from the Reverse Stock Split rounded up to the nearest whole share. The rights and privileges of the holders of shares of common stock are unaffected by the Reverse Stock Split.

The common stock traded on an as-adjusted basis upon market open on July 6, 2023. The purpose of the Reverse Stock Split was to enable the Company to regain compliance with the requirements of Minimum Bid Price Requirement. On July 20, 2023, we received notice from Nasdaq that we had regained compliance with the Minimum Bid Price Requirement.

The Reverse Stock Split did not change the par value of the common stock or the authorized number of shares of common stock. All share and per share amounts for common stock in these financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to the Reverse Stock Split, including reclassifying an amount equal to the reduction in the number of shares of common stock at par value to additional paid-in capital.

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, 2023 and 2022, 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 stock authorized 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.

As of December 31, 2023 and December 31, 2022, there were 29,863,674 shares of Series 1 convertible preferred stock issued and outstanding. There were 60,000,000 shares of Series 1 convertible preferred stock with a par value of $0.0001 per share authorized as of December 31, 2023 and December 31, 2022.

The Reverse Stock Split had no impact on the number of shares of the Company's Series 1 convertible preferred stock issued and outstanding. However, the conversion ratio of the outstanding Series 1 convertible preferred stock increased and the number of shares of common stock issuable upon conversion of such Series 1 convertible preferred stock decreased in proportion to the 1-for-15 ratio. The rights and privileges of the holders of shares of Series 1 convertible preferred stock are unaffected by the Reverse Stock Split.

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, 2023, 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 registrable securities pursuant to the Registration Rights Agreement, which registration statement was declared effective on May 24, 2022 (the "Resale Shelf Registration Statement"). Under the Registration Rights Agreement, the Baker Funds also have the right to one underwritten offering per calendar year, but no more than two underwritten offerings or block trades in any twelve-month period, to effect the sale or distribution of their registrable securities, subject to specified exceptions, conditions and limitations. The Registration Rights Agreement also includes customary indemnification obligations in connection with registrations conducted pursuant to the Registration Rights Agreement. In March 2024, the Resale Shelf Registration Statement was terminated because the Company was no longer eligible to register securities on Form S-3 and the Baker Funds waived their rights under the Registration Rights Agreement. This waiver of registration rights is effective for a period of thirty (30) days from the filing of this Form 10-K.

8. Stock-based compensation

Effective July 5, 2023, the Company completed a 1-for-15 Reverse Stock Split of its issued and outstanding shares of common stock, as further described in Note 1 and Note 7. All stock options and restricted stock units outstanding immediately prior to the Reverse Stock Split, as well as strike price and fair value amounts, were adjusted pursuant to the terms of the Company's equity incentive plans to give effect to the Reverse Stock Split. The number of shares of common stock issuable upon the exercise of each stock option and the settlement of each restricted stock unit decreased in proportion to the 1-for-15 ratio and the number of shares authorized and reserved for issuance pursuant to the Company's equity incentive plans was proportionately adjusted to give effect to the Reverse Stock Split.

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 was terminated during the twelve months ended December 31, 2023.

The ESPP is a compensatory plan as defined by the authoritative guidance for stock compensation; therefore, stock-based compensation expense of $0.01 million and $0.3 million related to the ESPP has been recorded for the twelve months ended December 31, 2023 and 2022, 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 twelve months ended December 31, 2023 is as follows:

	Number of Units Outstanding	Weighted Average Exercise Price per Unit	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	559,542	$ 52.87	8.6	$ —
Granted	318,122	$ 7.44		
Exercised	—	$ —		
Forfeited	(127,117)	$ 21.83		
Expired	(32,317)	$ 52.10		
Outstanding at December 31, 2023	718,230	$ 38.28	8.3	$ —
Options vested and expected to vest at December 31, 2023	718,230	$ 38.28	8.3	$ —
Options vested and exercisable at December 31, 2023	281,946	$ 65.08	7.4	$ —

As of December 31, 2023, the total unrecognized stock-based compensation related to stock options was $5.5 million, which is expected be recognized over a weighted-average period of approximately 2 years. During January 2024, $1.2 million of unrecognized stock-based compensation expense was cancelled as a result of stock option forfeitures related to the November 2023 RIF. See Note 4 for more information. Total options vested during the year were 126,596 with a total fair value of $4.0 million.

As of December 31, 2023, 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:

	Twelve months ended December 31,	
	2023	2022
Expected term (in years)	6.3	8.3
Expected Volatility	73.1%	71.3%
Risk-free interest rate	3.6%	2.9%
Expected Dividend yield	—%	—%

The weighted-average grant date fair value per share was $5.05 and $11.78 for stock options granted during the twelve months ended December 31, 2023 and 2022, 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 twelve months ended December 31, 2023 is as follows:

	Number of Units Outstanding	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2022	21,764	$ 41.18
Granted	2,598	$ 7.79
Vested	(5,719)	$ 46.43
Forfeited	(4,159)	$ 26.16
Outstanding at December 31, 2023	14,484	$ 37.43

As of December 31, 2023, the total unrecognized stock-based compensation related to RSUs was $0.5 million, which is expected to be recognized over a weighted average period of approximately 2 years. During January 2024, $0.4 million of unrecognized stock-based compensation expense was cancelled as a result of RSU forfeitures related to the November 2023 RIF. See Note 4 for more information. Outstanding RSUs as of December 31, 2023 includes 10 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):

	Twelve months ended December 31,	
	2023	2022
Research and development	$ 967	$ 1,313
Selling, general and administrative	3,384	4,055
Total stock-based compensation	$ 4,351	$ 5,368

9. Related-party transactions

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 twelve months ended December 31, 2023 and 2022, due to its history of operating losses. During the twelve months ended December 31, 2023 and 2022, the Company recorded a net loss of $62.0 million and $113.0 million, respectively.

The effective tax rate for the twelve months ended December 31, 2023 and 2022 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:

Effective income tax rate:	December 31, 2023	2022
Expected income tax benefit at the federal statutory rate	21.0%	21.0%
State taxes, net of federal benefit	7.0	6.0
Research and development tax credits	2.3	0.9
Permanent differences	(2.3)	(0.5)
Change in valuation allowance	(28.0)	(27.4)
Total provision for income taxes	—%	—%

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

	December 31, 2023	2022
Deferred tax assets:		
Federal and state operating loss carryforwards	$ 81,749	$ 66,709
Research and development tax credits	9,749	8,384
Lease liabilities	5,806	9,420
Manufacturing line and production equipment	29,413	27,875
Inventory related costs	12,624	12,669
Compensation related items	3,118	2,838
Capitalized research and development costs	20,706	17,880
Property and equipment	702	1,200
Other	583	905
Total gross deferred tax asset	164,450	147,880
Valuation allowance	(160,784)	(140,411)
Net deferred tax asset	3,666	7,469
Deferred tax liabilities:		
Operating lease right-of-use asset	(3,666)	(7,469)
Total deferred tax liabilities	(3,666)	(7,469)
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 $20.4 million and $29.4 million for the twelve months ended December 31, 2023 and 2022, respectively, primarily due to the increase in the Company's net loss and comprehensive loss.

NOLs and tax credit carryforwards as of December 31, 2023 are as follows (in thousands):

	Amount	Expiration Years
NOLs, federal (post December 31, 2017)	$ 258,223	Do not expire
NOLs, federal (pre January 1, 2018)	30,901	2033 - 2037
NOLs, state	242,793	2033 to 2041
Research and development tax credits, federal	11,356	2035 to 2041
Research and development tax credits, state	8,731	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,	
	2023	2022
Unrecognized tax benefits at the beginning of the period	$ 8,973	$ 7,244
Additions for current tax positions	1,365	1,729
Changes for previous tax positions	—	—
Unrecognized tax benefits at the end of the period	$ 10,338	$ 8,973

During the twelve months ended December 31, 2023 and 2022, 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, 2023 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,	
	2023	2022
Numerator:		
Net loss - basic and diluted	$ (62,007)	$ (113,012)
Denominator:		
Weighted-average number of shares of common stock outstanding - basic and diluted	1,817,506	1,800,447
Net loss per share - basic and diluted	$ (34.12)	$ (62.77)

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,	
	2023	2022
Series 1 convertible preferred stock (1)	29,863,674	29,863,674
Options to purchase common stock (2)	718,230	559,542
Shares estimated to be purchased under 2021 ESPP	—	13,104
Unvested RSUs (3)	14,484	21,764
Total	30,596,388	30,458,084

(1) The conversion ratio of the Company's Series 1 convertible preferred stock has been adjusted to proportionally reflect the 1-for-15 Reverse Stock Split upon conversion. See Note 1.
(2) During January 2024, 149,026 unvested stock options were forfeited due to the November 2023 RIF. See Note 4 for more information.
(3) During January 2024, 10,183 unvested RSUs were forfeited due to the November 2023 RIF. See Note 4 for more information.

12. Employee benefit plans

The Company has a qualified deferred compensation plan under Section 401(k) of the Internal Revenue Code of 1986, as amended (401(k) Plan). Under the 401(k) Plan, employees may elect to defer a percentage of their salary, subject to Internal Revenue Service limits. The 401(k) Plan follows the Safe Harbor Deferral provisions, met with a Company Basic Matching Provision in which we provide an automatic matching contribution as follows: one-for-one with respect to the first 3% of an employee’s contributions, and 50 cents on the dollar for the next 2% of the employee’s contributions, up to a maximum company match of 4%. The matching contribution under this provision totaled $0.6 million and $0.9 million for the twelve months ended December 31, 2023 and 2022.

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 twelve months ended December 31, 2023 and 2022.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer (CEO) and Interim Chief Financial Officer (Interim 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 Interim CFO, to allow timely decisions regarding required disclosure. Based on this evaluation, the CEO and Interim 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 Interim CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

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 twelve months ended December 31, 2023.

Item 9B. Other Information.

a) In March 2024, the Company terminated a previously filed registration statement on Form S-3 (the “Demand Registration Statement”) as the Company was no longer eligible to register securities on Form S-3. On March 25, 2024, the Company entered into a Waiver of Registration Rights (the “Waiver Agreement”) with Baker Brothers Life Sciences L.P. and 667, L.P. to obtain a waiver of the registration rights relating to all of these securities previously registered for resale by the Demand Registration

Statement. This waiver of the registration rights is effective for a period of thirty (30) days from the filing of this Form 10-K. The foregoing summary of the Waiver Agreement does not purport to be complete and is qualified in its entirety by the Waiver Agreement filed as Exhibit 10.24 to this Form 10-K and incorporated herein by reference. The foregoing disclosure of this Waiver Agreement is being made in this paragraph (a) of Part II. Item 9B. of Form 10-K in lieu of a separate disclosure under Items 1.01 and 9.01 of Form 8-K.

b) None.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers

The names, ages, and positions of all executive officers and directors as of March 19, 2024 are listed below.

Name	Age	Position(s)
Executive Officers		
Robert Kelley	52	Chief Executive Officer and Director
Rebecca Markovich (1)	51	Interim Chief Financial Officer
Non-Employee Directors		
Raymond Cheong, M.D., Ph.D.	42	Director
Rustem F. Ismagilov, Ph.D.	50	Director
Kimberly J. Popovits	65	Director
Matthew L. Posard	56	Director
Randal Scott, Ph.D.	66	Director
Heinrich Dreismann, Ph.D.	70	Director

(1) Ms. Markovich was appointed Interim Chief Financial Officer effective upon the close of business on April 21, 2023.

Robert Kelley has served as our Chief Executive Officer and a member of our Board of Directors since December 2021. Mr. Kelley previously served as our Chief Commercial Officer from September 2020 to December 2021. From October 2017 to August 2020, Mr. Kelley was Vice President, Sales and Commercial Development of Genalyte, Inc., a healthcare analytics and point-of-care diagnostics company. Prior to Genalyte, Inc., Mr. Kelley was Vice President, Marketing of Cardiff Oncology, Inc. (formerly Trovagene, Inc.), a publicly held liquid biopsy company, from March 2015 to May 2017. From December 2008 to March 2015, Mr. Kelley held various positions of increasing responsibility with Illumina Inc., a publicly held biotechnology company, including Global Sales Manager for clinical applications of NGS and Director, Market Development, New and Emerging Opportunities. Mr. Kelley received a B.S. in Biology from Duke University and an M.B.A. from the UCLA Anderson School of Management. Our Board of Directors believes Mr. Kelley's experience as the Company's Chief Executive Officer and his extensive commercial leadership experience in the biotechnology and diagnostics industry qualify him to serve on our Board of Directors.

Rebecca Markovich has served as the interim Chief Financial Officer since April 2023. Prior to her appointment, Ms. Markovich served as the Company's Vice President, Controller from May 2022 to April 2023 and as the Company's Vice President, Accounting from January 2022 to May 2022. Prior to joining the Company, Ms. Markovich was the Chief Financial Officer, Vice President and Corporate Controller of ApiJect, a medical device company from 2021 to January 2022. From 2019 to 2021, Ms. Markovich was the Vice President, Global Controller at Vyaire, a global respiratory company. Prior to Vyaire, Ms. Markovich was the Vice President, Chief Accounting Officer and Controller for Cars.com, a digital marketplace for car shoppers and sellers. Ms. Markovich is a graduate of Indiana University where she obtained a B.S. degree in Accounting from the Kelley School of Business. She is also an Illinois Certified Public Accountant.

Non-Employee Directors

Raymond Cheong, M.D., Ph.D. has served on our Board of Directors since June 2020. Dr. Cheong is a Managing Director at Baker Bros. Advisors, LP. Prior to joining Baker Brothers, Dr. Cheong completed an M.D. and a Ph.D. in Biomedical Engineering from Johns Hopkins University, where he was awarded the Michael A. Shanoff Award for best thesis research within the School of Medicine. Prior to Hopkins, he earned a B.S. in Chemical Engineering from the University of Maryland, College Park. Dr. Cheong serves on the Board of Directors of Istari Oncology, Inc., Madrigal Pharmaceuticals, Inc. and vTv Therapeutics Inc. Our Board of Directors believes Dr. Cheong's scientific and medical background and experience in the biotechnology industry qualify him to serve on our Board of Directors.

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

Kimberly J. Popovits has served on our Board of Directors since March 2020, and previously served as our Interim Chief Executive Officer from August 2021 to December 2021. Ms. Popovits served as President and Chief Executive Officer of Genomic Health, Inc., a life science company focused on the development and commercialization of genomic-based clinical diagnostic tests, from January 2009, and as Chair of the Board of Directors from March 2012, until its acquisition by Exact Sciences Corporation in November 2019. Prior to joining Genomic Health, Inc. in 2002, Ms. Popovits held several senior management roles at Genentech, Inc., a biotechnology company. Ms. Popovits served on the Board of Directors of MyoKardia, Inc., a public, clinical-stage biopharmaceutical company, from March 2017 until its acquisition in November 2020. Ms. Popovits has also served on the Board of Directors of 10x Genomics, Inc., a public biotechnology company, since March 2020 and currently serves on its compensation committee, and Kiniksa Pharmaceuticals, Ltd., a public biopharmaceutical company, since February 2018 and currently serves on its compensation committee. Ms. Popovits received a B.A. in Business from Michigan State University. Our Board of Directors believes Ms. Popovits' significant leadership, operations and commercial experience qualify her to serve on our Board of Directors.

Matthew L. Posard has served on our Board of Directors since March 2016. Mr. Posard is a Founding Principal at Explore-DNA, Inc., a life sciences and diagnostics consulting firm, a position he has held since March 2016. Mr. Posard served as President and Chief Commercial Officer of GenePeeks, Inc., a genetic research company, from February 2017 to April 2018, and as Executive Vice President and Chief Commercial Officer of Cardiff Oncology, Inc. (formerly Trovagene, Inc.), a publicly held liquid biopsy company, from March 2015 to May 2016. Mr. Posard also held various executive roles at Illumina Inc., a publicly held biotechnology company, from February 2006 to February 2015, including most recently as Senior Vice President, General Manager of New and Emerging Markets. Mr. Posard has served on the Board of Directors of Halozyme Therapeutics, Inc., a public biotechnology company that develops novel oncology therapies, since March 2013 and currently serves as the Chair of its nominating and corporate governance committee, DermTech, Inc., a public genomics company in dermatology, since July 2016 and currently serves on its nominating and corporate governance committee, and Nautilus Biotechnology, Inc., a public development stage life sciences company, since January 2019 and currently serves on its audit committee and as Chair of its compensation committee. Mr. Posard has also served as the Executive Chair of Stemson Therapeutics, LLC, a pre-clinical stage cell therapy company, since March 2019. Mr. Posard received a B.A. in Management Science from the University of California, San Diego. Our Board of Directors believes Mr. Posard's extensive experience as an executive and director of multiple biotechnology companies qualify him to serve on our Board of Directors.

Randal Scott, Ph.D. has served on our Board of Directors since February 2016. Dr. Scott is presently the CEO of Genomic Life, Inc., a private health technology company. Previously, Dr. Scott was a co-founder of Invitae Corporation, a publicly held genetic information company, where he served as Chair of the Board of Directors and Chief Executive Officer from August 2012 to January 2017 and Executive Chair from January 2017 to August 2019. Dr. Scott was re-appointed Chair of the Board of Directors in 2022. Prior to Invitae Corporation, Dr. Scott co-founded Genomic Health, Inc., a life science company focused on the development and commercialization of genomic-based clinical diagnostic tests, where he served as Chair of the Board of Directors and Chief Executive Officer from August 2000 to 2009 and Executive Chair from 2009 to August 2012. Dr. Scott has also served on the Board of Directors of BridgeBio Pharma, Inc., a publicly held genetic disease-focused company, since June 2020, and Freenome Holdings, Inc., a private health technology company, since December 2017; and as the co-chair of Genomic Life, Inc., a private health technology company, since January 2021. Dr. Scott received a B.S. in Chemistry from Emporia State University and a Ph.D. in Biochemistry from the University of Kansas. Our Board of

Directors believes Dr. Scott's extensive experience building and leading successful biopharmaceutical companies qualify him to serve on our Board of Directors.

Heinrich Dreismann Ph.D. has served on our Board of Directors since May 19, 2023. Dr. Dreismann has served as a director on numerous private and public company boards from 2006 to present, including on Myriad Genetics, a public company focused on genetic testing and precision medicine and Mainz BioMed, a public company developing market-ready molecular genetic diagnostic solutions for life-threatening conditions. Prior to his board service, Dr. Dreismann served as President and Chief Executive Officer of Roche Molecular Systems, Inc. from 2000 to 2006. Dr. Dreismann earned a Master of Science in Biology and a Ph.D. in Microbiology/Molecular Biology from the University of Munster in Germany. Our Board of Directors believes Dr. Dreismann's extensive experience as an executive and director of multiple biotechnology companies qualify him to serve on our Board of Directors.

Family Relationships

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

Board composition

Talis Biomedical's Board of Directors is divided into three classes and each class has a three-year term. Class I, Class II and Class III directors will serve until our annual meeting of our stockholders in 2025, 2023 and 2024, respectively. Our Board of Directors presently has eight members and each class consists, as nearly as possible, of one-third of the total number of directors. Vacancies on the Board of Directors may be filled only by persons elected by a majority of the directors then in office. A director elected by the Board of Directors to fill a vacancy in a class, including vacancies created by an increase in the number of directors, shall serve for the remainder of the full term of that class and until the director's successor is duly elected and qualified.

Board Diversity Matrix (As of January 31, 2024)

Total Number of Directors	7			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	1	6	—	—
Part II: Demographic Background				
African American or Black	—	—	—	—
Alaskan Native or Native American	—	—	—	—
Asian	—	1	—	—
Hispanic or Latinx	—	—	—	—
Native Hawaiian or Pacific Islander	—	—	—	—
White	1	5	—	—
Two or More Races or Ethnicities	—	—	—	—
LGBTQ+	—	—	—	—
Did Not Disclose Demographic Background	—	—	—	—

Independence of The Board of Directors

As required under The Nasdaq Stock Market ("Nasdaq") listing standards, a majority of the members of a listed company's Board of Directors must qualify as "independent," as affirmatively determined by the Board of Directors. Our Board of Directors consults with the Company's counsel to ensure that the Board of Director's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and the Company, its senior management and its independent auditors, our Board of Directors has affirmatively determined that all of the directors that served as a director during any part

of the twelve months ended December 31, 2023 other than Mr. Kelley, Dr. Cheong, Dr. Ismagilov and Dr. Baker (former director) are independent directors within the meaning of the applicable Nasdaq listing standards. In making this determination, our Board of Directors found that none of these directors or nominees for director had a material or other disqualifying relationship with the Company.

Board Leadership Structure

Our Bylaws provide that our Board of Directors may be led by a Chairman of the Board or a Lead Independent Director who would have authority, among other things, to call and preside over meetings of the Board of Directors, to set meeting agendas and to determine materials to be distributed to the Board of Directors. Dr. Felix Baker previously served as Chairman of the Board until he resigned from the Board of Directors in March 2023 and became the board observer of Baker Brothers (as further described in "Transactions with Related Persons and Indemnification—Agreements with Baker Brothers—Nominating Agreement"). Upon Mr. Baker's resignation from the Board of Directors, the Board of Directors assessed its composition and governance structure and in April 2023 appointed Ms. Popovits as Lead Independent Director Currently, the Company has separated the roles of Chief Executive Officer and Chairman of the Board or Lead Independent Director. The Company believes that at this time the separation of these roles permits the Chairman of the Board or Lead Independent Director to focus on oversight of the Company's long-term corporate development goals while the Chief Executive Officer focuses on the strategic direction of the Company and oversees the day-to-day performance of the management team in executing the Company's business plan. In addition, we have a separate appointed or acting chair for each committee of our Board of Directors. The chair of each committee is expected to report at least annually to our Board of Directors on the activities of their committee in fulfilling their responsibilities as detailed in their respective charters or specify any shortcomings should that be the case.

Role of the Board in Risk Oversight

One of the Board of Directors' key functions is informed oversight of the Company's risk management process. The Board of Directors does not have a standing risk management committee, but rather administers this oversight function directly through the Board of Directors as a whole, as well as through various standing committees of the Board of Directors that address risks inherent in their respective areas of oversight. In particular, our Board of Directors is responsible for monitoring and assessing strategic risk exposure, including a determination of the nature and level of risk appropriate for the Company. Our Audit Committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including the guidelines and policies to govern the process by which risk assessment and management is undertaken. The Audit Committee also monitors compliance with legal and regulatory requirements, in addition to oversight of the performance of our internal audit function. Audit Committee responsibilities also include oversight of information security and cyber risk management. Our Nominating and Corporate Governance Committee monitors the effectiveness of our corporate governance guidelines, including whether they are successful in preventing illegal or improper liability-creating conduct, as well as overseeing our sustainability and environmental, social and governance activities. Our Compensation Committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. Our Science, Technology and Clinical Affairs Committee assesses and monitors our research and development programs and strategy and technology initiatives, including the level of risk exposure they may present. In addition, the entire Board of Directors receives reports from time to time regarding various enterprise risks facing the Company, and the applicable committees of the Board of Directors receive related reports with respect to the committee's respective areas of oversight. The Board of Directors has delegated to the Lead Independent Director the responsibility of coordinating between the Board of Directors and management with regard to the determination and implementation of responses to any problematic risk management issues.

Meetings of The Board of Directors

The Board of Directors met 9 times during the twelve months ended December 31, 2023. Each director attended 75% or more of the aggregate number of meetings of the Board of Directors and of the committees on which he or she served, held during the portion of the last fiscal year for which he or she was a director or committee member.

Information Regarding Committees of the Board of Directors

Our Board of Directors has five committees: an Audit Committee, a Compensation Committee, a Nominating and Corporate Governance Committee, a Science, Technology and Clinical Affairs Committee and a Special Committee.

The following table provides membership on each committee as of December 31, 2023 and meeting information for the twelve months ended December 31, 2023 for each of the committees of the Board of Directors:

Name	Audit	Compensation	Nominating and Corporate Governance	Science, Technology and Clinical Affairs	Special Committee
Kimberly J. Popovits	X	X	X*		X
Matthew L. Posard	X	X*			X
Randal Scott, Ph.D.	X*		X		X
Raymond Cheong, M.D., Ph.D.				X	
Rustem F. Ismagilov, Ph.D.				X*	
Heinrich Dreismann, Ph.D.		X		X	X
Total meetings in fiscal 2023	4	5	3	5	7

* Committee Chairperson

Below is a description of each committee of the Board of Directors.

Our Board of Directors has determined that each member of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee meets the applicable Nasdaq rules and regulations regarding "independence" and each member is free of any relationship that would impair his or her individual exercise of independent judgment with regard to the Company.

Audit Committee

The Audit Committee of the Board of Directors was established by the Board of Directors in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), to oversee the Company's corporate accounting and financial reporting processes, the system of internal control over financial reporting and audits of its financial statements. For this purpose, the Audit Committee performs several functions including, among other things:

- evaluating the performance, independence and qualifications of our independent registered public accounting firm and determining whether to retain our existing independent registered public accounting firm or engage a new independent registered public accounting firm;
- reviewing and approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent registered public accounting firm on our engagement team as required by law;
- prior to engagement of any independent registered public accounting firm, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent registered public accounting firm;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent registered public accounting firm and management;
- reviewing with management and our independent registered public accounting firm any earnings announcements and other public announcements regarding material developments;

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

The Audit Committee is currently composed of three directors: Dr. Scott (chair), Ms. Popovits and Mr. Posard. The Audit Committee met 4 times during the twelve months ended December 31, 2023. The Board of Directors has adopted a written Audit Committee charter that is available to stockholders on the Company's website at https://investors.talisbio.com.

The Board of Directors reviews the Nasdaq listing standards definition of independence for Audit Committee members on an annual basis and has determined that all members of the Audit Committee are independent (as independence is currently defined in Rule 5605(c)(2)(A)(i) and (ii) of the Nasdaq listing standards).

The Board of Directors has also determined that Dr. Scott qualifies as an "audit committee financial expert," as defined in applicable SEC rules. The Board of Directors made a qualitative assessment of Dr. Scott's level of knowledge and experience based on a number of factors, including his prior experience as a chief executive officer for public reporting companies and his business acumen.

*Report of the Audit Committee of the Board of Directors**

The Audit Committee has reviewed and discussed the audited financial statements for the twelve months ended December 31, 2023 with management of the Company. The Audit Committee has discussed with the independent registered public accounting firm the matters required to be discussed by the applicable requirements of the Public Company Accounting Oversight Board ("PCAOB") and the SEC. The Audit Committee has also received the written disclosures and the letter from the independent registered public accounting firm required by applicable requirements of the PCAOB regarding the independent registered public accounting firm's communications with the audit committee concerning independence and has discussed with the independent registered public accounting firm the accounting firm's independence. Based on the foregoing, the Audit Committee has recommended to the Board of Directors that the audited financial statements be included in the Company's Annual Report on Form 10-K for the twelve months ended December 31, 2023.

Randal Scott, Ph.D., Chair
Kimberly J. Popovits
Matthew L. Posard

**The material in this report is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.*

Compensation Committee

The Compensation Committee is currently composed of three directors: Mr. Posard (Chair), Dr. Dreismann and Ms. Popovits. All members of the Compensation Committee are independent (as independence is currently defined in Rule 5605(d)(2) of the Nasdaq listing standards). The Compensation Committee met 5 times during the twelve months ended December 31, 2023.

The Board of Directors has adopted a written Compensation Committee charter that is available to stockholders on the Company's website at https://investors.talisbio.com.

The functions of the Compensation Committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full Board of Directors regarding) our overall compensation strategy and policies;
- reviewing and making recommendations to the full Board of Directors regarding the compensation and other terms of employment of our executive officers;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full Board of Directors regarding) performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full Board of Directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full Board of Directors regarding) the type and amount of compensation to be paid or awarded to our non-employee board members;
- establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation, to the extent required by law;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full Board of Directors regarding) the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
- reviewing with management and approving our disclosures under the caption "Compensation Discussion and Analysis" in our periodic reports or proxy statements to be filed with the SEC, to the extent such caption is included in any such report or proxy statement;
- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and assessing on an annual basis the performance of the Compensation Committee and the Compensation Committee charter.

Compensation Committee Processes and Procedures

Typically, the Compensation Committee meets at least once annually and with greater frequency if necessary. The agenda for each meeting is usually developed by the Chair of the Compensation Committee, in consultation with the Chief Financial Officer, the human resources and legal departments and Compensia, Inc. ("Compensia"), the Compensation Committee's independent compensation consultant. The Compensation Committee meets regularly in executive session. However, from time to time, various members of management and other employees as well as outside advisors or consultants may be invited by the Compensation Committee to make presentations, to provide financial or other background information or advice or to otherwise participate in Compensation Committee meetings. The Chief Executive Officer may not participate in, or be present during, any deliberations or determinations of the Compensation Committee regarding his or her compensation or individual performance objectives. The charter of the Compensation Committee grants it full access to all books, records, facilities and personnel of the Company. In addition, under the charter, the Compensation Committee has the authority to obtain, at the expense of the Company, advice and assistance from compensation consultants and internal and external legal, accounting or other advisors and other external resources that the Compensation Committee considers necessary or appropriate in the performance of its duties. The Compensation Committee has direct responsibility for the oversight of the work of any consultants or advisers engaged for the purpose of advising the Compensation Committee. In particular, the Compensation Committee has the sole authority to retain, in its sole discretion, compensation consultants to assist in its evaluation of senior executive and director compensation, including the authority to approve the consultant's reasonable fees and other retention terms. Under the charter, the Compensation Committee may select, or receive advice from, a compensation consultant, legal counsel or other adviser to the compensation committee, other than in-house legal counsel and certain other types of advisers, only after taking into consideration six factors, prescribed by the SEC and Nasdaq, that bear upon the adviser's independence; however, there is no requirement that any adviser be independent.

In 2020, after taking into consideration the six factors prescribed by the SEC and Nasdaq described above, the Compensation Committee engaged Compensia as compensation consultants. The Compensation Committee identified Compensia based on its general reputation in the industry. The Compensation Committee requested that Compensia:

- evaluate the efficacy of the Company's existing compensation strategy and practices in supporting and reinforcing the Company's long-term strategic goals;
- assist in refining the Company's compensation strategy and in developing and implementing an executive compensation program to execute that strategy; and
- develop a comparative group of companies and perform analyses of competitive performance and compensation levels for that group.

Under its charter, the Compensation Committee may form, and delegate authority to, subcommittees as appropriate, including but not limited to, a subcommittee composed of one or more members of the Board of Directors or officers of the Company to grant stock awards under the Company's equity incentive plans. In 2021, the Compensation Committee delegated authority to the Company's Chief Executive Officer to grant, without further action required by the Board of Directors or the Compensation Committee, stock awards to employees who are not executive officers of the Company or members of the Board of Directors. The purpose of this delegation of authority is to support the Company's recruiting and retention efforts by enhancing the flexibility of option administration within the Company and facilitating the timely grant of options to such employees within specified limits approved by the Compensation Committee. In particular, the maximum number of stock awards that the Chief Executive Officer may grant pursuant to such authority may not exceed stock awards to acquire more than an aggregate of 100,000 shares, as converted from 1,500,000 shares to reflect the 1-for-15 Reverse Stock Split, and each individual grant must fall within certain target grants by job level set by our Compensation Committee. Typically, as part of its oversight function, the Compensation Committee will review on a quarterly basis the list of grants made by the Chief Executive Officer.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee is currently composed of two directors: Ms. Popovits (Chair), and Dr. Scott. All members of the Nominating and Corporate Governance Committee are independent (as independence is currently defined in Rule 5605(a)(2) of the Nasdaq listing standards). The Nominating and Corporate Governance Committee met 3 times during the twelve months ended December 31, 2023. The Board of Directors has

adopted a written Nominating and Corporate Governance Committee charter that is available to stockholders on the Company's website and https://investors.talisbio.com.

The functions of the Nominating and Corporate Governance Committee include, among other things:

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

The Nominating and Corporate Governance Committee believes that candidates for director should have certain minimum qualifications, including the ability to read and understand basic financial statements, being over 21 years of age and having the highest personal integrity and ethics. The Nominating and Corporate Governance Committee also intends to consider such factors as possessing relevant expertise upon which to be able to offer advice and guidance to management, having sufficient time to devote to the affairs of the Company, demonstrated excellence in his or her field, having the ability to exercise sound business judgment and having the commitment to rigorously represent the long-term interests of the Company's stockholders. However, the Nominating and Corporate Governance Committee retains the right to modify these qualifications from time to time. Candidates for director nominees are reviewed in the context of the current composition of the Board of Directors, the operating requirements of the Company and the long-term interests of stockholders. In conducting this assessment, the Nominating and Corporate Governance Committee typically considers diversity (including gender, racial and ethnic diversity), age, skills and such other factors as it deems appropriate, given the current needs of the Board of Directors and the Company, to maintain a balance of knowledge, experience and capability.

The Nominating and Corporate Governance Committee appreciates the value of thoughtful Board of Director refreshment, and regularly identifies and considers qualities, skills and other director attributes that would enhance the composition of the Board of Directors, including, but not limited to, independence, age, diversity (including race, ethnicity, gender, age, education and cultural background), integrity and experience. In the case of incumbent directors whose terms of office are set to expire, the Nominating and Corporate Governance Committee reviews these directors' overall service to the Company during their terms, including the number of meetings attended, level of participation, quality of performance and any other relationships and transactions that might impair the directors' independence. The Nominating and Corporate Governance Committee also takes into account the results of the Board of Directors' self-evaluation, conducted annually on a group and individual basis and for which we utilize outside counsel. In the case of new director candidates, the Nominating and Corporate Governance Committee also determines whether the nominee is independent for Nasdaq purposes, which determination is based upon applicable Nasdaq listing standards, applicable SEC rules and regulations and the advice of counsel, if necessary. The Nominating and Corporate Governance Committee then uses its network of contacts to compile a list of potential candidates, but may also engage, if it deems appropriate, a professional search firm. The Nominating and Corporate Governance Committee conducts any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of the Board of Directors. The Nominating and Corporate Governance Committee meets to discuss and consider the candidates' qualifications and then selects a nominee for recommendation to the Board of Directors by majority vote.

The Nominating and Corporate Governance Committee will consider director candidates recommended by stockholders. In addition, pursuant to the Nominating Agreement with Baker Brothers (as further described in "Transactions with Related Persons and Indemnification—Agreements with Baker Brothers—Nominating Agreement"), we are obligated to support the nomination of certain individuals designated by Baker Brothers, subject to certain exceptions. The Nominating and Corporate Governance Committee does not intend to alter the manner in which it evaluates candidates, including the minimum criteria set forth above, based on whether or not the candidate was recommended by a stockholder, including Baker Brothers.

Stockholders who wish to recommend individuals for consideration by the Nominating and Corporate Governance Committee to become nominees for election to the Board of Directors may do so by delivering a written recommendation to the Nominating and Corporate Governance Committee at the following address: 1375 West Fulton Market, Suite 700, Chicago, Illinois 60607, no later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting of the stockholders. Submissions must include, among other things, (1) the name and address of the stockholder on whose behalf the submission is made; (2) number of our shares that are owned beneficially by such stockholder as of the date of the submission; (3) the full name of the proposed candidate; (4) description of the proposed candidate's business experience for at least the previous five years; (5) complete biographical information for the proposed candidate; (6) a description of the proposed candidate's qualifications as a director and (7) any other information required by our Bylaws. Any such submission must be accompanied by the written consent of the proposed nominee to be named as a nominee and to serve as a director if elected. We may require any proposed nominee to furnish such other information as we may reasonably require to determine the eligibility of such proposed nominee to serve as our independent director or that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such proposed nominee.

Science, Technology and Clinical Affairs Committee

The Science, Technology and Clinical Affairs Committee was established by the Board of Directors to review and advise the Board of Directors on the Company's research and development programs, its technology and relevant scientific advances. The Science, Technology and Clinical Affairs Committee is composed of three directors: Dr. Ismagilov (Chair), Dr. Cheong and Dr. Dreismann. The Science, Technology and Clinical Affairs Committee met 5 times during the twelve months ended December 31, 2023. The Board of Directors has adopted a written Science, Technology and Clinical Affairs Committee charter that is available to stockholders on the Company's website and https://investors.talisbio.com.

The functions of the Science, Technology and Clinical Affairs Committee include, among other things:

- reviewing and assessing current and planned research and development programs and technology initiatives from a scientific perspective, and providing observation and strategic recommendations to the Board of Directors;
- assessing the capabilities of the Company's key scientific personnel, and the depth and breadth of its scientific resources, as well as provide guidance on recruitment and retention of scientific personnel;
- periodically review, make recommendations to the Board of Directors and monitor significant emerging regulatory, research, scientific, and medical developments, processes, procedures, trends and competitive activity relevant to the Company's research and development strategy and preclinical and clinical trial programs, including their potential impact on the Company's programs, plans or policies; and
- reviewing and assessing on an annual basis the performance of the Science, Technology and Clinical Affairs Committee and the Science, Technology and Clinical Affairs Committee charter.

Special Committee

The Special Committee is currently composed of four directors: Dr. Dreismann, Ms. Popovits, Mr. Posard and Dr. Scott. All members of the Special Committee are independent (as independence is currently defined in Rule 5605(a)(2) of the Nasdaq listing standards) and disinterested directors within the meaning of the Delaware General

Corporation Law. The Special Committee met 7 times during the twelve months ended December 31, 2023. The Board of Directors formed the Special Committee in October 2023 and delegated the full power and authority of the Board of Directors to the Special Committee to consider a wide range of strategic alternatives, including, but not limited to, equity or debt financing alternatives, an acquisition, merger, reverse merger, divestiture of assets, licensing or other strategic transactions and a voluntary dissolution or liquidation of the Company.

Stockholder Communications With The Board Of Directors

The Board of Directors has adopted a formal process by which stockholders may communicate with the Board of Directors or any of its directors. Stockholders who wish to communicate with the Board of Directors may do so by sending written communications addressed to our Corporate Secretary at 1375 West Fulton Market, Suite 700, Chicago, Illinois 60607. These communications will be reviewed by our Corporate Secretary, who will determine whether the communication should be presented to the Board of Directors. The purpose of this screening is to allow the Board of Directors to avoid having to consider irrelevant or inappropriate communications (such as advertisements, solicitations and hostile communications). The screening procedures have been approved by a majority of the independent directors. All communications directed to the Audit Committee in accordance with the Company's Open Door Policy for Reporting Complaints Regarding Accounting and Auditing Matters that relate to questionable accounting or auditing matters involving the Company will be promptly and directly forwarded to the Audit Committee.

Code of Business Conduct and Ethics

The Company has adopted the Talis Biomedical Corporation Code of Business Conduct and Ethics that applies to all officers, directors and employees. The Code of Business Conduct and Ethics is available on the Company's website at https://investors.talisbio.com. If the Company makes any substantive amendments to the Code of Business Conduct and Ethics or grants any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director, the Company will promptly disclose the nature of the amendment or waiver on its website.

Insider Trading Policies and Procedures

The Company has adopted an insider trading policy governing the purchase, sale, and/or other dispositions of the Company's securities by directors, officers and employees. The insider trading policy requires compliance with all applicable laws, rules and regulations governing the offer and sale of securities and prohibits directors, officers and employees from engaging in transactions in the Company's securities while in possession of material nonpublic information. The insider trading policy establishes quarterly blackout periods during which trading in the Company's securities is prohibited. These blackout periods begin at the end of the day that is the 15th day of the third month of each fiscal quarter and end after two (2) trading days have elapsed since the public dissemination of Company's financial results for that quarter. In addition, the insider trading policy requires senior officers and key employees to obtain pre-approval of any transactions in Company securities from the Company's Chief Financial Officer or head of Legal. A copy of the Company's insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Hedging Policy

Our Insider Trading Policy prohibits our employees, including our executive officers, directors and consultants of the Company and members of their immediate family, persons which whom they share a household, persons who are their economic dependents and other individuals or entities whose transactions in securities such persons influence, direct or control from engaging in short sales, transactions in put or call options, hedging transactions, using margin accounts, pledges, standing and limit orders or other inherently speculative transactions involving our equity securities.

**The disclosure under the caption "Hedging Policy" is not to be incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.*

Item 11. Executive Compensation.

Summary compensation table

The following table summarizes information regarding the compensation awarded to, earned by, or paid to our principal executive officer and our other most highly compensated executive officers (the "named executive officers") during the twelve months ended December 31, 2023 and 2022.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Stock Awards ($)(2)	Option Awards ($)(2)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)(7)(8)(9)(10)	Total ($)
Robert Kelley *Chief Executive Officer and Director(3)*	2023	551,250	—	—	166,969	146,250	154,862	1,019,331
	2022	525,000	—	—	546,191	393,750	130,678(5)	65,546
J. Roger Moody, Jr. *Chief Financial Officer (4)*	2023	127,820	—	—	100,179	—	46,052	274,051
	2022	393,600	—	—	377,433	196,800	14,332	982,165
Rebecca Markovich *Interim Chief Financial Officer (5)*	2023	328,833	—	—	88,999	38,000	12,401	468,233
	2022	218,818	50,000	—	160,629	84,545	11,059	525,051
Andrew Lukowiak *President and Chief Scientific Officer (6)*	2023	187,500	—	—	149,438		454,900	791,838
	2022	—	—	—	—	—	—	—

(1) Amounts shown represent annual cash bonuses earned for the respective fiscal year. For more information, see below under "—Bonus Opportunity."
(2) This column reflects the aggregate grant date fair value of the stock option awards granted in the applicable year. These amounts have been computed in accordance with Financial Accounting Standards Board, Accounting Standards Codification Topic 718, Compensation—Stock Compensation (FASB ASC Topic 718). Assumptions used in the calculation of these amounts are described in Note 8 to our audited financial statements beginning on page 97 of our Annual Report on Form 10-K for the twelve months ended December 31, 2023. These amounts do not reflect the actual economic value that will be realized by our named executive officers upon the exercise of the stock options or the sale of the common stock underlying such stock options.
(3) Mr. Kelley commenced employment as our Chief Commercial Officer in August 2020. On December 8, 2021, he was appointed as our Chief Executive Officer.
(4) Mr. Moody served as our Chief Financial Officer from May 2020 through close of business on April 21, 2023.
(5) Ms. Markovich was appointed interim Chief Financial Officer effective upon the close of business on April 21, 2023.
(6) Mr. Lukowiak served as our President and Chief Scientific Officer from August 1, 2023 through close of business on January 14, 2024.
(7) Amounts shown for the twelve months ended December 31, 2023 for Mr. Kelley represent (i) $139,557 in housing and car allowances; (ii) $13,251 for 401(k) matching contributions, (ii) $794 in life insurance premiums paid on behalf of Mr. Kelley, (iii) $960 for cell and internet reimbursements, and (iv) $300 for gift cards.
(8) Amounts shown for the twelve months ended December 31, 2023 for Mr. Moody represent (i) $33,059 in paid time off cashout (i) $12,094 for 401(k) matching contributions, (ii) $600 in life insurance premiums, and (iii) $300 for cell and internet reimbursements.
(9) Amounts shown for for Ms. Markovich represent (i) $10,941 for 401(k) matching contributions, (ii) $960 for cell and internet reimbursements, and (iii) $500 for gift cards.
(10) Amounts shown for the twelve months ended December 31, 2023 for Mr. Lukowiak represent (i) $450,000 in cash severance, (ii) $4,500 for 401(k) matching contributions, and (ii) $400 for cell and internet reimbursements.

Narrative to the Summary Compensation Table

Annual Base Salary

The base salary of our named executive officers is generally determined and approved by our Board of Directors in connection with the commencement of employment of the named executive officer and may be adjusted from time to time thereafter as the Board of Directors determines appropriate, within the ranges recommended by Compensia, our independent compensation consultant.

The 2023 annual base salaries for our named executive officers are set forth in the table below.

Name	2023 Base Salary ($)
Robert Kelley	551,250
J. Roger Moody, Jr. (1)	127,820
Rebecca Markovich	328,833
Andrew A. Lukowiak (2)	187,500

(1) Mr. Moody served as our Chief Financial Officer from May 2020 through close of business on April 21, 2023.
(2) Mr. Lukowiak served as our President and Chief Scientific Officer from August 1, 2023 through January 14, 2024.

Bonus Opportunity

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

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

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our named executive officers' interests with those of our stockholders and to retain and incentivize our named executive officers over the long-term. Generally, our Board of Directors, or Compensation Committee of our Board of Directors, approves equity grants. In 2021, the Compensation Committee delegated authority to the Company's Chief Executive Officer to grant, without further action required by the Board of Directors or the Compensation Committee, stock awards to employees who are not executive officers of the Company or members of the Board of Directors. The purpose of this delegation of authority is to support the Company's recruiting and retention efforts by enhancing the flexibility of option administration within the Company and facilitating the timely grant of options to such employees within specified limits approved by the Compensation Committee. In particular, the maximum number of stock awards that the Chief Executive Officer may grant pursuant to such authority may not exceed stock awards to acquire more than an aggregate of 100,000 shares, as converted from 1,500,000 shares to reflect the 1-for-15 Reverse Stock Split, and each individual grant must fall within certain target grants by job level set by our Compensation Committee.

Vesting of equity awards is generally tied to continuous service with us and serves as an additional retention measure. Our named executive officers generally are awarded an initial new hire grant upon commencement of employment. Additional grants may occur periodically in order to specifically incentivize our named executive officers with respect to achieving certain corporate goals or to reward our named executive officers for exceptional performance.

Employment agreements with our named executive officers

Robert Kelley. In August 2020, we entered into an offer letter with Mr. Kelley in connection with his service as our Chief Commercial Officer that provided for, among other things, an initial annual base salary of $300,000, an annual target bonus equal to 30% of his annual base salary and a stock option to purchase 297,202 shares of our common stock (as reflected below under "—Outstanding Equity Awards at Fiscal Year End"). In connection with his appointment as our Chief Executive Officer, in December 2021, we entered into an offer letter with Mr. Kelley that provides for, among other things, an initial annual base salary of $525,000, an annual target bonus equal to 75% of his annual base salary beginning in 2022, continued eligibility for his 2021 annual target bonus pursuant to the terms of his Chief Commercial Officer offer letter and a stock option to purchase 450,000 shares of our common stock (as further described above under "—Equity Based Incentive Awards"). Mr. Kelley is also entitled to certain travel and housing reimbursements (plus tax gross ups) in connection with his weekly travel from his remote working location to one of our facilities, which began in fiscal 2022.

J. Roger Moody, Jr. In April 2020, we entered into an offer letter with Mr. Moody that provides for, among other things, an initial annual base salary of $360,000, an annual target bonus of 40% of his annual base salary, a stock option to purchase 302,797 shares of our common stock and an additional option to purchase 145,454 shares of our common stock (equal to 1.25% of the outstanding shares of common stock on an as converted basis of the Company) when we elected to take our Tranche 3 investments from our prior investment round, which condition was met and an option to purchase 147,100 shares of our common stock was granted in August 2020 (equal to 1.25% of the outstanding shares of common stock on an as converted basis of the Company on the grant date) (as reflected below under "—Outstanding Equity Awards at Fiscal Year End").

On April 7, 2023, Mr. Moody notified the Company that he would step down as the Company's Chief Financial Officer, effective as of the close of business on April 21, 2023, to accept a new role as chief executive officer of another public company. Mr. Moody's resignation was not as a result of any disagreement with the Company on any matter relating to its operations, policies, or practices, or to any issues regarding its accounting policies or practices.

Rebecca Markovich. In July 2023 in connection with her appointment as Interim Chief Financial Officer, Ms. Markovich was awarded the option to purchase 100,000 shares of common stock (as further described above under "—Equity Based Incentive Awards). In October of 2023 in connection with her role of Interim Chief Financial Officer, Ms. Markovich received a base salary increase to $357,000 annually. On November 13, 2023, the Company entered into a retention agreement (the "Retention Agreement") with Ms. Markovich. Under the terms of the Retention Agreement, Ms. Markovich is eligible to receive $59,500 if she maintains satisfactory job performance and remains employed with the Company through the completion of a sale, reverse merger or merger or a voluntary dissolution or liquidation of the Company.

Andrew Lukowiak. Effective August 1, 2023, Dr. Andrew Lukowiak was appointed as President and Chief Scientific Officer of the Company. In connection with Dr. Lukowiak's appointment as President and Chief Scientific Officer, the Company entered into an offer letter with Dr. Lukowiak, on July 28, 2023, that governs the terms of his employment with the Company. Among other things, the offer letter provides for an annual base salary of $450,000 and, beginning in calendar year 2023, an annual target bonus equal to 50% of his earned eligible compensation. On August 1, 2023, Dr. Lukowiak was granted (i) pursuant to the Company's 2021 Equity Incentive Plan, an incentive stock option to purchase up to 13,477 shares of the Company's Common Stock ("Common Stock") at an exercise price of $7.42 per share, the closing sales price of the Common Stock on the CSO Start Date (the "Incentive Option"), and (ii) pursuant to the Company's 2021 Inducement Plan, a nonqualified stock option to purchase 17,098 shares of Common Stock at an exercise price of $7.42 per share in accordance with Nasdaq Listing Rule 5635(c)(4) (together with the Incentive Option, the "Options"). Each Option will vest over a four-year period, with 25% of the shares subject to such Option vesting on the one-year anniversary of the CSO Start Date and the balance of the shares subject to such Option vesting in equal installments over the following 36 months.

In connection with the Company's decision to evaluate strategic alternatives, Dr. Lukowiak was terminated as President and Chief Scientific Officer effective January 14, 2024. In connection with his separation from the Company, Dr. Lukowiak is eligible to participate in the Company's Severance and Change in Control Plan and received benefits for a covered termination that is not a Change in Control. Upon his termination, Dr. Lukowiak received a lump sum payment of $450,000 the equivalent to twelve month's salary. Dr. Lukowiak will also have his COBRA premiums paid by the Company for up to twelve months.

Outstanding equity awards at fiscal year end

The following table shows for the twelve months ended December 31, 2023 certain information regarding outstanding equity awards at December 31, 2023 for the named executive officers.

		Option Awards[1]				
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable (2)(3)	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Robert Kelley	8/31/2020	16,512	3,303	—	63.65	9/3/2030
	9/28/2021	4,875	3,793	—	60.14	10/2/2031
	12/8/2021	15,000	15,000	—	41.91	12/8/2031
	6/1/2022	6,030	42,210	—	11.19	5/31/2032
	3/1/2023	—	33,334	—	7.43	2/28/2033
Rebecca Markovich	1/24/2022	2,524	2,743	—	32.10	1/23/2032
	6/1/2022	500	3,505	—	15.45	5/31/2032
	3/1/2023	—	4,667	—	7.43	2/28/2033
	4/21/2023	—	13,071	—	7.65	4/20/2033
Andrew A. Lukowiak	8/1/2023	—	30,575	—	7.42	7/31/2033

(1) All of the options granted before February 2021 were granted pursuant to our 2013 Plan. Options granted thereafter were granted pursuant to our 2021 Plan. The terms of the 2013 Plan and the 2021 Plan are described below under "—Equity Benefit Plans."
(2) Each option, other than as noted in footnote (3) below, vests as follows: 25% of the shares subject to the option vest on the 12-month anniversary of the vesting commencement date, and the balance of the shares vest in 36 equal monthly installments over the next three years, subject to the named executive officer's continued services to us, subject to full vesting acceleration, if a change in control occurs and the named executive officer's continuous service terminates due to an involuntary termination (not including death or disability) without cause or due to a voluntary termination with good reason as of or within 12 months after such change in control, then the vesting and exercisability of the option will be accelerated in full.
(3) The options vest as follows (i) 1/3 of awards vest as follows: 25% of the shares underlying this option shall vest on the first annual anniversary of the vesting commencement date of June 1, 2022 (VCD) and 1/48th of the shares underlying this option shall vest monthly thereafter over 36 months. (ii) 1/3 of the shares shall vest on the seventh anniversary of the VCD, subject to optionholder's continuous service as of such date, provided that such vesting shall be subject to acceleration based upon certain pre-determined commercial and regulatory milestones, (iii) 1/3 of the shares shall vest on the seventh anniversary of the VCD, subject to optionholder's continuous service as of such date, provided that such vesting shall be subject to partial or full acceleration based on pre-determined closing prices of the Company's common stock sustained for a certain number of consecutive trading days.

Potential Payments Upon Termination or Change in Control

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

Each of our named executive officers is eligible to receive benefits under the terms of our Severance and Change in Control Plan adopted by the Board of Directors in February 2021 ("Severance Plan"). The Severance Plan provides for severance and/or change in control benefits to the named executive officers upon (i) a "change in control termination" or (ii) a "regular termination" (each as described below). All severance benefits under the Severance Plan are subject to the executive's execution of an effective release of claims against the Company.

Upon a change in control termination, each of our named executive officers is entitled to a lump sum payment equal to a portion of his base salary (18 months for Mr. Kelley, 12 months for Mr. Lukowiak, and 9 months for Ms. Markovich), a lump sum payment equal to 150% (for Mr. Kelley) or 100% (for Mr. Lukowiak) or 75% (for Ms. Markovich) of his or her annual target cash bonus, payment of COBRA premiums for a period of time (up to 18 months for Mr. Kelley, 12 months for Mr. Lukowiak and 9 months for Ms. Markovich) and accelerated vesting of outstanding time-vesting equity awards.

To the extent an equity award is not assumed, continued or substituted for in the event of certain change in control transactions and the executive's employment is not terminated as of immediately prior to such change in control, the vesting of such equity award will also accelerate in full (and for equity awards subject to performance vesting, performance will be deemed to be achieved at target, unless otherwise provided in individual award documents).

Upon a regular termination, each of our named executive officers is entitled to a lump sum payment equal to a portion of his base salary (12 months for Mr. Kelley and Mr. Lukowiak and 4 months for Ms. Markovich) and payment of

COBRA premiums for a period of time (up to 12 months for Mr. Kelley and Mr. Lukowiak and 4 months for Ms. Markovich).

For purposes of the Severance Plan, a "regular termination" is an involuntary termination (i.e., a termination other than for cause (and not as a result of death or disability) or a resignation for good reason (as such terms are defined in the Severance Plan) that does not occur during the period of time beginning three months prior to, and ending 12 months following, a "change in control" (as defined in the 2021 Plan), or the "change in control period." A "change in control termination" is a regular termination that occurs during the change in control period. Mr. Moody's resignation effective April 21, 2023 was neither a regular termination or a change in control termination. Accordingly, Mr. Moody did not receive any severance benefits upon his resignation as chief financial officer.

Mr. Kelley holds options that were granted subject to the terms of our 2013 Plan. A description of the termination and change in control provisions in our 2013 Plan and applicable to the options granted to our named executive officers is provided under "—Equity Benefit Plans" and, with respect to our named executive officers, "—Outstanding Equity Awards at Fiscal Year-End."

Perquisites, health, welfare and retirement benefits

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

401(k) plan

We maintain a defined contribution employee retirement plan ("401(k) plan"), for our employees. Our named executive officers are each eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Code. The 401(k) plan provides that each participant may contribute up to the lesser of 100% of his or her compensation or the statutory limit, which is $22,500 for calendar year 2023. Participants that are 50 years or older can also make "catch-up" contributions, which in calendar year 2023 may be up to an additional $7,500 above the statutory limit. Participant contributions are held and invested, pursuant to the participant's instructions, by the plan's trustee.

We provide an automatic matching contribution as follows: 100% with respect to the first 3% of an employee's contributions, and 50% for the next 2% of the employee's contributions, up to a maximum company match of 4% of the employee's contributions. We may also elect to provide for discretionary profit sharing contributions, but we did not provide any such contributions in 2022 or 2023. The 401(k) plan currently does not offer the ability to invest in our securities.

Perquisites

We do not provide perquisites or personal benefits to our executive officers that we do not generally provide to our other employees (such as limited reimbursement of cell and internet expenses), except in limited circumstances. For example, in December 2021, we approved the reimbursement of certain travel and housing expenses, including tax gross ups, that may be incurred for business-related travel by Mr. Kelley. In 2022, the Compensation Committee approved for Mr. Kelley a monthly car allowance for reimbursement and waived the requirement that Mr. Kelley provide monthly receipts for his car and previously approved housing allowance.

Equity Benefit Plans

2021 Plan

Our Board of Directors adopted our 2021 Plan, and our stockholders approved our 2021 Plan, in February 2021. Our 2021 Plan is a successor to and continuation of our 2013 Equity Incentive Plan (the "2013 Plan"). Our 2021 Plan

became effective on the date of the underwriting agreement related to our initial public offering, which occurred on February 11, 2021. No further grants have been, or will be, made under the 2013 Plan following the effectiveness of the 2021 Plan.

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

Authorized shares. Initially, the maximum number of shares of our common stock issuable under our 2021 Plan was 12,840,904 shares of our common stock, which is the sum of (1) 213,334 new shares, as converted from 3,200,000 shares to reflect the 1-for-15 Reverse Stock Split, plus (2) 511,959 shares, as converted from 7,673,915 shares to reflect the 1-for-15 Reverse Stock Split, that remained available for the issuance of awards under our 2013 Plan as of immediately prior to the time our 2021 Plan became effective, plus (3) up to 344,466 shares, as converted from 5,166,989 shares to reflect the 1-for-15 Reverse Stock Split, subject to outstanding stock options or other stock awards granted under our 2013 Plan that, on or after the 2021 Plan became effective, terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, if any, as such shares become available from time to time.

In addition, the number of shares of our common stock reserved for issuance under our 2021 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2023 through (and including) January 1, 2031, in an amount equal to (i) 4% of the total number of shares of our common and preferred stock outstanding on December 31 of the preceding year, or (ii) a lesser number of shares determined by our Board of Directors prior to the applicable January 1. On January 1, 2023, the common stock reserved for issuance under our 2021 Plan automatically increased in an amount equal to the 4% of our total number of common shares outstanding on December 31, 2022.

The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2021 Plan is 2,600,000 shares as converted from 39,000,000 shares to reflect the 1-for-15 Reverse Stock Split.

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

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

Plan administration. Our Board of Directors, or a duly authorized committee of our Board of Directors, will administer our 2021 Plan and is referred to as the "plan administrator" herein. Our Board of Directors may also delegate to one or more of our officers the authority to (1) designate employees (other than officers) to receive specified stock awards and (2) determine the number of shares subject to such stock awards. Under our 2021 Plan, the plan administrator has

the authority to determine award recipients, grant dates, the numbers and types of stock awards to be granted, the applicable fair market value, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award.

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

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

The plan administrator determines the term of stock options granted under the 2021 Plan, up to a maximum of 10 years. Unless the terms of an optionholder's stock option agreement, or other written agreement between us and the recipient approved by the plan administrator, provide otherwise, if an optionholder's service relationship with us or any of our affiliates ceases for any reason other than disability, death, or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that either an exercise of the option or an immediate sale of shares acquired upon exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 18 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

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

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

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

Restricted stock unit awards. Restricted stock unit awards are granted under restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to our Board of Directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, or other written agreement between us and the

recipient approved by the plan administrator, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

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

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

The plan administrator determines the term of stock appreciation rights granted under the 2021 Plan, up to a maximum of 10 years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability, or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

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

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

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

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

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

In the event of a corporate transaction, any stock awards outstanding under the 2021 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction), and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

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

Under the 2021 Plan, a corporate transaction is generally defined as the consummation of: (i) a sale of all or substantially all of our assets, (ii) the sale or disposition of at least 50% of our outstanding securities, (iii) a merger or consolidation where we do not survive the transaction, or (iv) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

Change in control. Awards granted under the 2021 Plan may be subject to acceleration of vesting and exercisability upon or after a change in control (as defined in the 2021 Plan) as may be provided in the applicable stock award agreement or in any other written agreement between us or any affiliate and the participant, but in the absence of such provision, no such acceleration will automatically occur.

Under the 2021 Plan, a change in control is generally defined as: (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (ii) a consummated merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity) in substantially the same proportions as their ownership immediately prior to such transaction; (iii) a consummated sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than

50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction; or (iv) when a majority of our Board of Directors becomes comprised of individuals who were not serving on our Board of Directors on the date the 2021 Plan was adopted by the Board of Directors, or the incumbent Board of Directors, or whose nomination, appointment, or election was not approved by a majority of the incumbent Board of Directors still in office.

Plan amendment or termination. Our Board of Directors has the authority to amend, suspend, or terminate our 2021 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our Board of Directors adopts our 2021 Plan. No stock awards may be granted under our 2021 Plan while it is suspended or after it is terminated.

2021 Inducement Plan

On November 11, 2021, our Board of Directors adopted the 2021 Inducement Plan. The 2021 Inducement Plan was adopted without stockholder approval pursuant to Nasdaq Listing Rule 5635(c)(4) and will be administered by our Board of Directors. Our Board of Directors reserved 200,000 shares of common stock, as converted from 3,000,000 shares of common stock to reflect the 1-for-15 Reverse Stock Split, for issuance under the 2021 Inducement Plan. The only persons eligible to receive grants of Inducement Awards (as defined below) under the 2021 Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq Listing Rule 5635(c)(4) or 5635(c)(3), as applicable. Individuals who previously served as an employee or director of the Company will not be eligible to receive Inducement Awards under the 2021 Inducement Plan, other than following a bona fide period of non-employment. Inducement Awards may only be granted by: (i) the Compensation Committee, provided such committee is comprised solely of "independent directors" (as defined by Nasdaq Market Place Rule 5605(a)(2)) or (ii) a majority of the Company's "independent directors". An "Inducement Award" means any right to receive common stock, cash or other property granted under the 2021 Inducement Plan (including nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, or other stock-based awards). Our Board of Directors also adopted a (i) form of stock option grant notice, option agreement, and notice of exercise (the "Inducement Option Grant Package") and (ii) form of restricted stock unit award grant notice and award agreement (the "Inducement RSU Grant Package") for use under the 2021 Inducement Plan.

2013 Plan

Our Board of Directors and stockholders adopted our 2013 Plan in June 2013. The 2013 Plan was most recently amended by our Board of Directors and stockholders in October 2020. No further grants have been, or will be, made under the 2013 Plan following the effectiveness of the 2021 Plan.

Authorized shares. As of December 31, 2022, there were outstanding stock options covering a total of 181,651 shares of our common stock, as converted from 2,724,751 shares of our common stock to reflect the 1-for-15 Reverse Stock Split, that were granted under our 2013 Plan and there were 58,052 shares of common stock, as converted from 870,784 shares of common stock to reflect the 1-for-15 Reverse Stock Split, that were issued and outstanding pursuant to stock options that had been exercised. Any shares of common stock remaining available for issuance under the 2013 Plan upon the 2021 Plan's effectiveness became available for issuance under the 2021 Plan. In addition, shares subject to outstanding stock options or other stock awards granted under our 2013 Plan that, on or after the date that the 2021 Plan became effective, terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, if any, will become issuable under our 2021 Plan.

Stock awards. Our 2013 Plan provides for the grant of ISOs within the meaning of Section 422 of the Code, to employees, including employees of any parent or subsidiary, and for the grant of NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards and other forms of stock awards to employees, directors and consultants, including employees and consultants of our affiliates. The maximum number of shares of our common stock issuable pursuant to the exercise of ISOs under our 2013 Plan is 181,651 shares, as converted from 2,724,751 shares, to reflect the 1-for-15 Reverse Stock Split.

Plan administration. Our Board of Directors, or a duly authorized committee of our Board of Directors to which the Board of Directors delegates its administrative authority, administers our 2013 Plan and is referred to as the "plan administrator" herein. Under our 2013 Plan, the plan administrator has the authority to, among other things, determine award recipients, dates of grant, the numbers and types of stock awards to be granted, the applicable fair market value and the provisions of each stock award, including the period of their exercisability and the vesting schedule applicable to a stock award, to construe and interpret the 2013 Plan and awards granted thereunder (and to establish, amend and revoke any rules and regulations for the administration of the 2013 Plan and any such awards), or to accelerate the vesting of awards.

Under the 2013 Plan, the plan administrator also generally has the authority to effect, with the consent of any adversely affected participant, (A) the reduction of the exercise, purchase, or strike price of any outstanding award; (B) the cancellation of any outstanding award and the grant in substitution therefor of other awards, cash, or other consideration; or (C) any other action that is treated as a repricing under generally accepted accounting principles.

Stock options. ISOs and NSOs are granted under stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2013 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant (or 110% of the fair market value for certain major stockholders). Options granted under the 2013 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

The plan administrator determines the term of stock options granted under the 2013 Plan, up to a maximum of 10 years (or five years, for certain major stockholders). If an optionholder's service relationship with us or any of our affiliates ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of up to three months following the cessation of service. This period may be extended in the event that either an exercise of the option or an immediate sale of shares acquired upon exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of up to 18 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of up to 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order payable to us, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, (5) a deferred payment arrangement (to the extent permitted by applicable law), or (6) other legal consideration approved by the plan administrator and specified in the stock award agreement.

Unless the plan administrator provides otherwise, options generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the plan administrator or a duly authorized officer in each case, (i) an option may be transferred pursuant to a domestic relations order, official marital settlement agreement, or other divorce or separation instrument and (ii) an optionholder may designate a beneficiary who may exercise the option following the optionholder's death.

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

Changes to capital structure. In the event of a capitalization adjustment, the plan administrator will make appropriate and proportionate adjustments to (1) the class and maximum number of shares reserved for issuance under the 2013

Plan, (2) the class and maximum number of shares that may be issued on the exercise of ISOs, and (3) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate transactions. Our 2013 Plan provides that in the event of a corporate transaction, unless otherwise provided in an award agreement or other written agreement between us and the award holder, the plan administrator may take one or more of the following actions with respect to such stock awards:

- arrange for the assumption, continuation, or substitution of a stock award by a surviving or acquiring corporation;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring corporation;
- accelerate the vesting, in whole or in part, of the stock award and provide for its termination if not exercised (if applicable) at or before the effective time of the transaction;
- arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us;
- cancel or arrange for the cancellation of the stock award, to the extent not vested or not exercised before the effective time of the transaction, in exchange for such cash consideration, if any, as our Board of Directors, in its sole discretion, may consider appropriate; and
- make a payment equal to the excess, if any, of (A) the value of the property the participant would have received on exercise of the award immediately before the effective time of the transaction, over (B) any exercise price payable by the participant in connection with the exercise.

The plan administrator is not obligated to treat all stock awards or portions of stock awards in the same manner and is not obligated to treat all participants in the same manner.

Under the 2013 Plan, a corporate transaction is generally defined as the consummation of: (i) a sale or other disposition of all or substantially all of our assets, (ii) the sale or disposition of at least 50% of our outstanding securities, (iii) a merger or consolidation where we do not survive the transaction, or (iv) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

Change in control. A stock award may be subject to additional acceleration of vesting and exercisability upon or after a change in control as may be provided in an applicable award agreement or other written agreement, but in the absence of such provision, no such acceleration will occur.

Under the 2013 Plan, a change in control is generally defined as: (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (ii) a consummated merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity) in substantially the same proportions as their ownership immediately prior to such transaction; or (iii) a consummated sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction.

Plan amendment or termination. Our Board of Directors has the authority to amend, suspend, or terminate our 2013 Plan, provided that such action does not impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No stock awards may be granted under our 2013 Plan while it is suspended or after it is terminated. No further grants will be made under the 2013 Plan.

2021 ESPP

Our Board of Directors adopted our 2021 ESPP, and our stockholders approved our 2021 ESPP, in February 2021. The 2021 ESPP became effective immediately prior to, and contingent upon, the execution of the underwriting agreement related to our initial public offering, which occurred on February 11, 2021. The purpose of the 2021 ESPP

is to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. The 2021 ESPP includes two components. One component is designed to allow eligible U.S. employees to purchase our common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. In addition, purchase rights may be granted under a component that does not qualify for such favorable tax treatment because of deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the United States while complying with applicable foreign laws. Due to several factors, including low participation and the high administrative costs, the Compensation Committee voted in November 2022 to suspend the 2021 ESPP, with such suspension going into effect for the next cycle commencing in March 2023.

Share reserve. The 2021 ESPP authorizes the issuance of 36,667 shares of our common stock, as converted from 550,000 shares of our common stock to reflect the 1-for-15 Reverse Stock Split, under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance automatically increases on January 1 of each calendar year, beginning on January 1, 2022, through (and including) January 1, 2031, by the lesser of (i) 1% of the total number of shares of our common and preferred stock outstanding on December 31st of the preceding year and (ii) 103,334 shares of common stock, as converted from 1,550,000 shares of common stock to reflect the 1-for-15 Reverse Stock Split; provided that before the date of any such increase, our Board of Directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii).

Administration. Our Board of Directors administers the 2021 ESPP and may delegate its authority to administer the 2021 ESPP to our Compensation Committee. The 2021 ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the 2021 ESPP, we may specify offerings with durations of not more than 27 months and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering under the 2021 ESPP may be terminated under certain circumstances. In February 2022, our Board of Directors adopted an offering document that governs offerings under the 2021 ESPP (the "Offering Document") pursuant to which offerings will generally be for consecutive, non-overlapping periods of six months, commencing on March 10 and September 10 each year.

Payroll deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the 2021 ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings (as defined in the 2021 ESPP) for the purchase of our common stock under the 2021 ESPP. Unless otherwise determined by our Board of Directors, common stock will be purchased for the accounts of employees participating in the 2021 ESPP at a price per share that is at least the lesser of (1) 85% of the fair market value of a share of our common stock on the first date of an offering, or (2) 85% of the fair market value of a share of our common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the 2021 ESPP, as determined by our Board of Directors, including: (1) being customarily employed for more than 20 hours per week, (2) being customarily employed for more than five months per calendar year, or (3) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the 2021 ESPP at a rate in excess of $25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each calendar year such a purchase right is outstanding. In addition, no employee will be eligible for the grant of any purchase rights under the 2021 ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code. Finally, pursuant to the Offering Document, in no event may an employee purchase more than 317 shares of our common stock, as converted from 4,750 shares of our common stock to reflect the 1-for-15 Reverse Stock Split, during any six month offering.

Changes to capital structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, the Board of Directors will make appropriate adjustments to: (1) the class(es) and maximum number of shares reserved under the 2021 ESPP, (2) the class(es) and maximum

number of shares by which the share reserve may increase automatically each year, (3) the class(es) and number of shares subject to and purchase price applicable to outstanding offerings and purchase rights, and (4) the class(es) and number of shares that are subject to purchase limits under ongoing offerings.

Corporate transactions. In the event of certain significant corporate transactions, any then-outstanding rights to purchase our stock under the 2021 ESPP may be assumed, continued, or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within 10 business days before such corporate transaction, and such purchase rights will terminate immediately after such purchase.

Under the 2021 ESPP, a corporate transaction is generally the consummation of: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 50% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction, and (4) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

2021 ESPP amendment or termination. Our Board of Directors has the authority to amend or terminate our 2021 ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our 2021 ESPP as required by applicable law or listing requirements.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2023, with respect to shares of our common stock that may be issued under our existing equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by stockholders	732,714 (1)	$ 38.28	394,577 (2)
Equity compensation plans not approved by stockholders	—	$ —	200,000(3)

(1) All awards were granted under our 2013 Plan, our 2021 Plan and our 2021 ESPP.
(2) The weighted average exercise price does not take into account the shares subject to outstanding RSUs, if any, which have no exercise price. Includes our 2021 Plan and our 2021 ESPP. The number of shares of common stock reserved for issuance under our 2021 Plan automatically increases on January 1 of each year, continuing through and including January 31, 2031, by 4% of the total number of shares of our common stock and preferred stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our Board of Directors. Pursuant to this provision, we added 151,092 shares of common stock, as converted from 2,266,379 shares of common stock to reflect the 1-for-15 Reverse Stock Split, that are eligible for issuance under the 2021 Plan on January 1, 2023, which is not reflected in the table above. The number of shares of common stock reserved for issuance under our 2021 ESPP automatically increases on January 1 of each year, continuing through and including January 31, 2031, by the lesser of (i) 1% of the total number of shares of common stock and preferred stock outstanding on December 31 of the preceding calendar year and (ii) 1,550,000 shares of common stock. Pursuant to this provision, we added 37,107 shares of common stock, as converted from 556,595 shares of common stock to reflect the 1-for-15 Reverse Stock Split, that are eligible for issuance under the 2021 ESPP on January 1, 2023, which is not reflected in the table above. The total number of shares of common stock available for issuance under the 2021 ESPP is 40,157, converted from 602,350 to reflect the 1-for-15 Reverse Stock Split, which does not reflect the reserve increase. Effective as of February 11, 2021, no additional awards will be granted under the 2013 Plan, and all awards granted under the 2013 Plan that are repurchased, forfeited, expire, are cancelled or otherwise not issued will become available for grant under the 2021 Plan in accordance with its terms.
(3) Consists of securities available for issuance under the Talis Biomedical Corporation 2021 Inducement Plan (the "2021 Inducement Plan"). See "—2021 Inducement Plan" above for a narrative description of the plan.

Director compensation

The following table sets forth in summary form information concerning the compensation that we paid or awarded during the twelve months ended December 31, 2023 to each of our non-employee directors.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)(2)	All Other Compensation ($)	Total ($)
Felix Baker, Ph.D.	15,111	—	—	15,111
Raymond Cheong, M.D., Ph.D.	36,500	8,792	—	45,292
Melissa Gilliam, M.D., M.P.H.	39,290	35,268	—	74,558
Rustem F. Ismagilov, Ph.D.	50,000	35,268	3,952	89,220
Matthew L. Posard	64,000	35,268	—	99,268
Randal Scott, Ph.D.	65,000	35,268	—	100,268
Heinrich Dreismann	32,143	2,032	—	34,175
Kimberly J. Popovits	81,835	35,268	—	117,103

(1) As of December 31, 2023, the number of shares underlying unexercised options that are exercisable held by our non-employee directors were: Dr. Cheong, 790; Dr. Ismagilov, 42,022; Dr. Gilliam, —; Mr. Posard, 18,566; Dr. Scott, 18,566; Dr Dreismann 183; and Ms. Popovits, 35,408.
(2) In accordance with SEC rules, this amount reflects the aggregate grant date fair value of stock option awards. These amounts have been computed in accordance with Financial Accounting Standards Board, Accounting Standards Codification Topic 718, Compensation—Stock Compensation. Assumptions used in the calculation of these amounts are described in Note 8 to our audited financial statements in our Annual Report on Form 10-K for the twelve months ended December 31, 2023. This amount does not reflect the actual economic value that will be realized upon the exercise of the stock options or the sale of the common stock underlying such stock options.

Narrative To Director Compensation Table

In May 2023 in connection with his appointment to the Board of Directors, Dr. Dreismann was awarded the option to purchase 190,000 shares of our common stock. Dr. Dreismann will also receive an annual cash retainer of $40,000 as a member of the Board of Directors, annual cash retainer of $7,500 as a member of the Compensation Committee, and annual cash retainer of $5,000 as co-chair of the Science, Technology and Clinical Affairs Committee.

In May of 2023, Ms. Popovits was appointed as the Lead Independent Director. Ms. Popovits will receive an annual cash retainer of $22,500 for her services as Lead Independent Director.

Outstanding equity awards held by our non-employee directors are subject to the terms of our 2013 Plan and 2021 Plan, as described above under "— Equity Benefit Plans."

Non-employee director compensation policy

Our Board of Directors adopted a non-employee director compensation policy in February 2021, effective upon the date of our initial public offering, which we amended in December 2021 to add the annual cash retainers for the chair and non-chair members of our Science, Technology and Clinical Affairs Committee, that is applicable to all of our non-employee directors. We further amended the compensation policy in May 2022 to update the option grant amounts. This compensation policy provides that each such non-employee director will receive the following compensation for service on our Board of Directors. Cash retainers are paid in equal quarterly installments, in arrears on the last day of each fiscal quarter in which service occurs, and are prorated based on days served in the applicable fiscal year:

- an annual cash retainer of $40,000;
- an additional annual cash retainer of $40,000 for service as non-employee Chair of the Board of Directors;
- an additional annual cash retainer of $22,500 for service as Lead Independent Director;
- an additional annual cash retainer of $10,000, $7,000, $5,000 and $5,000 for service as a (non-Chair) member of the Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee and Science, Technology and Clinical Affairs Committee, respectively;

- an additional annual cash retainer of $20,000, $14,000, $10,000 and $10,000 for service as the Chair of the Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee and Science, Technology and Clinical Affairs Committee, respectively (in lieu of the above);
- an initial option grant to purchase the number of shares of our common stock that is equal to the lesser of (x) 190,000 or (y) the number of shares of common stock with an aggregate Black-Scholes option value of $340,000, vesting in 36 equal monthly installments following the date of grant; and
- an annual option grant to purchase the number of shares of our common stock that is equal to the lesser of (x) 95,000 or (y) the number of shares of common stock with an aggregate Black-Scholes option value of $190,000, vesting in 12 equal monthly installments following the date of grant (provided that in any event such option will be fully vested on the date of the next-following annual stockholder meeting). With respect to an eligible non-employee director who is first elected or appointed to the Board of Directors on a date other than the date of our annual stockholder meeting, upon our first annual stockholder meeting following such non-employee director's first joining the Board of Directors, such director's first annual option grant will be prorated.

Each of the option grants described above will be granted under our 2021 Plan, the terms of which are described in more detail above under "—Equity Benefit Plans—2021 Plan." Each such option grant will vest and become exercisable subject to the director's continuous service with us, provided that each option will vest in full upon a change in control of the company. The exercise price per share of each option will be 100% of the Fair Market Value (as defined in our 2021 Plan) of the underlying common stock on the date of grant. The term of each option will be 10 years, subject to earlier termination as provided in the 2021 Plan (provided that upon a termination of service other than by death or for cause, the post-termination exercise period will be 12 months from the date of termination).

We have reimbursed and will continue to reimburse all of our non-employee directors for their travel, lodging and other reasonable expenses incurred in attending meetings of our Board of Directors and committees of our Board of Directors.

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

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding the ownership of the Company's common stock, as of January 31, 2024 by: (i) each director and nominee for director; (ii) each of the executive officers named in the Summary Compensation Table; (iii) all current executive officers and directors of the Company as a group; and (iv) all those known by the Company to be beneficial owners of more than five percent of its common stock.

The table is based upon information supplied by officers, directors and principal stockholders, and found in Schedules 13D and 13G filed with the SEC and other sources believed to be reliable by the Company. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, the Company believes that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 1,821,986 shares of common stock and 29,863,674 shares of Series 1 convertible preferred stock which is convertible into 1,990,914 shares of common stock (as adjusted for the 1-for-15 Reverse Stock Split effective July 5, 2023) outstanding on January 31, 2024, adjusted as required by rules promulgated by the SEC. The number of shares of common stock and Series 1 Preferred Stock used to calculate the percentage ownership of each listed beneficial owner includes the shares of common stock underlying options or convertible securities held by such beneficial owner that are exercisable or convertible within 60 days following January 31, 2024. Unless otherwise indicated, the address for each person or entity listed in the table is c/o Talis Biomedical Corporation, 1375 West Fulton Market, Suite 700, Chicago, Illinois 60607.

Beneficial Owner	Beneficial Ownership				
	Common Stock		Series 1 Preferred Stock**		Total Outstanding Capital Stock
	Number of Shares	Percent of Total	Number of Shares	Percent of Total	Percent of Total
5% or Greater Stockholders					
Entities Affiliated with Baker Brothers Advisors, L.P. (1)	508,371	28 %	1,990,914	100 %	66 %
Named Executive Officers and Directors					
Robert Kelley (2)	56,095	3 %	—	—	1 %
Rebecca Markovich (3)	4,604	*	—	—	*
Kimberly J. Popovits (4)	51,369	3 %		—	1 %
Melissa Gilliam, M.D., M.P.H.	7	*	—	—	*
Rustem F. Ismagilov (5)	61,904	3 %	—	—	2 %
Matthew L. Posard (6)	24,512	1 %	—	—	*
Randal Scott, Ph.D.(7)	135,229	7 %	—	—	4 %
Raymond Cheong (8)	1,185	*	—	—	*
Heiner Dreisman (9)	274	*	—	—	*
All executive officers and directors as a group (9 persons) (10)	335,179	18 %	—	—	9 %

(1) Consists of (i) 38,111 shares of common stock and 156,366 shares (restated for the 1-for-15 Reverse Stock Split effective July 5, 2023) of Series 1 Preferred Stock held by 667, L.P. (“667”), (ii) 470,212 shares of common stock and 1,834,117 shares (restated for the 1-for-15 Reverse Stock Split effective July 5, 2023) of Series 1 Preferred Stock held by Baker Brothers Life Sciences, L.P. (“Baker Bros Life Sciences” and, together with 667, the “Funds”), (iii) 40 shares of common stock and 362 shares (restated for the 1-for-15 Reverse Stock Split effective July 5, 2023) of Series 1 Preferred Stock held by FBB Associates (“FBB”), and (iv) 8 shares of common stock and 69 shares (restated for the 1-for-15 Reverse Stock Split effective July 5, 2023) of Series 1 Preferred Stock held by FBB3 LLC (“FBB3”). Baker Bros. Advisors LP (“Adviser”) is the management company and investment adviser to the Funds and has sole voting and investment power with respect to the shares held by the Funds. Baker Bros. Advisors (GP) LLC (“Adviser GP”) is the sole general partner of Adviser. Julian C. Baker and Felix J. Baker are managing members of Adviser GP. Adviser GP, Felix J. Baker, Julian C. Baker and Adviser may be deemed to be beneficial owners of the securities directly held by the Funds. Felix J. Baker and Julian C. Baker are the sole partners of FBB and as such may be deemed to be beneficial owners of the securities owned by FBB. Felix J. Baker and Julian C. Baker are the sole managers of FBB3 and by policy they do not transact in or vote the securities of the Company held by FBB3. The address for the above referenced entities and persons is 860 Washington Street, 3rd Floor, New York, NY 10014.
(2) Consist of (i) 683 shares of common stock held by Mr. Kelley, and (ii) 55,412 shares of common stock issuable to Mr. Kelley pursuant to options exercisable within 60 days of January 31, 2024.
(3) Consists of 4,604 shares of common stock issuable to Mrs. Markovich pursuant to options exercisable within 60 days of January 31, 2024.
(4) Consists of (i) 1,719 shares of common stock held by Ms. Popovits, (ii) 37,514 shares of common stock issuable to Ms. Popovits pursuant to options exercisable within 60 days of January 31, 2024 and, (iii) 12,136 shares of common stock held by MSL FBO Kimberly J. Popovits Patrick J. Popovits TTEE U/AD 05-17-2020 FBO Popovits 2010 Trust (“Popovits Trust”). Ms. Popovits and her spouse are trustees of the Popovits Trust and share voting and dispositive power.
(5) Consists of (i) 7,963 shares of common stock held by Dr. Ismagilov and 44,192 shares of common stock issuable to Dr. Ismagilov pursuant to options exercisable within 60 days of January 31, 2024 and (ii) 9,749 shares of common stock held by Dr. Ismagilov’s spouse.
(6) Consists of (i) 20,345 shares of common stock issuable to Mr. Posard pursuant to options exercisable within 60 days of January 31, 2024 and (ii) 4,167 shares of common stock held by Mr. Posard.
(7) Consists of (i) 20,345 shares of common stock issuable to Dr. Scott pursuant to options exercisable within 60 days of January 31, 2024, (ii) 92,671 shares of common stock held by the Thinking Bench Capital, LLC (“Thinking Bench”) (iii) 20,834 shares of common stock held by the OG Family Trust, u/d/t May 30, 2014 (“OG Trust”), and (iv) 1,379 shares of common stock held by Dr. Scott in a self-directed individual retirement account. Dr. Scott and his spouse are trustees of the OG Trust and share voting and dispositive power over the shares held by the OG Trust. Dr. Scott is the manager and CEO of Thinking Bench and the OG Trust is the sole member of Thinking Bench, accordingly Dr. Scott and his spouse share voting and dispositive power over the shares held by Thinking Bench.
(8) 1,185 shares of common stock issuable to Mr. Cheong pursuant to options exercisable within 60 days of January 31, 2024.
(9) 274 shares of common stock issuable to Mr. Driesman pursuant to options exercisable within 60 days of January 31, 2024.
(10) Includes the shares described in Footnotes (2)-(9).

* Less than one percent.
** 29,863,674 shares of Series 1 convertible preferred stock which is convertible into 1,990,914 shares of common stock, as adjusted for the 1-for-15 Reverse Stock Split effective July 5, 2023. The conversion ratio of the outstanding Series 1 convertible preferred stock increased and the number of shares of common stock issuable upon conversion of such Series 1 convertible preferred stock decreased in proportion to the 1-for-15 ratio of the Reverse Stock Split. Our Series 1 convertible preferred stock is a voting common stock equivalent, subject to certain limitations.

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

TRANSACTIONS WITH RELATED PERSONS AND INDEMNIFICATION

The following includes a summary of transactions since January 1, 2022 to which we have been a party, in which the amount involved in the transaction exceeded $120,000 or, if less, 1% of the average of our total assets as of December 31, 2023 and 2022, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation" above.

Investor Agreements

Stockholder Registration Rights

Pursuant to the amended and restated investor rights agreement, holders of shares of our common stock, including certain holders of five percent of our capital stock and entities affiliated with certain of our directors, are entitled to certain registration rights with respect to their registrable securities. The registration of shares of our common stock pursuant to the exercise of such registration rights would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We are required to pay the registration expenses, other than underwriting discounts and selling commissions, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the Company, based on consultation with the underwriter, if any, may, subject to specified conditions, limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will terminate upon the earlier of (i) a deemed "Liquidation Event" (as defined in our amended and restated certificate of incorporation) and (ii) with respect to any particular holder, at such time that such holder can sell its registrable securities under Rule 144 of the Securities Act without restrictions on volume of shares sold and frequency of sales or compliance with Rule 144(c)(1) of the Securities Act during any 90 day period.

Demand Registration Rights

Following October 30, 2022, holders of at least 75% of the registrable securities then outstanding may make a written request that we register all or a portion of their registrable securities, subject to certain specified exceptions. Such request for registration must cover a majority of the registrable securities then outstanding (or a lesser percent if the anticipated aggregate offering price, net of underwriting discounts and commissions, would exceed $10 million). We are not obligated to effect more than one demand registration.

Piggyback Registration Rights

In the event that we propose to register any of our securities under the Securities Act in an offering, either for our own account or for the account of other security holders, the holders of registrable securities will be entitled to certain "piggyback" registration rights allowing them to include their registrable securities in such registration, subject to specified conditions and limitations.

Form S-3 Registration Rights

The holders of at least 30% of the registrable securities then outstanding can make a written request that we register all or a portion of their registrable securities on Form S-3 if we are qualified to file a registration statement on Form S-3, subject to certain specified exceptions. Such registration on Form S-3 must cover securities with an aggregate offering price to the public of at least $5 million. We are not obligated to effect more than two registrations on Form S-3. As of the date of filing of this Annual Report on Form 10-K, the Company is not currently eligible to register securities on Form S-3.

Consulting Arrangements

In January 2019, we entered into a consulting agreement, as amended in December 2020, with Rustem F. Ismagilov, one of our co-founders and a member of our Board of Directors, pursuant to which Dr. Ismagilov provides general scientific, and strategic consulting regarding our development and commercialization efforts. Pursuant to his amended consulting agreement, Dr. Ismagilov received a consulting fee of $75,000 per year for services rendered, as requested

from time to time. Further, pursuant to his amended consulting agreement, Dr. Ismagilov, during a partial sabbatical from Caltech from August 2020 through December 2020, devoted three days per week to support our efforts to complete development of our Talis One system and is entitled to an option to purchase shares of our common stock with a value of $300,000, which option was granted in September 2020. By its terms, unless terminated earlier, the amended consulting agreement expired as of December 31, 2022, however, the parties agreed to terminate this consulting agreement in June 2022. We entered into a new consulting agreement, effective July 2022 through December 31, 2022, which capped Dr. Ismagilov's consulting fees at $40,000.

In January 2023, we entered into a new consulting agreement with Dr. Ismagilov through June 30, 2023, which capped his consulting fees at $20,000.

In July 2023, we entered into a consulting agreement with Heiner Dreismann through January 17, 2024 which capped his consulting fees at $20,000.

Transactions with Members of our Board of Directors

In 2023 and 2022, we granted equity awards and paid compensation to members of our Board of Directors as further described in "Executive and Director Compensation—Director Compensation."

Agreements with Baker Brothers

Nominating Agreement

On November 1, 2019, we entered into a nominating agreement (the "Nominating Agreement"), with Baker Brothers Life Sciences, L.P. and 667, L.P. (together, "Baker Brothers"). Pursuant to the Nominating Agreement, during the period beginning at the closing our initial public offering until such time as Baker Brothers no longer beneficially owns at least 354,474 shares (as converted from 5,317,097 shares of our common stock to reflect the 1-for-15 Reverse Stock Split and subject to adjustment for future stock splits, combinations, recapitalizations and similar transactions), of our common stock (the "Initial Period"), we will have the obligation to support the nomination of, and to cause our Board of Directors to include in the slate of nominees recommended to our stockholders for election, two individuals designated by Baker Brothers (each, a "Baker Designee") and during the period beginning at the closing of our initial public offering until such time as Baker Brothers no longer beneficially owns at least 132,928 shares (as converted from 1,993,91 shares of our common stock to reflect the 1-for-15 Reverse Stock Split and subject to adjustment for future stock splits, combinations, recapitalizations and similar transactions) of our common stock (together with the Initial Period, the "Nominating Period"), we will have the obligation to support the nomination of, and to cause our Board of Directors to include in the slate of nominees recommended to our stockholders for election one Baker Designee, unless a majority of our disinterested directors reasonably and in good faith determines that such Baker Designee would not be qualified to serve as our director under law, rules of the stock exchange on which our shares are listed, our Bylaws, or any of our company policies. In such case, we would notify Baker Brothers sufficiently in advance of the date on which the proxy materials related to such Baker Designee are to be mailed to enable Baker Brothers to propose a replacement Baker Designee. If a Baker Designee resigns his or her seat on our Board of Directors or is removed or does not become a director for any reason, the vacancy will be filled by the election or appointment of another Baker Designee as soon as reasonably practicable, subject to compliance with applicable laws, rules and regulations.

Furthermore, during the Nominating Period, we will have the obligation to invite one Board of Directors observer designee of Baker Brothers, to attend all meetings of our Board of Directors and all meetings of the committees of our Board of Directors as a nonvoting observer. The Nominating Agreement automatically terminates upon the earlier of (i) such time as Baker Brothers, together with its affiliates, no longer beneficially owns at least 88,619 shares (as converted from 1,329,274 shares of our common stock to reflect the 1-for-15 Reverse Stock Split and subject to adjustment for future stock splits, combinations, recapitalizations and similar transactions) of our common stock, (ii) the consummation of an "Acquisition" as defined in our fourth amended and restated certificate of incorporation (as in effect on the date of the Nominating Agreement) and (iii) mutual consent of the parties.

Baker Bros Registration Rights Agreement

On March 26, 2021, we entered into a registration rights agreement (the "Baker Bros Registration Rights Agreement") with Baker Brothers (each, an "Investor"), pursuant to which each Investor is entitled to certain resale registration rights with respect to certain registrable securities held by such Investor. Following a request by any Investor made after February 1, 2022, we are obligated to file a resale registration statement on Form S-3, or other appropriate form, covering the registrable securities held by Baker Brothers, subject to certain specified exceptions. On May 10, 2022, we filed a registration rights statement on Form S-3 with the SEC to register the registrable securities pursuant to the Baker Bros Registration Rights Agreement, which registration statement was declared effective on May 24, 2022 (the "Resale Shelf Registration Statement"). Baker Brothers also has the right to one underwritten offering per calendar year, but no more than three underwritten offerings in total and 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. We are required to pay the registration expenses, other than underwriting discounts and selling commissions, incurred in connection with the registrations described above. The Baker Bros Registration Rights Agreement also includes customary indemnification obligations in connection with registrations described above. The agreement will automatically terminate once all registrable securities cease to be registrable securities pursuant to the terms of the agreement. In March 2024, the Resale Shelf Registration Statement was terminated because the Company was no longer eligible to register securities on Form S-3 (the "Demand Registration Statement"). On March 25, 2024, the Company entered into a Waiver of Registration Rights (the "Waiver Agreement") with Baker Brothers Life Sciences L.P. and 667, L.P. to obtain a waiver of the registration rights relating to all of these securities previously registered for resale by the Demand Registration Statement. This Waiver Agreement is effective for a period of thirty (30) days from the filing of this Form 10-K.

Indemnification Agreements

Our amended and restated certificate of incorporation contains provisions limiting the liability of directors, and our Bylaws provide that we will indemnify each of our directors and officers to the extent not prohibited by the Delaware General Corporation Law or other applicable law, subject to certain exceptions. Our amended and restated certificate of incorporation and Bylaws also provide us with discretion to indemnify our employees and other agents to the fullest extent permitted by applicable law.

We have also entered, and intend to continue to enter, into separate indemnification agreements with each of our directors, officers and certain employees and other agents. The indemnification agreements provide, among other things, that we will indemnify such director, officer, employee or other agent, under the circumstances and to the extent provided for in the agreement, against any and all expenses and liabilities incurred by such director, officer, employee or other agent in any actions or proceedings which he or she is or may be made a party by reason of his or her position as a director, officer, employee or other agent of the Company, and otherwise to the fullest extent permitted by law. In addition, the indemnification agreements provide that, to the fullest extent permitted by law, we will advance all expenses incurred by such director, officer, employee or other agent in connection with any such action or proceeding.

Policies and Procedures for Transactions with Related Persons

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of "related-person transactions." For purposes of our policy only, a "related-person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any "related person" are, were or will be participants involving an amount that exceeds $120,000 or, if less, 1% of the average of our total assets at year-end for the prior two completed fiscal years. Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A related person is any executive officer, director, nominee to become a director or a holder of more than five percent of our voting securities, including any of their immediate family members and affiliates, including entities owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our Audit Committee (or, where review by our Audit Committee would be inappropriate, to another independent body of our Board of Directors) for review. The presentation must include a description of, among other things, all of the parties thereto, the direct and indirect interests of the related persons, the purpose of the transaction, the material facts, the benefits of the transaction to us and whether

any alternative transactions are available, an assessment of whether the terms are comparable to the terms available from unrelated third parties and management's recommendation. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our audit committee or another independent body of our Board of Directors takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval. All of the transactions described in this section occurred prior to the adoption of this policy.

Item 14. Principal Accountant Fees and Services.

The following table presents fees for professional audit services by Ernst & Young LLP for the audit of the Company's financial statements for the years ended December 31, 2023 and December 31, 2022 and fees billed for other services rendered by Ernst & Young LLP during these periods.

	Fiscal Year Ended	
	2023	2022
	(in thousands)	
Audit Fees[1]	$ 540	$ 625
Audit-related Fees	—	—
Tax Fees	—	—
All Other Fees[2]	2	2
Total Fees	$ 542	$ 627

(1) Audit fees of Ernst & Young LLP for the years ending December 31, 2023 and 2022 were for professional services rendered for the audits of our financial statements, including accounting consultation, reviews of quarterly financial statements and professional services rendered in connection with our registration statements.
(2) All other fees of Ernst & Young LLP for the years ending December 31, 2023 and 2022 were for publication and online subscriptions of training materials offered by Ernst & Young LLP.

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 139 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	Certificate of Amendment to Certificate of Incorporation of the Registrant dated June 30, 2023 (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 July 5, 2023).
3.3	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).
10.7+	Talis Biomedical Corporation Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 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	Lease Agreement, dated January 20, 2021, by and between the Registrant and Westport Office Park, LLC (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-252360), filed with the SEC on February 8, 2021).
10.17	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).
10.18*	Lease Termination Agreement, dated March 17, 2023, by and between the Registrant and Westport Office Park, LLC. (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K (File No. 001-40047), filed with the SEC on March 22, 2023).
10.19*	Sublease, dated March 17, 2023, by and between the Registrant and Kriya Therapeutics, Inc. (incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K (File No. 001-40047), filed with the SEC on March 22, 2023).
10.20*	Consent to Sublease, dated March 17, 2023, by and between the Registrant, Westport Office Park, LLC, and Kriya Therapeutics, Inc. (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K (File No. 001-40047), filed with the SEC on March 22, 2023).
10.21*	Termination and Release Agreement, dated March 22, 2023, by and between the Registrant and thinXXS Microtechnology AG. (incorporated by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K (File No. 001-40047), filed with the SEC on March 22, 2023).
10.22*	License Agreement, dated March 22, 2023, by and between the Registrant and thinXXS Microtechnology AG. (incorporated by reference to Exhibit 10.22 to the Registrant's Annual Report on Form 10-K (File No. 001-40047), filed with the SEC on March 22, 2023).
10.23	Offer Letter dated July 27, 2023 by and between the Registrant and Andrew Lukowiak (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-40047), filed with the SEC on August 2, 2023).
10.24	Waiver of Registration Rights entered into as of March 25, 2024 by and between the Registrant and Baker Brothers Life Sciences L.P. and 667, L.P.
19.1	Insider Trading Policy
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
104	Cover page formatted as Inline XBRL and contained in Exhibit 101

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

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

TALIS BIOMEDICAL CORPORATION

Date: March 28, 2024

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

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

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

Name	Title	Date
/s/ Robert J. Kelley **Robert J. Kelley**	Chief Executive Officer and Member of the Board of Directors (*Principal Executive Officer)*	March 28, 2024
/s/ Rebecca L. Markovich **Rebecca L. Markovich**	Interim Chief Financial Officer *(Interim Principal Financial and Accounting Officer*)	March 28, 2024
/s/ Heinrich Dreismann, Ph.D. **Heinrich Dreismann, Ph.D.**	Member of the Board of Directors	March 28, 2024
/s/ Rustem F. Ismagilov, Ph.D. **Rustem F. Ismagilov, Ph.D.**	Member of the Board of Directors	March 28, 2024
/s/ Kimberly J. Popovits **Kimberly J. Popovits**	Member of the Board of Directors	March 28, 2024
/s/ Matthew L. Posard **Matthew L. Posard**	Member of the Board of Directors	March 28, 2024
/s/ Raymond Cheong **Raymond Cheong**	Member of the Board of Directors	March 28, 2024
/s/ Randal Scott, Ph.D. **Randal Scott, Ph.D.**	Member of the Board of Directors	March 28, 2024

WAIVER OF REGISTRATION RIGHTS

This Waiver of Registration Rights is entered into as of March 25, 2024 by and between Talis Biomedical Corporation, a Delaware corporation (the "Company"), and the undersigned holders of shares of capital stock of the Company (the "Stockholders"). Capitalized terms used herein and not defined shall have the meaning ascribed to them in that certain Registration Rights Agreement dated March 26, 2021 by and among the Company and the Stockholders (the "Registration Rights Agreement").

WHEREAS, the Company previously filed a registration statement on Form S-3, File No. 333-264839, registering the resale by the Stockholders of up to 2,499,285 shares of the Company's common stock (as adjusted to reflect the 1-for-15 reverse stock split effective July 5, 2023), which registration statement was declared effective by the Securities and Exchange Commission on May 24, 2022 (the "Registration Statement");

WHEREAS, effective upon the Company's filing of its annual report on Form 10-K for the year ended December 31, 2023 (the "Form 10-K"), the Company will not be eligible to continue the registration of Registrable Securities on Form S-3, and immediately prior to the filing of the Form 10-K, the Company will post-effectively amend the Registration Statement to withdraw the registration statement and terminate its effectiveness;

WHEREAS, the undersigned Stockholders desire to waive their registration rights under the Registration Rights Agreement for a period of thirty (30) days from the filing of the Form 10-K in order to preserve for the Company maximum flexibility in meeting the Company's financial and other needs in pursuing strategic alternatives and/or the filing of a new registration statement on Form S-1 to register the resale by the Stockholders of the Registrable Securities covered by the Registration Statement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Upon the execution of this Waiver of Registration Rights by the Company and the undersigned Stockholders, and pursuant to Sections 2.1(b) and 3.1 of the Registration Rights Agreement, the undersigned Stockholders hereby waive the registration rights with respect to all Registrable Securities beneficially owned by the Stockholders under the Registration Rights Agreement in connection with the Registration Statement for a period of thirty (30) days from the date that the Company files the Form 10-K with the Securities and Exchange Commission.

2. Except as modified by this Waiver of Registration Rights, all other terms and conditions of the Registration Rights Agreement and the obligations of the Company and the Stockholders thereunder shall remain in full force and effect.

3. This Waiver of Registration Rights may be executed in several counterparts, and all so executed shall constitute one agreement, binding on all of the parties hereto, notwithstanding that all of the parties are not signatory to the original or the same counterpart.

4. This Waiver of Registration Rights shall be binding on the undersigned and the successors, heirs, personal representatives and assigns of the undersigned.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties have executed this Waiver of Registration Rights effective as of the date first above written.

TALIS BIOMEDICAL CORPORATION

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

BAKER BROTHERS LIFE SCIENCES L.P.

By: BAKER BROS. ADVISORS LP, management company and investment adviser to BAKER BROTHERS LIFE SCIENCES, L.P., pursuant to authority granted to it by Baker Brothers Life Sciences Capital, L.P., general partner to BAKER BROTHERS LIFE SCIENCES, L.P., and not as the general partner

By: /s/ Scott Lessing
Scott Lessing
President

667, L.P.

By: BAKER BROS. ADVISORS LP, management company and investment adviser to 667, L.P., pursuant to authority granted to it by Baker Biotech Capital, L.P., general partner to 667, L.P., and not as the general partner

By: /s/ Scott Lessing
Scott Lessing
President

TALIS BIOMEDICAL CORPORATION INSIDER TRADING POLICY
2 FEBRUARY 2024

POLICY PRINCIPLES AND OVERVIEW

1. Personnel of Talis Biomedical Corporation ("**Talis**") are responsible for understanding the obligations that come with having access to material nonpublic information and wanting to transact in Talis's securities.

2. Talis personnel who are aware of material nonpublic information relating to Talis are not permitted to engage in transactions in Talis's securities except as permitted by this policy and applicable law.

3. Talis personnel who are aware of material nonpublic information relating to Talis may not recommend the purchase or sale of any of Talis's securities.

4. Talis personnel may not disclose material nonpublic information to persons within the Talis organization whose jobs do not require them to have that information.

5. Talis personnel may not disclose material nonpublic information outside of the Talis organization unless the disclosure is made in accordance with the Talis Corporate Disclosure Policy.

6. Unless authorized by a Talis policy and as required by their role at the company, Talis personnel may not assist anyone engaged in transactions in Talis's securities, the recommendation to buy or sell Talis's securities, or the disclosure of material nonpublic information.

7. Talis reserves the right to update this policy over time.

POLICY Q&A

Policy Scope and Purpose

Q: Why have an insider trading policy?

A: During the course of your relationship with Talis, you may receive material information that is not yet publicly available ("**material nonpublic information**") about Talis or other publicly traded companies with which Talis has business relationships. Material nonpublic information may give you, or someone to whom you pass that information, a leg up over others when deciding whether to buy, sell, or otherwise transact in Talis's securities or the securities of another publicly traded company. This policy sets forth guidelines with respect to transactions in Talis's securities by persons subject to this policy.

Q: Who is subject to this policy?

A: This policy applies to you and all other employees, directors, and designated consultants of Talis. This policy also applies to members of your immediate family, persons with whom you share a household, persons who are your economic dependents, and, unless otherwise determined by Talis,

any other individuals or entities whose transactions in securities you influence, direct, or control. The foregoing persons who are deemed subject to this policy are referred to in this policy as "**Related Persons**." However, Related Persons shall not include, and this policy shall not apply to, an entity controlled by or affiliated with a director if the entity's principal business is the investment of securities (an investment fund or partnership) and the entity has established its own insider trading controls and procedures in compliance with applicable securities laws that is inclusive of transactions in Talis's securities. You are responsible for making sure that your Related Persons comply with this policy.

In addition, if you are Covered Person (as defined below), you and your Related Persons are subject to the quarterly trading blackout periods described below.

Q: Whose responsibility is it to comply with this policy?

A: Persons subject to this policy have ethical and legal obligations to maintain the confidentiality of information about Talis and to not engage in transactions in Talis's securities while aware of material nonpublic information. In all cases, it is the individual's responsibility for determining whether that person is aware of material nonpublic information. Any action on the part of Talis or any employee or director of Talis pursuant to this policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by Talis or the United States government for any conduct prohibited by this policy or applicable securities laws.

Q: What transactions are subject to this policy?

A: This policy applies to all transactions in securities issued by Talis, as well as derivative securities that are not issued by Talis, such as exchange-traded put or call options or swaps relating to Talis's securities. Accordingly, for purposes of this policy, the terms "**trade**," "**trading**," and "**transactions**" include not only purchases and sales of Talis's common stock in the public market but also any other purchases, sales, transfers, or other acquisitions and dispositions of common or preferred equity, options, warrants, and other securities (including debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities.

Insider Trading and Material Nonpublic Information

Q: What is insider trading?

A: Generally speaking, insider trading is the buying or selling of stocks, bonds, futures, or other securities by someone who possesses or is otherwise aware of material nonpublic information about the securities or the issuer of the securities. Insider trading also includes trading in derivatives (such as put or call options) where the price is linked to the underlying price of a company's stock. It does not matter whether the decision to buy or sell was influenced by the material nonpublic information, how many shares you buy or sell, or whether it has an effect on the stock price. Bottom line: **IF YOU ARE AWARE OF MATERIAL NONPUBLIC INFORMATION ABOUT TALIS OR ANOTHER PUBLICLY TRADED COMPANY THAT TALIS HAS BUSINESS RELATIONSHIPS WITH, AND YOU TRADE IN TALIS'S OR SUCH OTHER COMPANY'S SECURITIES, YOU HAVE BROKEN THE LAW.**

Q: Why is insider trading illegal?

A: If company insiders are able to use their confidential knowledge to their financial advantage, other investors would not have confidence in the fairness and integrity of the market. This ensures that there is an even playing field by requiring those who are aware of material nonpublic information to refrain from trading.

Q: What is material information?

A: It is not always easy to figure out whether you are aware of material nonpublic information. But there is one important factor t determine whether nonpublic information you know about a public company is material: **whether the information could be expected to affect the market price of that company's securities or to be considered important by investors who are considering trading that company's securities**. If the information makes you want to trade, it would probably have the same effect on others. Keep in mind that both positive and negative information can be material.

Q: What are examples of material information?

A: There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by relevant enforcement authorities with the benefit of hindsight. Depending on the specific details, the following items may be considered material nonpublic information until publicly disclosed within the meaning of this policy. There may be other types of information that would qualify as material information as well; use this list merely as a non-exhaustive guide:

- financial results or forecasts;
- acquisitions, dispositions or other strategic transactions;
- events regarding our securities (e.g., repurchase plans, stock splits, public or private equity or debt offerings, or changes in our dividend policies or amounts);
- major contracts or contract cancellations;
- gain or loss of a significant customer;
- pricing or reimbursement changes;
- new product releases;
- significant product recalls, customer complaints, or FDA communications;
- status of product or product candidate development or regulatory approvals;
- clinical data or regulatory results;
- timelines for clinical or regulatory developments;
- top management, Board of Directors or control changes;
- financial restatements or significant write-offs;
- liquidity problems;
- extraordinary borrowing;

- employee layoffs;
- cybersecurity incidents;
- a disruption in Talis's operations or breach or unauthorized access of its property or assets, including its facilities or information technology infrastructure;
- proxy fights;
- actual or threatened major litigation, SEC or other investigations, or a major development in or the resolution of any such litigation or investigation;
- impending bankruptcy;
- communications with government agencies; and
- notice of issuance of patents.

Q: When is information considered public?

A: The prohibition on trading when you have material nonpublic information lifts once that information is publicly disseminated. But for information to be considered publicly disseminated, it must be widely disseminated through a press release, a filing with the SEC or other widely disseminated announcement. Once information is publicly disseminated, it is still necessary to afford the investing public with sufficient time to absorb the information. Generally speaking, information will be considered publicly disseminated for purposes of this policy only after two full trading days have elapsed since the information was publicly disclosed. For example, if we announce material nonpublic information before trading begins on Wednesday, then information would be considered to be publicly disseminated by the time trading begins on Friday; if we announce material nonpublic information after trading ends on Wednesday, then information would be considered to be publicly disseminated by the time trading ends on Friday. Depending on the particular circumstances, Talis may determine that a longer or shorter waiting period should apply to the release of specific material nonpublic information. Any disclosure of nonpublic information, material or otherwise, must be done in accordance with Talis's Corporate Disclosure Policy.

Q: Who can be guilty of insider trading?

A: Anyone who buys or sells a security while aware of material nonpublic information or provides material nonpublic information that someone else uses to buy or sell a security, may be guilty of insider trading. This applies to all individuals, including officers, directors, and others who don't even work at Talis. Regardless of who you are, if you know something material about the value of a security that not everyone knows and you trade (or convince someone else to trade) in that security, you may be found guilty of insider trading.

Q: What if I am aware of material nonpublic information when I trade, but the reason I trade is because of something else, like to pay medical bills?

A: The prohibition against insider trading is absolute. It applies even if the decision to trade is not based on such material nonpublic information. It also applies to transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency

expenditure) and also to very small transactions. All that matters is whether you are aware of any material nonpublic information relating to Talis at the time of the transaction.

Q: Do the U.S. securities laws take into account mitigating circumstance, like avoiding a loss or planning a transaction before I had material nonpublic information?

A: No. The U.S. federal securities laws do not recognize any mitigating circumstances to insider trading. In addition, even the appearance of an improper transaction must be avoided to preserve Talis's reputation for adhering to the highest standards of conduct. In some circumstances, you may need to forgo a planned transaction even if you planned it before becoming aware of the material nonpublic information. So, even if you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting to trade, you must wait.

Q: What if I don't buy or sell anything, but I tell someone else material nonpublic information and he or she buys or sells?

A: That is called "tipping." You are the "tipper" and the other person is called the "tippee." If the tippee buys or sells based on that material nonpublic information, both you and the "tippee" could be found guilty of insider trading. In fact, if you tell family members who tell others and those people then trade on the information, those family members and the "tippee" might be found guilty of insider trading too. To prevent this, you may not discuss material nonpublic information about the company with anyone outside Talis, including spouses, family members, friends, or business associates (unless the disclosure is made in accordance with Talis's policies regarding the protection or authorized external disclosure of information regarding Talis). This includes anonymous discussions on the internet about Talis or companies with which Talis does business.

You can be held liable for your own transactions, as well as the transactions by a tippee and even the transactions of a tippee's tippee. For these and other reasons, **NO EMPLOYEE, DIRECTOR, OR DESIGNATED CONSULTANT OF TALIS (OR ANY OTHER PERSON SUBJECT TO THIS POLICY) MAY EITHER:**

(A) RECOMMEND TO ANOTHER PERSON THAT THEY BUY, HOLD, OR SELL TALIS'S SECURITIES AT ANY TIME OR

(B) DISCLOSE MATERIAL NONPUBLIC INFORMATION TO PERSONS WITHIN TALIS WHOSE JOBS DO NOT REQUIRE THEM TO HAVE THAT MATERIAL NONPUBLIC INFORMATION, OR OUTSIDE OF TALIS TO OTHER PERSONS (UNLESS THE DISCLOSURE IS MADE IN ACCORDANCE WITH TALIS'S POLICIES REGARDING THE PROTECTION OR AUTHORIZED EXTERNAL DISCLOSURE OF INFORMATION REGARDING TALIS).

Q: What if I don't tell someone inside information itself; I just tell him or her whether to buy or sell?

A: That is still tipping, and you can still be responsible for insider trading. You may never recommend to another person that they buy, hold or sell Talis's common stock or any derivative security related to Talis's common stock, since that could be a form of tipping.

Q: Does this policy or the insider trading laws apply to me if I work outside the U.S.?

A: Yes. The same rules apply to U.S. and foreign employees and consultants. The Securities and Exchange Commission (the U.S. government agency in charge of investor protection, the "**SEC**"), and the Financial Industry Regulatory Authority (a private regulator that oversees U.S. securities exchanges) routinely investigate trading in a company's securities conducted by individuals and firms based abroad. In addition, as a Talis director, employee, or consultant, our policies apply to you no matter where you work.

Q: Am I restricted from trading securities of any companies other than Talis, for example a customer or competitor of Talis?

A: Possibly. U.S. insider trading laws generally restrict everyone aware of material nonpublic information about a company from trading in that company's securities, regardless of whether the person is directly connected with that company, except in limited circumstances. Therefore, if you have material nonpublic information about another company, you should not trade in that company's securities. You should be particularly conscious of this restriction if, through your position at Talis, you sometimes obtain sensitive, material information about other companies and their business dealings with Talis.

In addition, it is Talis policy that no employee, director, or designated consultant of Talis (or any other person subject to this policy) who, in the course of working for Talis, learns of or is otherwise aware of material nonpublic information about another publicly traded company with which Talis does business, including a customer or partner of Talis, may trade in that company's securities until the information becomes public or is no longer material.

Q: If I do not trade Talis's securities when I have material nonpublic information, and I don't "tip" other people, I am in the clear, right?

A: Not necessarily. Even if you do not violate U.S. law, you may still violate our policies. For example, employees and consultants may violate our policies by breaching their confidentiality obligations or by recommending Talis's stock as an investment, even if these actions do not violate securities laws. Our policies are stricter than the law requires so that we and our employees and consultants can avoid even the appearance of wrongdoing. Therefore, please review the entire policy carefully.

Q: So, when can I buy or sell my Talis securities?

A: If you are aware of material nonpublic information, you may not buy or sell our common stock until two full trading days have elapsed since the information was publicly disclosed. At that point, the information is considered publicly disseminated for purposes of our insider trading policy. For example, if we announce material nonpublic information before trading begins on Wednesday, then you may execute a transaction in our securities on Friday; if we announce material nonpublic information after trading ends on Wednesday, then you may execute a transaction in our securities on Monday. **Even if you are not aware of any material nonpublic information, you may not trade our common stock during any trading "blackout" period that applies to you**. Our insider trading policy describes the quarterly trading blackout period, and

additional event-driven trading blackout periods (which may apply to you even if the quarterly trading blackout periods do not) may be announced by email.

Blackout Periods

Q: What is a quarterly trading blackout period?

A: To minimize the appearance of insider trading among our officers, directors, employees, and their Related Persons, we have established "quarterly trading blackout periods" during which they— regardless of whether they are aware of material nonpublic information or not—may not conduct any trades in Talis's securities. That means that, except as described in this policy, all (i) directors of the Company, (ii) officers of the Company and (iii) employees listed on Appendix A, and (iv) and certain other individuals designated by the Chief Financial Officer or head of Legal (collectively, "Covered Persons"), and their Related Persons will be able to trade in Talis's securities only during limited open trading window defined below. Of course, even during an open trading window period, you may not (unless an exception applies) conduct any trades in Talis's securities if you are otherwise in possession of material nonpublic information.

Q: What are Talis's quarterly trading blackout periods?

A: Each "**quarterly trading blackout period**" will generally begin at the end of the day that is the 15th day of the third month of each fiscal quarter and end after two (2) trading days have elapsed since the public dissemination of Talis's financial results for that quarter.

Q: Can Talis's quarterly trading blackout periods change?

A. The quarterly trading blackout period may commence early or may be extended if, in the judgment of the Chief Financial Officer or the head of Legal, there exists undisclosed information that would make trades by Covered Persons or their Related Persons inappropriate. It is important to note that the fact that the quarterly trading blackout period has commenced early or has been extended should be considered material nonpublic information that should not be communicated to any other person.

Q: Does Talis have blackout periods other than quarterly trading blackout periods?

A: Yes. From time to time, an event may occur that is material to Talis and is known by only a few directors, officers, and/or employees. So long as the event remains material and nonpublic, the persons designated by the Chief Financial Officer or the head of Legal may not trade in Talis's securities. In that situation, Talis will notify the designated individuals that neither they nor their Related Persons may trade in Talis's securities. The existence of an event-specific trading blackout should also be considered material nonpublic information and should not be communicated to any other person.

Questions Regarding Blackout Periods Generally

Q: If I am subject to a blackout period and I have an open order to buy or sell Talis's securities on the date a blackout perio commences, can I leave it to my broker to cancel the open order and avoid executing the trade?

A: No, unless it is in connection with a 10b5-1 Trading Plan (as defined below). If you have any open orders when a blackout period commences other than in connection with a 10b5-1 Trading Plan, it is your responsibility to cancel these orders with your broker. If you have an open order and it executes after a blackout period commences not in connection with a 10b5-1 Trading Plan, you will have violated our insider trading policy and may also have violated insider trading laws.

Q: What if I think I have a special circumstance that would require me to trade during a blackout period otherwise applicable to me?

A: You should consult the head of Legal. Permission to trade during a blackout period applicable to you will be granted only where (a) the circumstances are extenuating, (b) the head of Legal concludes that you are not in fact aware of any material nonpublic information relating to Talis or its securities, and (c) there appears to be no significant risk that the trade may subsequently be questioned. However, our expectation is that very few if any exceptions will be made.

Q: Am I subject to trading blackout periods if I am no longer an employee, director or consultant of Talis?

A: It depends. If your employment with Talis ends during a trading blackout period, you will be subject to the remainder of that trading blackout period. If your employment with Talis ends on a day that the trading window is open, you will not be subject to the next trading blackout period. However, even if you are not subject to our trading blackout period after you leave Talis, you should not trade in Talis's securities if you are aware of material nonpublic information. That restriction stays with you as long as the information you possess is material and not publicly disseminated within the meaning of our insider trading policy.

Q: Are there any exceptions to this policy?

A: There are no exceptions to this policy, except as specifically noted below.

Q: Can I exercise options granted to me by Talis, or participate in a Talis employee stock purchase plan, during a tradin blackout period or when I possess material nonpublic information?

A: Yes. You may purchase shares by exercising your options or participating in a Talis employee stock purchase plan, but you may not sell the shares (even to pay the exercise price or any taxes due) during a trading blackout period or any time that you are aware of material nonpublic information. To be clear, you may not effect a broker-assisted cashless exercise (because these cashless exercise transactions include a market sale) during a trading blackout period or any time that you are aware of material nonpublic information

Q: What tax withholding transactions are not restricted by this policy?

A: This policy does not apply to the surrender of shares directly to Talis to satisfy tax withholding obligations as a result of the issuance of shares upon exercise of options or settlement of restricted stock units issued by Talis. Of course, any market sale of the stock received upon exercise or settlement of any such equity awards remains subject to all provisions of this policy whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

Q: Are mutual fund shares holding Talis's common stock subject to the trading blackout periods?

A: No. You may trade in mutual funds holding Talis's stock at any time.

Q: What are the rules that apply to 10b5-1 Automatic Trading Programs?

A: Under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended ("**Exchange Act**"), any person may establish a trading plan under which a broker is instructed to buy and sell Talis's securities based on pre-determined criteria (a "**Trading Plan**"). So long as a Trading Plan is properly established, purchases and sales of Talis's securities pursuant to that Trading Plan are not subject to this policy. To be properly established, a person's Trading Plan must be established in compliance with the requirements of Rule 10b5-1 of the Exchange Act and any applicable 10b5-1 trading plan guidelines of Talis at a time when they were unaware of any material nonpublic information relating to Talis and when you were not otherwise subject to a trading blackout period, and directors and officers subject to Section 16 of the Exchange Act must certify to such compliance in any Trading Plan adopted by them. After a Rule 10b5-1 Trading Plan is adopted, trades under the Trading Plan may not be commenced until after the expiration of a cooling-off period that is at least 30 days for employees and at least 90 days for directors and officers subject to Section 16 of the Exchange Act. Moreover, all Trading Plans to be adopted by any director, officer, or employee of the Company must be reviewed and approved by the head of Legal before being established to confirm that the Trading Plan complies with all pertinent company policies and applicable securities laws.

Q: Can I gift stock while I possess material nonpublic information or during a trading blackout period?

A: Because of the potential for the appearance of impropriety, as a general matter gifts should only be made when you are not in possession of material nonpublic information and not subject to a trading blackout period. For example, charities that receive gifted stock typically immediately sell the stock into the public market, potentially subjecting you to "tipper" liability if you were in possession of material nonpublic information at the time of the gift. You may only make bona fide gifts of our stock when you are not aware of material nonpublic information or during a trading blackout period applicable to you only if the gift has been pre-cleared by the Chief Financial Officer or the head of Legal or their designee. Pre-clearance must be obtained at least two (2) business days in advance of the proposed gift, and pre-cleared gifts not completed within five (5) business days will require new pre-clearance. Talis may choose to shorten this period.

Margin Accounts, Pledging Shares, Hedging and Other Speculation in Talis Stock

Q: Can I purchase Talis's securities on margin or hold them in a margin account?

A: No. "Purchasing on margin" is the use of borrowed money from a brokerage firm to purchase our securities. Holding our securities in a margin account includes holding the securities in an account in which the shares can be sold to pay a loan to the brokerage firm. You may not purchase our common stock on margin or hold it in a margin account at any time.

Q: Can I pledge my Talis shares as collateral for a loan?

A: No. Pledging your shares as collateral for a loan could cause the pledgee to transfer your shares during a trading blackout period or when you are otherwise aware of material nonpublic information. As a result, you may not pledge your shares as collateral for a loan.

Q: What is problematic about margin accounts and pledged securities?

A: Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in Talis's securities, all Talis employees, directors, and designated consultants are prohibited from holding Talis's securities in a margin account or otherwise pledging Talis's securities as collateral for a loan.

Q: Can I hedge my ownership position in Talis?

A: No. Hedging or monetization transactions, including through the use of financial instruments such as prepaid variable forwards equity swaps, collars, and exchange funds are prohibited by our insider trading policy. Since such hedging transactions allow you to continue to own Talis's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership, you may no longer have the same objectives as Talis's other shareholders. Therefore, our insider trading policy prohibits you from engaging in any such transactions.

Q: Why are hedging transactions prohibited?

A: Such transactions may permit a person subject to this policy to continue to own Talis's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the person may no longer have the same objectives as Talis's other stockholders. Therefore, all persons subject to this policy are prohibited from engaging in any such transactions.

Q: Am I allowed to trade derivative securities of Talis's common stock?

A: No. You may not trade in derivative securities related to our common stock, which include publicly traded call and put options. In addition, you may not engage in short selling of our common stock at any time.

Q: What are derivative securities?

A: "Derivative securities" are securities other than common stock that are speculative in nature because they permit a person to leverage their investment using a relatively small amount of money. Examples of derivative securities include "put options" and "call options." These are different from employee options and other equity awards granted under our equity compensation plans, which are not derivative securities for purposes of our policy.

Q: What is short selling?

A: "Short selling" is profiting when you expect the price of the stock to decline and includes transactions in which you borrow stock from a broker, sell it, and eventually buy it back on the

market to return the borrowed shares to the broker. Profit is realized if the stock price decreases during the period of borrowing.

Q: Why does Talis prohibit trading in derivative securities and short selling?

A: Many companies with volatile stock prices have adopted similar policies because of the temptation it represents to try to benefit from a relatively low-cost method of trading on short-term swings in stock prices, without actually holding the underlying common stock, and encourages speculative trading. We are dedicated to building stockholder value, short selling our common stock conflicts with our values and would not be well-received by our stockholders.

Q: What if I purchased publicly traded options or other derivative securities before I became subject to this policy?

A: The same rules apply as for employee stock options. You may exercise the publicly traded options at any time, but you may not sell the securities during a trading blackout period or at any time that you are aware of material nonpublic information.

Q: What are the concerns about standing and limit orders?

A: Standing and limit orders (except standing and limit orders under approved Trading Plans, as discussed above) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a Talis employee, director, or designated consultant is in possession of material nonpublic information. Talis therefore discourages placing standing or limit orders on Talis's securities. If a person subject to this policy determines that they must use a standing order or limit order (other than under an approved Trading Plan as discussed above), the order should be limited to short duration and the person using such standing order or limit order is required to cancel such instructions immediately in the event restrictions are imposed on their ability to trade pursuant to the "Quarterly Trading Blackouts" and "Event-Specific Trading Blackouts" provisions above.

Pre-Clearance of Transactions in Talis Stock

Q: Who is required to pre-clear and provide advance notice of transactions?

A: In addition to the requirements above, certain Talis employees (" **Specified Personnel**") face a further restriction: Even during an open trading window, they may not engage in any transaction in Talis's securities without first obtaining pre-clearance of the transaction from the Chief Financial Officer or the head of Legal or their designee at least two business days in advance of the proposed transaction. He or she will then determine whether the transaction may proceed and, if so, will direct the Compliance Coordinator (as identified in Talis's Section 16 Compliance Program) to help comply with any required reporting requirements under Section 16(a) of the Exchange Act. Pre-cleared transactions not completed within two business days will require new pre-clearance. Talis may choose to shorten this period. Specified Personnel are listed on Appendix B, which Talis may update in its discretion from time to time.

Q: Are individuals subject to pre-clearance required to provide advanced notice of stock option exercises?

A: Yes. Persons subject to pre-clearance must also give advance notice of their plans to exercise an outstanding stock option to the Compliance Coordinator. Once any transaction takes place, the officer, director, or applicable member of management must immediately notify the Compliance Coordinator so that Talis may assist in any Section 16 reporting obligations.

Q: What additional requirements apply to individuals subject to Section 16?

A: Officers and directors, who are subject to the reporting obligations under Section 16 of the Exchange Act, should take care to avoid short-swing transactions (within the meaning of Section 16(b) of the Exchange Act) and the restrictions on sales by control persons (Rule 144 under the Securities Act of 1933, as amended), and should file all appropriate Section 16(a) reports (Forms 3, 4, and 5), which are described in Talis's Section 16 Compliance Program, and any notices of sale required by Rule 144.

Other Information

Q: What happens if I violate our insider trading policy?

A: Violating our policies may result in disciplinary action, which may include termination of your employment or other relationship with Talis.

Q: What are the sanctions if I trade on material nonpublic information or tip off someone else?

A: In addition to disciplinary action by Talis—which may include termination of employment—you may be liable for civil sanctions for trading on material nonpublic information. The sanctions may include return of any profit made or loss avoided as well as penalties of up to three times any profit made or any loss avoided. Persons found liable for tipping material nonpublic information, even if they did not trade themselves, may be liable for the amount of any profit gained or loss avoided by everyone in the chain of tippees as well as a penalty of up to three times that amount. In addition, anyone convicted of criminal insider trading could face prison and additional fines.

Q: What is "loss avoided"?

A: If you sell common stock or a related derivative security before negative news is publicly announced, and as a result of the announcement the stock price declines, you have avoided the loss caused by the negative news.

Q: Who should I contact if I have questions about our insider trading policy or specific trades?

A: You should contact our head of Legal or our Chief Financial Officer.

Q: Do changes to this policy require approval by Talis's Board of Directors?

A: Yes. Changes to this policy require approval by Talis's Board of Directors or a duly appointed committee of the Board of Directors.

APPENDIX A

COVERED PERSONS

The following roles and individuals are subject to quarterly blackout windows:

Executive Leadership Team
All members of the executive leadership team

Management
Vice Presidents or above in any department

Disclosure Committee:
All members of the Disclosure Committee, as set forth in Talis's Corporate Disclosure Policy

Legal Department:
All personnel in the legal department

Finance Department:
All personnel in the finance department

Commercial Department:
Enterprise Account Executives, members of the Customer Success team and all other Directors and above in Commercial.

Other:
Individuals with administrator access to key enterprise systems including, but not limited to, NetSuite, Salesforce, Agiloft.

Individuals with any other user access to enterprise systems and platforms that would allow for visibility into key data including but not limited to national opportunities, critical customer or financial data (i.e. customer disputes, revenue, shipments), as determined by the CFO or head of Legal.

*This list is subject to change by the CFO or head of Legal.

REVISION APPROVED BY:
/s/ Rebecca L. Markovich

Rebecca Markovich
Interim Chief Financial Officer

Revised 20-Feb-2024

Appendix B

Specified Personnel*
(Non-Officer Employees and Designated Consultants Subject to Trading Pre-Clearance)

Trading in Talis stock by the following roles is subject to pre-clearance from CFO or head of Legal: Section 16 Officers and Directors

*This list is subject to change by the CFO or head of Legal.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

- Registration Statement (Form S-8 No. 333-273889) pertaining to the 2021 Equity Incentive Plan and the 2021 Employee Stock Purchase Plan of Talis Biomedical Corporation,
- Registration Statement (Form S-8 No. 333-266470) 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 28, 2024, 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, 2023.

/s/ Ernst & Young LLP

Chicago, Illinois
March 28, 2024

Exhibit 31.1

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

I, Robert J. Kelley, certify that:

1. I have reviewed this Annual Report on Form 10-K of Talis Biomedical Corporation;

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

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

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

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

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

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

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

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

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

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

Date: March 28, 2024

/s/ Robert J. Kelley

Robert J. Kelley
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Rebecca L. Markovich, 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 28, 2024

/s/ Rebecca L. Markovich.

Rebecca L. Markovich
Interim Chief Financial Officer
(*Interim Principal Financial and Accounting Officer*)

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Talis Biomedical Corporation (the "Company") for the year ending December 31, 2023 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 28, 2024

/s/ Robert J. Kelley

Robert J. Kelley
Chief Executive Officer
(Principal Executive Officer)

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

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K of Talis Biomedical Corporation (the "Company") for the year ending December 31, 2023 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 28, 2024

/s/ Rebecca L. Markovich.

Rebecca L. Markovich.
Interim Chief Financial Officer
(*Interim Principal Financial and Accounting 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.