2023

ANNUAL REPORT TO STOCKHOLDERS

T2Biosystems®

TO OUR STOCKHOLDERS, EMPLOYEES AND FRIENDS:

The T2 Biosystems team continues to make meaningful progress on our mission by providing clinicians with the tools to enable faster targeted antimicrobial treatment. We are focused on driving the adoption of our sepsis products – including the T2Dx® Instrument, the T2Bacteria® Panel, the T2Candida® Panel, and the T2Resistance® Panel – to improve patient outcomes, reduce the threat of antimicrobial resistance, drive long-term sustained growth, and enhance the standard of care for treating patients at risk of sepsis.

Sepsis is the body's overwhelming and often life-threatening response to infection that can lead to tissue damage, organ failure, and death. Sepsis is the leading cause of death in U.S. hospitals, claiming the lives of approximately 350,000 Americans annually. Sepsis also represents the leading cost of U.S. hospitalization, costing our healthcare system an estimated $62 billion annually. Lastly, sepsis is the leading cause of 30-day hospital readmission in the U.S., with 19% of sepsis survivors re-hospitalized within 30 days and 40% within 90 days. These statistics serve as a stark reminder of why T2 Biosystems exists – to deliver life-saving innovations to achieve targeted antimicrobial therapy, faster!

The current standard of care for treating patients at risk of sepsis relies on blood cultures, which can take 1-5 days, and the administration of antimicrobial therapy following empiric probability-based protocols, which are only optimal in about one-half of cases. Our aim is to enhance the current standard of care by enabling faster, targeted antimicrobial therapy through the deployment of our proprietary technology. T2 Biosystems has the only U.S. Food and Drug Administration (FDA) cleared products for detecting sepsis-causing pathogens directly from blood, in only 3-5 hours, without the need to wait days for a positive culture. In the battle against sepsis, speed is critical to achieving targeted antimicrobial therapy, as each hour of delayed treatment increases the risk of death by up to eight percent.

2023 MILESTONES

Our team achieved a number of important milestones during the 2023 calendar year that we expect to further advance our mission and pave the way for future success:

- Achieved full year 2023 total revenue of $7.2 million, including sepsis and related product revenue of $6.8 million and research and contribution revenue of $0.4 million.
- Executed contracts for 26 T2Dx Instruments in 2023, including 19 T2Dx Instruments from outside the U.S. and 7 T2Dx Instruments from the U.S.
- Expanded international distribution network to include the Netherlands, Belgium, Vietnam, and the re-entry into Switzerland.
- Submitted three FDA 510(k) premarket notifications, including 1) the T2Biothreat™ Panel to detect high-priority bioterrorism pathogens, 2) the T2Bacteria Panel expansion to include detection of *A. baumannii*, and 3) the T2Candida Panel extension to include pediatric testing.
- Received Phase 2 award from the U.S. Department of Health and Human Services and the Steven & Alexandra Cohen Foundation's LymeX Diagnostics Prize for the T2Lyme™ Panel.
- Advanced the T2Resistance Panel toward U.S. FDA 510(k) submission, expected to occur in the fourth quarter of 2024.
- Executed an agreement with CRG to convert $10 million of the outstanding term loan into shares of T2 Biosystems common and preferred stock.
- Amended term loan agreement with CRG, extending the maturity date and interest-only period to December 31, 2025, and reducing the minimum cash covenant from $5.0 million to $500,000.

2024 OUTLOOK

We are focused on three corporate priorities: 1) accelerating our sales, 2) enhancing our operations, and 3) advancing our pipeline. Commercially, we are focused on expanding the installed base of T2Dx Instruments and increasing the utilization of our sepsis test panels. Operationally, we are focused on increasing product gross margins and continuing to scale our manufacturing processes. Finally, our new product pipeline is focused on expanding the test menu on our FDA-cleared T2Dx Instrument – including the addition of novel direct from blood tests like the T2Resistance Panel, the T2Lyme Panel, and the expanded T2Candida Panel to add detection of *Candida auris*.

In closing, I would like to thank our stockholders, customers, and employees for their support as we continue to execute our mission to improve the lives of patients around the world.

John J. Sperzel III

Chairman, President, and Chief Executive Officer

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

☐ **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: 001-36571

T2 Biosystems, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-4827488**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
101 Hartwell Avenue, Lexington, MA	**02421**
(Address of principal executive offices)	**(Zip code)**

Registrant's telephone number, including area code: 781-761-4646

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, par value $0.001	TTOO	The Nasdaq Capital Market

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 of 1933, as amended. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended. 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, a smaller reporting company, or an emerging growth company. See 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. ☐

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). ☐

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

As of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $17.1 million based on the closing price for the common stock of $7.06 on that date. Shares of common stock held by each executive officer, director, and their affiliated stockholders have been excluded from this calculation as such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock on March 28, 2024 was 5,512,332.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy, prospective products and product candidates, their expected performance and impact on healthcare costs, marketing clearance from the U.S. Food and Drug Administration, or the FDA, regulatory clearance, reimbursement for our product candidates, research and development costs, timing of regulatory filings, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that 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. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "forecast," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described under the sections in this Annual Report on Form 10-K entitled "Item 1A.—Risk Factors." Unless required by U.S. federal securities laws, we do not intend to update any of these forward-looking statements to reflect circumstances or events that occur after the statement is made or to conform these statements to actual results.

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. In evaluating our company, you should consider carefully the summary risks and uncertainties described below together with the other information included in this Annual Report on Form 10-K, including the risks and uncertainties described in more detail in "Risk Factors" in Part I, Item 1A and our consolidated financial statements and related notes included in Part II, Item 8, "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K. The occurrence of any of the following risks may materially and adversely affect our business, financial condition, results of operations and future prospects;

- *our ability to continue as a going concern;*
- *our ability to regain and maintain compliance with Nasdaq listing requirements;*
- *our expectation that we will incur losses in the future and be unable to utilize limited net operating losses against future profitability, if any;*
- *compliance with the terms of our debt instruments;*
- *our future capital needs and our ability to raise additional funds;*
- *impact of litigation, including our ability to adequately resolve current legal claims;*
- *our status as an early-stage commercial company;*
- *the market acceptance of our technology;*
- *our ability to timely and successfully develop and commercialize our existing products and future product candidates;*
- *the length and variability of our anticipated sales and adoption cycle;*
- *our ability to gain the support of hospitals and key thought leaders and publish the results of our clinical studies in peer-reviewed journals;*
- *our ability to successfully manage our growth;*
- *fluctuations in demand for, and prices of, raw materials and other supplies;*
- *our ability to recruit, train and retain key personnel;*
- *the performance of our diagnostics;*
- *our ability to compete in the highly competitive diagnostics market;*
- *manufacturing and other product risks, including unforeseen interruptions in the manufacturing of our products and backlogs in order fulfillment;*
- *our dependence on third parties;*
- *the impact of cybersecurity risks, including ransomware, phishing, and data breaches on our information technology systems;*

- *our ability to obtain marketing clearance from the U.S. Food and Drug Administration or regulatory clearance or certifications for new product candidates in other jurisdictions. including IVDR in the European Union;*
- *federal, state, and foreign regulatory requirements, including diagnostic product reimbursements and FDA regulation of our products and product candidates;*
- *our ability to protect and enforce our intellectual property rights, including our trade secret-protected proprietary rights in our technology;*
- *an active trading market for our common stock;*
- *volatility of our stock price which may be impacted by short sellers and day traders; and*
- *our ability to maintain an effective system of internal control over financial reporting.*

PART I.

Item 1. BUSINESS

Overview

We are an in vitro diagnostics company and leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes. Our technology enables rapid detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, plasma, serum, saliva, sputum and urine, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter, or CFU/mL. We are currently targeting what we believe to be a range of critically underserved healthcare conditions, focusing initially on those for which rapid detection may enable faster targeted antimicrobial treatment, improve patient outcomes, and reduce cost. Our current focus includes three areas – sepsis, bioterrorism, and Lyme disease – which we believe collectively represent a multi-billion dollar market opportunity.

Our primary commercial products for the year ended December 31, 2023 include the T2Dx® Instrument, the T2Bacteria® Panel, the T2Candida® Panel, the T2Resistance® Panel, and the T2Biothreat™ Panel. Our sepsis products – including the T2Dx Instrument, the T2Bacteria Panel, and the T2Candida Panel – are FDA-cleared products able to detect sepsis-causing pathogens directly from blood. Where traditional diagnostics like blood cultures and post-culture diagnostics may take days to produce results, our products are designed to detect these pathogens in three to five hours. We believe our products provide a significant and sustainable competitive advantage compared to other products in our markets.

History

We were incorporated under the laws of the State of Delaware in 2006. In September 2014, we received marketing authorization from the United States Food and Drug Administration, or FDA, for our first two products, the T2Dx Instrument and the T2Candida Panel, or T2Candida. T2Candida, which runs on the T2Dx Instrument, has the ability to rapidly identify the five most clinically relevant species of *Candida*, a fungal pathogen known to cause sepsis, directly from blood specimens. The T2Dx Instrument and T2Candida were CE marked in the European Union, or the EU, in July 2014.

In May 2018, we received market clearance from the FDA for the T2Bacteria Panel, or T2Bacteria, which runs on the T2Dx Instrument and has the ability to rapidly identify six of the most common and deadly sepsis-causing bacteria directly from blood specimens. T2Bacteria was CE marked in the EU in June 2017.

In February 2019, our T2Resistance Panel, or T2Resistance, was granted FDA Breakthrough Device designation and, in November 2019, was CE marked in the EU. In December 2021, we initiated a U.S. clinical trial for T2Resistance. The clinical trial is expected to be completed in 2024, and we believe the data from this trial may enable submission of a marketing application to the FDA in 2024.

In September 2019, the Biomedical Advanced Research and Development Authority, or BARDA, an office of the U.S. Department of Health and Human Services, or HHS, awarded us a milestone-based contract for the development of a next-generation diagnostic instrument, a comprehensive sepsis panel and a multi-target biothreat panel. In September 2020, BARDA exercised the first contract option valued at $10.5 million. In April 2021, BARDA agreed to modify the contract to accelerate product development by advancing future deliverables and adding a U.S. T2Resistance Panel into Option 1 of the contract. In September 2021, BARDA exercised Option 2A valued at approximately $6.4 million to further advance the new product development initiatives. In December 2021, we initiated the U.S. clinical trials for T2Resistance and the T2Biothreat Panel, or T2Biothreat. In March 2022, BARDA exercised Option 2B valued at approximately $4.4 million. In May 2022, BARDA exercised Option 3 valued at approximately $3.7 million to complete the U.S. clinical trials for T2Resistance and T2Biothreat and subsequently submit applications to the FDA for U.S. regulatory clearance for those product candidates. In December 2022 the T2Biothreat clinical evaluation was completed. In May 2023, we submitted a 510(k) premarket notification to the FDA for T2Biothreat and in September 2023, we received 510(k) clearance from the FDA to market T2Biothreat. The BARDA contract expired in September 2023.

In June 2020, we launched a COVID-19 molecular diagnostic test, the T2SARS-CoV-2 Panel, or T2SARS-CoV-2, after validation of the test pursuant to the FDA's policy permitting COVID-19 tests to be marketed prior to receipt of an Emergency Use Authorization, or EUA, subject to certain prerequisites. In August 2020, the FDA granted an EUA to T2SARS-CoV-2 for the qualitative direct detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens and bronchoalveolar lavage specimens from individuals suspected of COVID-19 by their healthcare provider. We marketed and sold T2SARS-CoV-2 between 2020 and 2023, with peak sales occurring during 2021. In 2023, we experienced decreased demand for the product as the incidence of COVID-19 infections decreased significantly and, as a result, we have stopped marketing, selling and manufacturing T2SARS-CoV-2.

In July 2022, we received Breakthrough Device designation for the T2Lyme Panel, or T2Lyme, a direct-from-blood molecular diagnostic test designed to run on the T2Dx Instrument and detect *Borrelia burgdorferi*, the bacteria that cause Lyme disease. T2Lyme is intended to test individuals with signs and symptoms of Lyme disease and aid in the diagnosis of early Lyme disease. In November 2022, the HHS and the Steven

& Alexandra Cohen Foundation, or Cohen Foundation, selected T2 Biosystems as a Phase 1 winner in the LymeX Diagnostics Prize, a LymeX Innovation Accelerator prize competition intended to accelerate the development of Lyme disease diagnostics. As a Phase 1 winner, we received $100,000 and an invitation to participate in a second phase.

In July 2023, we received Breakthrough Device Designation for our *Candida auris* (*C. auris*) test, a direct-from-blood molecular diagnostic test designed to run on the T2Dx Instrument and detect *C. auris*. *C. auris* is a multidrug-resistant fungal pathogen recognized as a serious global health threat with a mortality rate of up to 60%, and is difficult to identify with standard laboratory methods, which can lead to inappropriate treatment. We plan to expand the test menu on the T2Dx Instrument by seeking 510(k) clearance from the FDA to add *C. auris* detection to the FDA-cleared T2Candida Panel.

In October 2023, we submitted a 510(k) premarket notification to the FDA to expand the number of pathogens detected on the FDA-cleared T2Bacteria Panel to include the detection of *Acinetobacter baumannii* (*A. baumannii*). *A. baumannii* is a cause of bloodstream infections especially in critically ill patients, which can range from a benign transient bacteremia to septic shock.

In December 2023, we submitted a 510(k) premarket notification to the FDA to expand the use of the T2Candida Panel to include pediatric testing. *Candida* species are a major contributor to morbidity and mortality in hospitalized children.

Clinical Need

Sepsis is the body's overwhelming and potentially life-threatening response to infection that can lead to tissue damage, organ failure, and death. Globally, sepsis causes the death of an estimated 11 million people each year, accounting for one in five deaths globally, and more deaths than all cancers combined. Sepsis is a leading cause of death in U.S. hospitals, claiming at least 350,000 American lives each year from patients who develop sepsis and die during their hospitalization or are discharged to hospice according to the CDC. Sepsis-related costs in U.S. hospitalizations total nearly $38 billion annually according to the US Agency for Healthcare Research & Quality in 2020. Finally, sepsis is a leading cause of 30-day hospital readmissions. Nearly 20% of sepsis survivors are re-hospitalized within 30 days after discharge, and nearly 40% of sepsis survivors are re-hospitalized within 90 days after discharge.

The rapid detection of sepsis-causing pathogens is critical as each hour of delayed targeted antimicrobial treatment increases mortality risk by up to 8%. Today, the standard of care for patients at risk of sepsis relies on broad empiric protocols to administer antimicrobial (i.e., antibiotic and antifungal) therapy, despite the fact that data shows those protocols are only optimal in approximately 50% of cases. The current standard of care continues to rely on a positive blood culture to identify the presence of a blood stream infection and target therapy for patients suspected of sepsis. However, studies show blood cultures can take 1-5 days to achieve the growth necessary for species identification and may. require multiple blood cultures to minimize false negative results.

Without the ability to rapidly identify pathogens, physicians typically start treatment of at-risk patients with broad-spectrum antimicrobials and switch therapies every 12 to 24 hours if a patient is not responding. These antimicrobials can be costly, are often ineffective and unnecessary, and have contributed to the spread of antimicrobial resistance. The administration of inappropriate antimicrobial therapy is a driving force behind the spread of antimicrobial-resistant pathogens, which the Centers for Disease Control and Prevention, or CDC, has called "one of our most serious health threats."

In 2021, the results of a meta-analysis were published in a peer-reviewed medical journal, Expert Review of Medical Devices, analyzing fourteen controlled studies and comparing the use of our sepsis products to the use of blood culture-based diagnostics. The use of our products resulted in species identification 77 hours earlier than blood culture-based diagnostics, enabled patients testing positive with T2's products to receive targeted antimicrobial therapy 42 hours earlier than blood culture-based diagnostics, enabled patients testing negative with T2's products to be de-escalated from empirical antimicrobial therapy seven hours earlier than those using blood culture-based diagnostics, and allowed a reduction of stay in the ICU and hospital of 5.0 and 4.8 days, respectively, compared to the use of blood culture-based diagnostics.

Products - Commercially Available

T2Dx Instrument

Our T2Dx Instrument, which is FDA-cleared and CE marked, is a fully automated, easy-to-use, bench-top instrument that is capable of running a broad range of diagnostic tests from patient samples, eliminating the need for manual workflow steps, such as pipetting, that can introduce risks of cross-contamination. To operate the system, a tube containing the patient's blood sample is placed onto a disposable test cartridge, which is pre-loaded with all necessary reagents and consumables. The cartridge is then inserted into the T2Dx Instrument, which automatically processes the sample and then delivers a diagnostic test result in three to five hours. Test results are displayed on screen and can be printed or connected directly to the hospital or laboratory information system.

The T2Dx Instrument eliminates the need for sample purification and analyte extraction often required by other diagnostic technologies, which increases sensitivity and specificity, enables a broad menu of tests to be run on a single platform, and greatly reduces the complexity of the consumables. The T2Dx Instrument is designed to have a simple user interface and to efficiently process up to seven specimens simultaneously.

The commercially available test panels are designed to run on the T2Dx Instrument include T2Bacteria, T2Candida, T2Resistance, and T2Biothreat.

T2Bacteria Panel

T2Bacteria, which is FDA-cleared and CE marked, is a direct-from-blood molecular diagnostic test panel that detects bacterial pathogens found in blood stream infections including: Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Escherichia coli. T2Bacteria received FDA clearance in 2018 after the clinical trial demonstrated overall sensitivity of 90% and overall specificity of 98%. In October 2023, we submitted a 510(k) premarket notification to the FDA to expand the number of pathogens detected on the FDA-cleared T2Bacteria Panel to include the detection of Acinetobacter baumannii and we received FDA 510(k) clearance in February 2024. These six bacterial pathogens account for approximately 75% of bacterial blood stream infections. These pathogens are often referred to as the ESKAPE pathogens, which are responsible for the majority of nosocomial infections and are often capable of "escaping" the biocidal action of antimicrobial agents, exhibiting multidrug resistance and virulence.

A systematic review of the clinical and economic impact of antibiotic resistance reveals that the ESKAPE pathogens are associated with the highest risk of mortality, thereby resulting in increased health care costs. In the T2Bacteria clinical trial, the mean time for the T2Bacteria Panel to result was 6.46 hours, while the result for blood culture was substantially longer with a mean time to result of 123.8 ± 9 hrs. for a negative result and 51.0 ± 43.0 hrs. for a positive result, and the mean time to species identification was 83.7 ± 47.6 hours. A study published in the Microbiology Open found that T2Bacteria decreased the time to species identification on average by 55 hours faster than blood culture. The rapid detection and identification of the pathogens by T2Bacteria in positive specimens also allowed for the early antimicrobial stewardship interventions with faster initiation of an effective targeted antibiotic therapy in some of the patients, which was captured in another study presented by Paggi R, et al. July 2021 with 29.2% of patients with T2Bacteria positive results switched to an appropriate therapy. In a 2019 study published in Open Forum Infectious Diseases, the data showed that patients diagnosed using T2Bacteria had shorter hospital stays, on average, as compared with patients diagnosed using blood culture alone. In August 2019, Centers for Medicare & Medicaid Services, or CMS, granted approval for a New Technology Add-on Payment, or NTAP, for T2Bacteria, effective October 1, 2019, which was extended until September 30, 2022. In its 2020 inpatient prospective payments system final rule, CMS explained: "the T2Bacteria Panel represents a substantial clinical improvement over existing technologies because it reduces the proportion of patients on inappropriate therapy, thus reducing the rate of subsequent diagnostic or therapeutic intervention as well as length of stay and mortality rates caused by sepsis causing bacterial infections."

We believe T2Bacteria can enable clinicians to achieve faster targeted antibiotic therapy, improve patient outcomes, and reduce costs. We further believe that the adoption of the T2Dx Instrument and T2Bacteria can enable clinicians to make earlier and more informed decisions by providing positive test results to direct therapy and negative test results to reduce the use of antibiotics.

T2Candida Panel

T2Candida, which is FDA-cleared and CE marked, is a direct-from-blood molecular diagnostic test panel that detects the most lethal form of common blood stream infections that cause sepsis, candidemia, which has an average mortality rate of approximately 40%. T2Candida detects five species of *Candida*, directly from certain human whole blood specimens, including *Candida albicans*, *Candida tropicalis*, *Candida krusei*, *Candida glabrata*, and *Candida parapsilosis*. T2Candida received FDA clearance in 2014 after the clinical trial demonstrated overall sensitivity of 91% and overall specificity of 99%. These five *Candida* species account for approximately 90% of *Candida* blood stream infections.

According to a 2005 report published in Antimicrobial Agents and Chemotherapy, the high mortality rate associated with *Candida* infection can be reduced to 11% with the initiation of targeted therapy within 12 hours of presentation of symptoms. Currently, a typical patient with a *Candida* infection averages 40 days in the hospital, including nine days in intensive care, resulting in an average cost per hospital stay of over $130,000 per patient. In a study published in the American Journal of Respiratory and Critical Care Medicine in 2009, providing targeted antifungal therapy within 24 hours of the presentation of symptoms decreased the length of hospital stay by approximately ten days and decreased the average cost of care by approximately $30,000 per patient. In addition, many hospitals initiate antifungal drugs, such as caspofungin or micafungin, while waiting for blood culture-based diagnostic results. We estimate this practice costs approximately $500 per patient and is currently in use for over 40% of high-risk patients on average and for all high-risk patients in some hospitals. A negative result from T2Candida can provide timely data allowing physicians to avoid unnecessary antifungal treatment and potentially reduce the treatment cost further. In 2014 we received FDA marketing authorization for T2Candida in the U.S. and in July 2014 T2Candida was CE marked in the EU.

In April 2015, *Future Microbiology* published the results of an economic study regarding the use of T2Candida conducted by IMS Health, a healthcare economics agency. In the study, IMS demonstrated that an average hospital admitting 5,100 patients at risk for *Candida* infections could save approximately $5.8 million annually due to decreased hospital stays for patients, reduction in use of antifungal drugs and other associated savings. The economic study further showed T2Candida potentially reduced the costs of care by $26,887 per *Candida* patient and that

rapid detection of *Candida* reduced patient deaths by 60.6%. Results from a data analysis of T2Candida for the detection and monitoring of *Candida* infection and sepsis were published comparing aggregated results from the use of T2Candida to blood culture-based diagnostics for the detection of invasive candidiasis and candidemia. The analysis included samples acquired from more than 1,900 patients. Out of 55 prospective patient cases that were tested with T2Candida and blood culture and determined to be positive or likely to be positive for a *Candida* infection, T2Candida detected 96.4% of the patients (53 cases) compared to blood culture which detected only 60% of the patients (33 cases).

Candidiasis disproportionally affects critically ill children, and we believe a pediatric testing claim for our FDA-cleared T2Candida will allow clinicians to improve outcomes and reduce cost by achieving faster targeted antifungal treatment for their pediatric patients. According to the *Journal of Fungi*, a peer-reviewed scientific journal that provides an advanced forum for studies related to pathogenic fungi, *Candida* species are a major contributor to morbidity and mortality in hospitalized children. Additionally, children with invasive candidiasis present a significant burden to the U.S. healthcare system, with a mean increased hospital length of stay of 21 days and approximately $92,000 in excess hospital costs.

Clinical use in Europe and research studies in the United States indicate the strong potential utility for T2Candida in pediatric patients. A *Journal of Clinical Microbiology* (2022) study conducted at the Bambino Gesù hospital in Rome, Italy found that pediatric patients suspected of fungal bloodstream infections that were tested with T2Candida received species identification results 121.8 hours faster compared to blood culture. The study also found a higher detection rate with T2Candida as six additional probable or possible fungal bloodstream infections in pediatric patients were detected by T2Candida and missed by blood culture. In addition, a prospective observational study published in *Clinical Infectious Diseases* (2022) evaluated the performance of four pre-blood culture tests for detecting the presence of invasive candidiasis in pediatric patients and found that T2Candida had the highest sensitivity and specificity of all four assays among five hundred patients enrolled. T2Candida was the only test recommended for individual use as a tool for the diagnosis of invasive candidiasis in at-risk children and adolescents.

We believe T2Candida can enable clinicians to achieve faster targeted antifungal therapy, improve patient outcomes, and reduce costs. We further believe that the adoption of the T2Dx Instrument and T2Candida can decrease the high mortality rate of *Candida* infections because these products can enable clinicians to make earlier and more informed decisions by providing positive test results to direct therapy and negative test results to reduce the use of antifungal drugs.

T2Resistance Panel

T2Resistance, which is CE marked, is a direct-from-blood molecular diagnostic test panel that simultaneously detects thirteen antibiotic resistance genes from both gram-positive and gram-negative pathogens. T2Resistance is designed to identify the most clinically important carbapenem resistance genes KPC, OXA-48, NDM, VIM, and IMP. Carbapenem resistance has been listed on the CDC Urgent Threat list for antibiotic resistance according to the latest CDC “AR Threats Report”. T2Resistance also detects a major source of extended spectrum beta lactamases, or ESBLs, CTXM-14 and CTXM-15; AmpC beta-lactamase genes (CMY, DHA); *vanA vanB* resistance genes, which are responsible for vancomycin resistant gram-positive enterococcus; and the detection of the methicillin resistance genes *mecC* and *mecA*, which cause methicillin resistant Staphylococcus aureus. Clinical performance data demonstrated that the T2Resistance Panel identified carbapenemase resistance genes with an average time of 5.3 hours. Antibiotic resistance was recognized by the World Health Organization in 2017 as “one of the biggest threats to global health, food security, and development today” and in 2022 released the Global Antimicrobial Resistance and Use Surveillance System (GLASS) report.

T2Resistance received FDA Breakthrough Device designation in February 2019 and CE marked in the EU in November 2019 and is available for purchase in the United States as a Research-Use-Only, or RUO, product, meaning that it is in the laboratory research phase of development and is being shipped or delivered for an investigation that is not subject to FDA regulations governing investigational device studies. In December 2021 we initiated a U.S. clinical trial for the T2Resistance Panel. The clinical trial is expected to be completed in 2024, and we believe the data from this trial may enable submission of a marketing application to the FDA in 2024.

We believe T2Resistance can help to prevent the spread of multidrug-resistant organisms and improve patient outcomes by enabling rapid identification of the genes associated with antibiotic resistance – enabling correct targeted therapy and the reduction of unnecessary antibiotic use, which is a primary cause of antibiotic resistance. We further believe that the adoption of the T2Dx Instrument and T2Resistance can enable more patients to get on appropriate targeted therapy faster, thereby reducing mortality and lowering hospitalization costs.

T2Biothreat Panel

T2Biothreat is a direct-from-blood molecular diagnostic test panel that runs on the T2Dx Instrument and simultaneously detects six biothreat pathogens, including the organisms that cause 1) anthrax (*Bacillus anthracis*); 2) tularemia (*Francisella tularensis*); 3) glanders (*Burkholderia mallei*); 4) melioidosis (*Burkholderia pseudomallei*); 5) plague (*Yersinia pestis*); and 6) typhus (*Rickettsia prowazekii*). These pathogens have been identified as threats by the CDC and identified as material biological threats under section 319-2(c)(2)(A)(ii) of the Public Health Service Act. If not treated promptly, these pathogens can have mortality rates of 40-90%. T2Biothreat is indicated as an aid in the diagnosis of anthrax, tularemia, melioidosis, glanders, typhus fever and plague.

In December 2021, we initiated a U.S. clinical evaluation for T2Biothreat that included positive samples being prepared and analyzed at a high-containment Biosafety Level 3 laboratory and negative samples being analyzed at a clinical site. Our clinical evaluation of T2Biothreat demonstrated positive percent agreement, or sensitivity, of 100% for all targets except *Francisella tularensis*, which was 94.3%, and negative

percent agreement, or specificity, for all six targets of 100%. On May 8, 2023, we submitted a 510(k) premarket notification to the FDA for T2Biothreat. On September 19, 2023, we received 510(k) clearance from the FDA for T2Biothreat.

The six biothreat pathogens detected by the T2Biothreat are identified as biological threats by the U.S. Administration for Strategic Preparedness and Response, or ASPR. ASPR engages partners through Public Health Emergency Medical Countermeasures Enterprise activities to share information and coordinate plans and actions to ensure the nation has and can use medical countermeasures to protect Americans during disasters and emergencies resulting from known and unknown chemical, biological, radiological, or nuclear threats and emerging infectious diseases.

We believe T2Biothreat can help to protect Americans from the consequences of deliberate or naturally occurring outbreaks of these biothreat pathogens by enabling clinicians to achieve faster targeted antibiotic therapy, improve patient outcomes, and reducing mortality. We further believe that the adoption of the T2Dx Instrument and T2Biothreat can enable clinicians to make earlier and more informed decisions by providing positive test results to direct therapy and negative test results to reduce the use of antibiotics.

Products In Development

T2Lyme Panel

T2Lyme is a direct-from-blood molecular diagnostic test designed to run on the T2Dx Instrument and detect *Borellia burgdorferi*, the bacteria that causes Lyme disease. We believe T2Lyme may benefit from similar advantages provided by our technology, including the potential for high sensitivity, high specificity, ease of use and more rapid time to result. T2Lyme is designed to provide accurate and timely diagnosis of early Lyme disease, enabling faster targeted treatment, with the goal of preventing the evolution of the disease to its later stages with associated neurological and musculoskeletal diseases.

According to the CDC, Lyme disease affects approximately 30,000 people in the U.S. each year, but the CDC also estimates that the actual number is closer to 476,000 due to under-reporting because of poor diagnostic methods. Approximately 3.4 million tests are run for Lyme disease each year, including serology testing, PCR techniques and blood culture, which has low sensitivity and takes approximately two to three weeks to provide results. Inadequate identification of Lyme disease may lead to antibiotic resistance, significant costs, and transmission of the disease through healthcare procedures such as blood transfusion. The misdiagnosis of Lyme disease has been reported to have an annual cost of more than $10,000 per patient in the United States, representing over $3 billion per year.

We believe that our technology can address the significant unmet need associated with Lyme disease, a tick-borne illness that can cause prolonged neurological disease and musculoskeletal disease. For patients with Lyme disease, early diagnosis and appropriate treatment significantly reduces both the likelihood of developing neurological and musculoskeletal disorders, as well as the significant costs associated with treating these complications. Multiple diagnostic methods are used to test for Lyme disease today, which are labor-intensive, can take weeks to process, and are subject to high false negative rates due to their inability to detect the disease, making each method unreliable in the diagnosis of the condition. Because of these limitations, patients are frequently misdiagnosed or are delayed in the diagnosis of this disease.

In November 2022, the T2Lyme Panel was selected as a Phase 1 winner of the LymeX Diagnostics Prize, a LymeX Innovation Accelerator prize competition, a partnership between the HHS and Cohen Foundation, the largest public-private partnership for Lyme disease, that includes up to $10 million in funding to accelerate the development of Lyme disease diagnostics. The T2Lyme Panel received FDA Breakthrough Device designation in July 2022 as an aid in the diagnosis for the detection of early Lyme disease caused by *Borrelia burgdorferi*, directly from human whole blood. We are currently exploring commercial opportunities with partners and initially plan to launch T2Lyme as a Laboratory Developed Test, or LDT.

T2Cauris Panel

Our T2Cauris™ Panel is a direct-from-blood molecular diagnostic test designed to run on the T2Dx Instrument and detect *Candida auris*. We currently intend to complete product development and seek FDA 510(k) clearance to include the detection of *Candida auris* on T2Candida, which is already FDA-cleared and CE marked. T2Cauris received FDA Breakthrough Device designation in July 2023.

Candida auris, or *C. auris*, is a multi-drug resistant pathogen recognized by the CDC as a serious global health threat. *C. auris* has a mortality rate of up to 60% and some strains of *C. auris* are resistant to all three available classes of antifungal therapies. According to the CDC, *C. auris* is difficult to identify with standard laboratory methods, including blood culture, which can lead to inappropriate treatment. Unlike most other species of *Candida*, *C. auris* can spread quickly in a hospital and rapid detection may assist in containing these outbreaks. The CDC has called on public health professionals to help lower the burden of fungal disease by continuing to raise awareness of the life-saving benefits of early diagnosis and proper treatment.

Reported cases of *C. auris* have surged internationally, and the CDC has reported a significant increase in infected patients in the United States since the CDC issued an alert on *C. auris* in 2016. According to the European Centre for Disease Prevention and Control, hospital outbreaks have occurred in the United Kingdom and Spain. Because *C. auris* can be resistant to most antifungal treatment options and can spread so quickly, these hospital outbreaks have been difficult to contain.

We previously collaborated with the CDC regarding *C. auris* detection using our technology. The goals of the CDC collaboration were to use the T2Dx Instrument to (i) validate the detection of *C. auris* from patient skin samples and hospital environmental samples, (ii) validate a process for surveillance of *C. auris* in healthcare facilities from skin and environmental samples, and (iii) assist state and local public health labs in combating the outbreak. The CDC evaluated the T2Cauris swab test on patient skin samples and published their findings in *Mycoses*. Additionally, in a study presented at ASM Microbe 2018 regarding the detection of *C. auris*, it was found that our technology provided accurate diagnostic results from patient skin samples.

Following our collaboration with the CDC, we have completed feasibility and early development of a diagnostic test to detect the *C. auris* pathogen directly-from-blood and we plan to seek FDA 510(k) clearance to add this test to T2Candida. We believe adding *C. auris* detection to our existing T2Candida Panel will increase the value proposition of T2Candida by covering approximately 95% of all sepsis-causing *Candida* pathogens commonly found in blood stream infections. The current FDA-cleared T2Candida Panel simultaneously detects five *Candida* species, including *Candida albicans*, *Candida tropicalis*, *Candida parapsilosis*, *Candida krusei*, and *Candida glabrata*. Rapid detection of these pathogens, as well as *Candida auris*, is essential to getting infected patients on appropriate antifungal therapy, improving patient outcomes, and reducing cost.

Strategy

Our objective is to establish our products as the standard of care for clinical diagnostics. To achieve this objective, our strategy is to focus on the following three corporate objectives:

- ***Accelerating our Sales.*** Our sales strategy consists of two primary objectives: 1) increasing our sepsis test panel revenue by driving broader utilization among new and existing customers, and 2) expanding our T2Dx Instrument installed base globally by selling or placing new instruments.
- ***Enhancing our Operations***. Our operations strategy consists of four primary objectives: 1) reducing inventory, 2) reduce scrap, 3) improve on-time delivery, and 4) complete Oracle ERP system cutover. We believe that we will continue to meet our current manufacturing needs with our operations at our Lexington and Wilmington, Massachusetts facilities.
- ***Advancing our Pipeline***. Our product pipeline strategy is focused on expanding the test menu on the T2Dx Instrument and consists of three primary objectives: 1) developing new tests or test panels, 2) completing clinical evaluation, and 3) obtaining regulatory clearance (e.g., FDA 510(k), CE mark, etc.).

Sales, Marketing and Distribution

Our sales team and our distribution partners employ a strategic approach focusing on the clinical value of our products, improved patient outcomes and economic value for hospitals, including providing these hospitals with a customized budget-impact analysis. They also demonstrate the ease-of-use of our products and highlight the advantages of our products over existing culture-based diagnostics and empiric therapy practices.

In the U.S., we market and sell the T2Dx Instrument, T2Bacteria Panel, and T2Candida Panel products directly to hospitals. We have received FDA 510(k) clearance for these products, and we expect to receive FDA 510(k) clearance for additional products currently in our pipeline. At the end of 2023, our direct commercial organization consisted of 27 people, including sales, marketing, medical affairs, service, and support. If hospitals optimize the full extent of our technology, we expect a positive network effect in the hospital community, helping to accelerate adoption of T2Bacteria and T2Candida. We believe key aspects of healthcare reform, including a sensitivity to the growing problem of antimicrobial resistance, the focus on cost containment, risk-sharing, and outcomes-based treatment and reimbursement, are aligned with the value proposition of our sepsis products, helping to contribute positively to their adoption.

Internationally, we market and sell the T2Dx Instrument, T2Bacteria, T2Candida, and T2Resistance products through territory exclusive distribution partners. We have received marketing authorization, or certifications, covering Europe, Australia, and certain countries in the Middle East, Latin America, Asia Pacific, and Africa, and expect to seek regulatory authorizations or certifications in additional international markets. We have affixed a CE mark on the T2Dx Instrument and the T2Candida, T2Bacteria and T2Resistance panels. As of the end of 2023, we had distributors throughout the EU, and in a growing number of countries in Asia Pacific, Latin America, and the Middle East. These distributors typically have strong, existing relationships with key opinion leaders, have relationships with important hospitals in their respective countries, and have experience marketing and selling infectious disease and/or microbiology products. We have employed a small regionally-focused commercial team of business managers and field service personnel primarily to support the efforts of our international distributors, and we plan to further expand our distribution channels in other key international markets.

We are marketing, and intend to sell, T2Biothreat directly to U.S. government agencies tasked with defending the United States from bioterrorism threats.

Customers

Our total revenues are concentrated among a small number of large customers. For fiscal year 2023, two customers represented 29% of our total revenue, and for fiscal year 2022 our BARDA contract represented 50% of our total revenue. For a discussion of risks related to customer concentration, see "Risk Factors - We have relied on a few large customers for a significant portion of our business, and the loss of any of these customers has in the past and could in the future materially and adversely impact our results of operations and financial condition." and Note 2, Significant Accounting Policies, to the Consolidated Financial Statements included in Part II, Item 8, Financial Statements and Supplementary Data, of this Annual Report on Form 10-K.

Medical and Clinical Affairs

We believe the key decision-makers at hospitals are infectious disease and critical care physicians, laboratory directors, hospital pharmacy, chief medical officers, and hospital administrators. Accordingly, we continue to educate these key decision makers through in-person meetings, publishing scientific data in peer-reviewed journals, presenting at major industry conferences, and conducting and supporting clinical studies. Our clinical and medical affairs team is raising awareness by amplifying clinical value messaging for our products. The team is actively engaged with key opinion leaders to generate and share real world data via scientific journal publications, at medical conferences, and at industry trade shows. During 2023, our products were mentioned in over 35 publications, posters, and presentations.

In response to the severity and complexity of managing bloodstream infections, a growing number of hospitals have instituted sepsis committees or antimicrobial stewardship committees to control hospital practices related to infections, including the use of antibiotic and antifungal therapy. These committees typically include key decision-makers, and we believe they can provide a central forum to present the benefits of our products. In addition, we plan to continue to publish scientific data in peer-reviewed journals, present at major medical and scientific conferences and conduct and support clinical trials to provide additional data relative to the performance of T2Bacteria, T2Candida, and T2Resistance to these key decision-makers.

Manufacturing

We manufacture our proprietary T2Dx Instrument, and our sepsis test panels and reagents at our manufacturing facilities in Lexington and Wilmington, Massachusetts. We perform all manufacturing and packaging of final components in accordance with applicable guidelines for medical device manufacturing. Our particles are supplied by a sole source supplier, Cytiva (a Danaher company), formerly GE Healthcare. We believe we can secure arrangements with other suppliers on commercially reasonable terms for the products and parts we outsource.

We have implemented a quality management system designed to comply with FDA regulations and International Standards Organization, or ISO, standards governing medical device products. These regulations govern the design, manufacture, testing, release, installation and service of diagnostic products as well as raw material receipt and control. We have received ISO 13485:2016 certification from the National Standards Authority of Ireland. Our key outsourcing partners are also ISO-certified.

We plan to continue to manufacture components that we determine are proprietary or require special processes to produce, while outsourcing the supply of more commodity-like components. We expect to establish additional outsourcing partnerships as we manufacture more products. We believe our facilities in Lexington and Wilmington, Massachusetts are adequate to meet our current manufacturing needs and that additional manufacturing space is readily available for future expansion.

During 2023, we experienced process and raw material challenges that impacted our ability to timely deliver our sepsis test panels to our global customers. We took a variety of actions to address these challenges, including the hiring of a new Vice President of Operations, advanced procurement of raw materials, process improvements, and investments in equipment. As of the end of December 2023, we had resolved the backorders for T2Bacteria and T2Candida, and as of the end of January 2024, we had resolved the backorder for T2Resistance.

Raw Materials

We purchase many different types of raw materials, including plastics, magnets, metals, electronic and mechanical sub-assemblies and various biological and chemical products. We seek to ensure continuity of raw material supply by securing multiple options for sourcing and also review relevant sources for compliance with conflict minerals requirements. Some of our components are custom-made by only a handful of external suppliers. In certain instances, we have a sole source supply for key product components of the T2Dx Instruments and certain components for our test kits. We have entered into supply agreements with most of our suppliers to help ensure component availability and flexible purchasing terms with respect to the purchase of such components. We have reviewed our suppliers and quantities of key materials and believe we have sufficient stocks and alternate sources of critical materials should our supply chains become disrupted, although raw materials and plastics for the manufacturing of reagents and consumables are in high demand, and interruptions in supply are difficult to predict. We are also experiencing cost increases from many of our suppliers, primarily as a result of increased inflation. The areas of cost increases include raw materials, components, and value-add supplier labor. We believe that we can continue to take actions to limit the impact of cost increases on such devices, including bulk purchases and entering into long term supply agreements. See *"Risk Factors - Risks Related to Our Business and Strategies - We*

utilize third-party, single-source suppliers for some components and materials used in our products and product candidates, and the loss of any of these suppliers could have an adverse impact on our business." for additional information.

Intellectual Property

We strive to protect and enhance the proprietary technologies that we believe are important to our business and seek to obtain and maintain patents for any patentable aspects of our product and product candidates, including their methods of use and any other inventions that are important to the development of our business. We own or exclusively license over 40 issued U.S. patents and U.S. patent applications. We also own or license over 50 pending or granted counterpart applications worldwide. We possess substantial know-how and trade secrets which protect various aspects of our business and products. The patent families comprising our patent portfolio are primarily focused on protection of a range of general and specific attributes of our proprietary assay architecture and assay instrumentation for our T2Bacteria, T2Candida, T2Resistance, T2Biothreat, T2Lyme, and T2Cauris Panels and our product candidates, as well as protection of certain aspects of the conduct of the assays and detection of analytes. The Company's patent portfolio includes issued patents that cover T2Bacteria, T2Candida and T2Lyme.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important proprietary technology, inventions and know-how related to our business, including our methods, processes and product candidate designs, and our ability to defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on trademarks, copyrights, know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the fields targeted by our products and product candidates. Protecting these rights is a primary focus in our relationships with other parties, and we seek to protect such rights, in part, by entering into confidentiality and non-disclosure agreements with such third parties and including protections for such proprietary information and intellectual property rights in our other contracts with such third parties, including material transfer agreements, licenses and research agreements.

Proprietary Rights and Processes

We rely, in some circumstances, on proprietary technology and processes (including trade secrets) to protect our technology. However, these can be difficult to protect. We require all full-time and temporary employees, scientific advisors, contractors and consultants working for us who have access to our confidential information to execute confidentiality agreements in order to safeguard our proprietary technologies, methods, processes, know-how, and trade secrets. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. All of our full-time and temporary employees and independent contractors and consultants are also bound by invention assignment obligations, pursuant to which rights to all inventions and other types of intellectual property conceived by them during the course of their employment are assigned to us.

While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. To the extent that our employees, consultants, scientific advisors, contractors, or any future collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Further, any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed or misappropriated, or such intellectual property and proprietary rights may not be sufficient to provide competitive advantages. For more information, please see "Risk Factors - Risks Related to Intellectual Property."

Trademarks

We have trademarks and intend to continue to seek trademark protection.

License Agreements

In 2006, we entered into an exclusive license agreement with Massachusetts General Hospital, or MGH, pursuant to which MGH granted to us an exclusive, worldwide, sublicensable license under certain patent rights to make, use, import and commercialize products and processes for diagnostic, industrial and research and development purposes. In 2008 and 2011, we amended our agreement with MGH to add patent rights and to modify, among other things, our diligence and payment obligations.

We are required to use reasonable commercial efforts to develop and make available to the public products and processes covered by the agreement, and to achieve specified organizational, development and commercialization milestones by specified dates. To date, we have met all of our diligence obligations pursuant to this agreement.

We paid MGH an upfront fee and issued to MGH shares of our common stock equal to a low single-digit percentage of our then-outstanding common stock, subject to limited adjustments to prevent dilution in certain circumstances. In addition, we are responsible for reimbursing MGH's

costs associated with prosecution and maintenance of the patent rights licensed to us under the agreement. We will also be required to make payments for achievement of specified regulatory milestones with respect to products and processes covered by the agreement. In addition, we are required to pay an annual license maintenance fee, which is creditable against any royalty payments we are obligated to make to MGH under the agreement.

We are required to pay royalties to MGH on net sales of products and processes that are covered by patent rights licensed to us under the agreement at percentages in the low single digits, subject to reductions and offsets in specified circumstances. The products and processes covered by the agreement include T2Bacteria, T2Candida and other particle-based test panels that we may develop in the future. Our royalty obligations, if any, and their duration, will depend on the specific patent rights covering the product or process being sold, and the particular category of product or process, as noted above. With respect to T2Bacteria, T2Candida and other potential particle-based test panels we may develop in the future, our obligation to pay royalties to MGH will expire upon the later of ten years after the first commercial sale of the first product or process in the particular category and the expiration of the patent rights licensed to us under the agreement. We will also be required to pay to MGH a low double-digit percentage of specified gross revenue that we receive from our sublicensees. In addition, we will be required to pay royalties to MGH of less than one percent on net sales of specified products and processes that are not covered by the patent rights licensed to us under the agreement. Our obligation to pay royalties to MGH with respect to such products and processes will expire upon the earlier of 12 years after the first commercial sale of the first such product or process and the termination by MGH of all of the licenses granted to us under the agreement.

We have the right to terminate our agreement with MGH for any reason upon 90 days' written notice to MGH. MGH may terminate our agreement in its entirety if we fail to make a payment required under the agreement and do not cure such failure within a specified time period, if we fail to maintain adequate insurance coverage or if we become insolvent. MGH may also terminate our agreement, with respect to a given category of products or processes, on 60 days' notice for our uncured breach with respect to such category of products or processes. Absent earlier termination, our agreement with MGH will remain in force until the later of the expiration or abandonment of the licensed patents and patent applications, and the expiration of our obligations under the agreement.

Supply Agreement with SMC Ltd.

We are currently party to a supply agreement with SMC Ltd. for the supply and manufacture of plastic injection molded parts that are used across all T2 Biosystems' test panels. The agreement contains other terms and conditions generally consistent with an agreement for the manufacture and supply of materials or products for use in the development and commercialization of diagnostics such as our products and product candidates, including with respect to ordering, supply of such product in accordance with specifications, and quality assurance and quality control activities.

The supply agreement may be terminated prior to the end of its term upon the occurrence of certain specified events and further provides that upon termination, including upon the expiration of the term, SMC shall continue to manufacture and ship products subject to outstanding purchase orders and we shall be responsible for purchasing finished products, inventory, raw materials and work-in-progress held by SMC to the extent SMC, after the use of commercially reasonable efforts to use such inventory, cannot use such inventory in a financially viable way.

BARDA Contract

In September 2019, BARDA awarded us a milestone-based contract for the development of a next-generation diagnostic instrument, a comprehensive sepsis panel and a multi-target biothreat panel. In September 2020, BARDA exercised the first contract option valued at $10.5 million. In April 2021, BARDA agreed to modify the contract to accelerate product development by advancing future deliverables and adding a U.S. T2Resistance Panel into Option 1 of the contract. In September 2021, BARDA exercised Option 2A valued at approximately $6.4 million to further advance the new product development initiatives. In December 2021, we initiated the U.S. clinical trials for the T2Resistance Panel and T2Biothreat Panel. In March 2022, BARDA exercised Option 2B valued at approximately $4.4 million. In May 2022, BARDA exercised Option 3 valued at approximately $3.7 million to complete the U.S. clinical trials for the T2Resistance Panel and T2Biothreat Panel and subsequently submit applications to the FDA for U.S. regulatory clearance for those product candidates. In December 2022, the T2Biothreat clinical evaluation was completed. In May 2023, we submitted a 510(k) premarket notification to the FDA for the T2Biothreat Panel and in September 2023, we received 510(k) clearance from the FDA to market the T2Biothreat Panel. The BARDA contract expired in September 2023

Competition

While we believe that we are currently the only diagnostic company with FDA-cleared or CE marked commercial products capable of detecting sepsis-causing pathogens and antibiotic resistance genes directly from blood in three to five hours, at limits of detection as low as 1 CFU/mL, without the need to wait days for a positive blood culture, we compete with commercial diagnostics companies for the limited resources of our customers. Our principal competition is from a number of companies that offer blood culture-dependent diagnostic platforms, most of which are more established commercial organizations with considerable name recognition and significant financial resources.

Companies that currently provide traditional blood culture-based diagnostics include Becton Dickinson & Co. and bioMerieux, Inc. In addition, companies offering post-culture species identification using both molecular and non-molecular methods include bioMerieux, Inc. (and its affiliate, BioFire Diagnostics, Inc.), Bruker Corporation, Accelerate Diagnostics, Luminex, Roche, Cepheid and Beckman Coulter, a Danaher company. These post-culture competitors rely on a positive result from blood culture in order to perform their tests, significantly prolonging their results when compared to our technology. Some of the products offered by our competitors require hours of extensive hands-on labor by an operator, while some rely on high concentrations of pathogens present in a positive blood culture, which can require a final concentration of at least 1,000,000 CFU/mL. In addition, there may be a number of new market entrants in the process of developing other post-blood culture diagnostic technologies that may be perceived as competitive with our technology. Karius, Inc. offers a lab developed culture independent diagnostic test for the identification of pathogens that has not been cleared by the FDA but may be perceived as competitive with our technology.

We believe that we have a number of competitive advantages, including:

- our products' ability to detect targets directly from blood, without the need to wait days for positive blood culture results;
- our products' ability to provide rapid, highly-sensitive and highly-specific diagnostic results, which can provide timely information to enable clinicians to make therapeutic decisions that can improve patient outcomes and reduce healthcare costs;
- our products' ability to detect a broad range of targets, providing a wider variety of potential applications both within and outside of the *in vitro* diagnostics market;
- our applications in the field of sepsis that we believe will not require separate reimbursement codes due to the established payment and reimbursement structure in place;
- our applications may provide substantial economic benefits to hospitals that can accrue the savings related to the rapid treatment of sepsis patients; and
- our ability to develop easily operable products for end users.

Government Regulation

Our products and our operations are subject to significant government regulation by the FDA and other federal, state, and local regulatory authorities, as well as comparable authorities in other jurisdictions. Our products are subject to regulation as medical devices under the Federal Food, Drug, and Cosmetic Act, or FDCA, as implemented and enforced by the FDA.

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

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical studies;
- product safety;
- marketing, sales and distribution;
- pre-market clearance, certification, and approval;
- record keeping procedures;
- advertising and promotion;
- recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market approval studies; and
- product import and export.

FDA Premarket Clearance and Approval Requirements

Each medical device we seek to commercially distribute in the United States must first receive 510(k) clearance, *de novo* classification, or pre-market approval, or PMA, from the FDA, unless specifically exempted by the FDA. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of

manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device based on the substantial equivalence of the device to a previously cleared device using the same pathway. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device are categorized as Class III. These devices require submission and approval of a PMA application.

510(k) Clearance Process

A certain number of our products have received 510(k) clearance from the FDA for various indications for use. To obtain 510(k) clearance, we must submit a pre-market notification to the FDA demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device, a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of pre-market approval applications, or is a device that has been reclassified from Class III to either Class II or I. The FDA's 510(k) clearance process usually takes from three to 12 months from the date the application is submitted and accepted by the FDA but may take significantly longer. The FDA may have questions on data provided or require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, FDA collects user fees for certain medical device submissions and annual fees for registering medical device establishments. 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.

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, depending on the modification, could require pre-market approval or *de novo* classification. 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, issuance of a *de novo* classification or approval of a PMA is obtained. Under these circumstances, the FDA may also subject a manufacturer to significant regulatory fines or other penalties.

Premarket Approval Process

Most Class III devices require PMA approval before they can be marketed. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by human clinical and non-clinical data. The PMA must also contain a full description of the device, its manufacturing, and proposed labeling. FDA review of a PMA application typically takes between one and three years, but may take significantly longer. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the QSR before approving a PMA application.

Certain changes to an approved device which affect the safety or effectiveness of the device, require submission of a PMA supplement. application, and Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that the data that were submitted with the original PMA are not applicable for the changed device.

De novo Classification Process

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The FDCA contains a route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. The *de novo* classification pathway allows a manufacturer to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. The FDA is required to classify the device within 120 days following receipt of the *de novo* application. If the manufacturer seeks reclassification into

Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the *de novo* request if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low-to-moderate-risk or that general controls would be inadequate to control the risks and/or that special controls cannot be developed. On September 22, 2014, the FDA agreed with the *de novo* classification request for the T2Dx and T2Candida Panel and classified these products as Class II medical devices.

Clinical Trials

Clinical trials are typically required to support a PMA application or *de novo reclassification* request, and are sometimes required to support a 510(k) pre-market notification. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical trials, but must still comply with abbreviated IDE requirements when conducting such trials.

Regardless of the degree of risk (significant or nonsignificant) presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE and may pose additional requirements for the conduct of the study. During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, the sponsor, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Expedited Development and Review Programs

Following passage of the 21st Century Cures Act, the FDA implemented the Breakthrough Devices Program, which is a voluntary program offered to manufacturers of certain medical devices and device-led combination products that may provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and health care providers with more timely access to qualifying devices by expediting their development, assessment and review, while preserving the statutory standards for PMA approval, 510(k) clearance and *de novo* classification. The program is available to medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and that the device meets one of the following criteria: (i) the device represents a breakthrough technology, (ii) no approved or cleared alternatives exist, (iii) the device offers significant advantages over existing approved or cleared alternatives, or (iv) the availability of the device is in the best interest of patients. Breakthrough Device designation provides certain benefits to device developers, including more interactive and timely communications with FDA staff, use of post-market data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device, opportunities for efficient and flexible clinical study design, and expedited review of premarket submissions. In February 2019, our T2Resistance Panel was granted FDA Breakthrough Device designation, in July 2022, we received Breakthrough Device Designation for the T2Lyme Panel, and in July 2023, we received Breakthrough Device designation for our *Candida auris* test.

Emergency Use Authorization

The Commissioner of the FDA, under delegated authority from the Secretary of HHS may, under certain circumstances in connection with a declared public health emergency, allow for the marketing of a product that does not otherwise comply with FDA regulations by issuing an EUA for such product. Before an EUA may be issued by HHS, the Secretary must declare an emergency based a determination that public health emergency exists that effects or has the significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or CBRN, or a specified disease or condition that may be attributable to such CBRN. On February 4, 2020, the HHS Secretary determined that there is such a public health emergency that involves the virus now known as SARS-CoV-2, the virus that causes the COVID-19 infection. Once the determination of the threat or emergency has been made, the Secretary of HHS must then declare that an emergency exists justifying the issuance of EUAs for certain types of products (referred to as EUA declarations). On February 4, 2020, the Secretary of HHS declared – on the basis of his determination of a public health emergency that has the potential to affect national security or the health and security of U.S. citizens living abroad that involves SARS-CoV-2 – that circumstances exist justifying authorization of *in vitro* diagnostic devices during the COVID-19 pandemic, subject to the terms of any EUA that is issued.

Once an EUA declaration has been issued, the FDA can issue EUAs for products that fall within the scope of that declaration. To issue an EUA, the FDA Commissioner must conclude that 1) the CBRN that is referred to in the EUA declaration can cause serious or life-threatening diseases or conditions; 2) based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the disease or condition attributable to the CBRN and that the product's known and potential benefits outweigh its known and potential risks; and 3) there is no adequate, approved, and available alternative to the product. Products subject to an EUA must still comply with the conditions of the EUA, including labeling and marketing requirements. Moreover, the authorization to market products under an EUA is limited to the period of time the EUA declaration is in effect, and the FDA can revoke an EUA in certain circumstances.

At certain points during the COVID-19 pandemic, the FDA issued policies indicating that it would not object to test developers distributing or offering their validated tests prior to receipt of an EUA, provided the test developers met certain criteria set forth in published enforcement policies. In June 2020, we launched the T2SARS-CoV-2 Panel, our COVID-19 molecular diagnostic test, after validation of the test pursuant to the FDA's policy permitting COVID-19 tests to be marketed prior to receipt of an EUA, subject to certain prerequisites. In August 2020, the FDA granted an EUA to the T2SARS-CoV-2 Panel for the qualitative direct detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal, and oropharyngeal swab specimens) and bronchoalveolar lavage specimens from individuals suspected of COVID-19 by their healthcare provider.

Research-Use-Only Devices

Some of our products, including our T2Resistance Panel and T2Cauris Panel are currently available RUO. An RUO device is an *in vitro* diagnostic device, or IVD, that is in the laboratory research phase of development. IVDs that are marketed for RUO are not intended for use in a clinical investigation or for clinical diagnostic use outside an investigation and must be labeled "For Research Use Only. Not for use in diagnostic procedures." Products that are intended for RUO and are properly labeled as RUO are exempt from compliance with the FDA's requirements applicable to medical devices more generally, including the requirements for clearance or approval and compliance with the FDA's QSR. A product labeled RUO but intended to be used diagnostically may be viewed by the FDA as adulterated and misbranded under the FDCA and is subject to FDA enforcement activities. The FDA may consider the totality of the circumstances surrounding distribution and use of an RUO product, including how the product is marketed, when determining its intended use.

Pervasive and Continuing U.S. Food and Drug Administration Regulation

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

- 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.
- post-market surveillance QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and 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 cleared devices or devices authorized through the *de novo* classification process that could significantly affect safety or effectiveness, or that would constitute a major change in intended use of such devices, or approval of certain modifications to PMA-approved devices;
- labeling regulations, which prohibit "misbranded" devices from entering the market, as well as prohibit the promotion of investigational products or promotion of "off-label" uses for cleared or approved products; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; and
- 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.

Manufacturing processes for medical devices are required to comply with the applicable portions of the QSR, which cover the methods, facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master

file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled FDA inspections. Failure to maintain compliance with the QSR requirements could result in the shutdown of, or restrictions on, manufacturing operations and the recall or seizure of marketed products. The discovery of previously unknown problems with marketed medical devices, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. Failure to comply with applicable regulatory requirements may result in enforcement action by the FDA, which may include one or more of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions 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 pre-market approval of new product versions;
- revocation of 510(k) clearance or pre-market approvals previously granted; and
- criminal prosecution and penalties.

International Regulation

Medical devices (including in vitro diagnostic medical devices, or IVD MDs) are subject to extensive foreign government regulations are subject, such as premarket review, marketing authorization or certification, by similar agencies or notified bodies outside the United States, and which vary substantially from country to country. In order to market our products in other countries, we must obtain regulatory approvals or certifications 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. International regulators and notified bodies are independent and not bound by the findings of the FDA.

Regulation of In Vitro Diagnostic Medical Devices in the European Union

The EU has adopted specific directives and regulations regulating the design, manufacture, clinical investigations, conformity assessment, labeling and adverse event reporting for medical devices (including IVD MDs).

Until May 25, 2022, IVD MDs were regulated by Directive 98/79/EC, or EU IVDD, which has been repealed and replaced by Regulation (EU) No 2017/746, or EU IVDR. The transition period to implement EU IVDR requirements is currently underway now, with extensions applied due to the low number of EU Notified Bodies that are accredited to certify to the new Regulation and the high number of IVD companies that require certification. Changes from the IVDD to IVDR have been impactful. Under IVDR, there are now four (4) regulatory classifications for IVD MDs. Class A IVD MDs, such as our T2Dx Instrument, allow us to self-assess the conformity of its products with IVDR requirements. The remaining Classes B, C and D, which include our T2Candida, T2Bacteria and T2Resistance Panels, require a conformity assessment procedure requires the intervention of a Notified Body who is accredited by an EU Competent Authority to certify products to the EU IVDR.

Notified Bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A Notified Body would typically audit and examine a product's technical documentation per the requirements of EU IVDR. If satisfied that the relevant product conforms to the relevant essential requirements, the Notified Body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. While we had assessed that the T2Dx Instrument and T2Candida met the requirements of the EU IVDD in late 2014, based upon an EC declaration of conformity dated July 7, 2014, and updated on September 9, 2015 and May 26, 2016, allowing us to affix the CE mark to these products.

The Class A T2Dx Instrument was self-certified by us on August 12, 2022. While the T2Bacteria, T2Candida, T2Biothreat and T2Resistance Panels were allowed to continue to be self-declared under EU IVDD, EU IVDR requirements have determined that these products are of a higher classification than Class A, therefore we must now pursue conformity routes for each product as we continue to complete the transition to EU IVDR. This work was delayed by our Notified Body accreditation to certify to EU IVDR on February 25, 2023. We will continue to work with our Notified Body to achieve full transition to EU IVDR requirements and certification throughout 2023 with an expected completion in 2024. Class B devices are expected to fully transition to EU IVDR certification by May 26, 2027. Class C devices are expected to fully

complete transition May 26, 2026. It is currently assumed that the Panel products will be classified as Class B or Class C for our Notified Body per EU IVDR requirements.

Our current certificates for the T2 Panels have been granted under the EU IVDD whose regime is described below. However, as of May 26, 2022, some of the EU IVDR requirements apply in place of the corresponding requirements of the EU IVDD with regard to registration of economic operators and of devices, post-market surveillance and vigilance requirements. Pursuing marketing of IVD MDs in the EU will notably require that our devices be certified under the new regime set forth in the EU IVDR by the time the transition period of the applicable IVD classification under IVDR expires.

In Vitro Diagnostic Medical Devices Directive

Under the EU IVDD, all IVD MDs placed on the market in the EU must meet the essential requirements laid down in Annex I to the EU IVDD, including the requirement that an IVD MD must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter as it creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the EU IVDD, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration of conformity of IVD MDs and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. Except for (general) IVD MDs (i.e., all IVD MDs other than those covered by Annex II to the EU IVDD and IVD MDs for self-testing), where the manufacturer can self-assess the conformity of its products with the essential requirements, a conformity assessment procedure requires the intervention of a Notified Body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A Notified Body would typically audit and examine a product's technical dossiers and the manufacturers' quality system (Notified Body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485:2016 for Quality Management Systems – conform to these requirements). If satisfied that the relevant product conforms to the relevant essential requirements, the Notified Body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU.

Throughout the term of the certificate of conformity, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the Notified Body before it will renew the relevant certificate(s).

In Vitro Diagnostic Medical Devices Regulation

The EU regulatory landscape related to IVD MDs recently evolved. On April 5, 2017, the EU IVDR, was adopted with the aim of ensuring better protection of public health and patient safety. The EU IVDR establishes a uniform, transparent, predictable and sustainable regulatory framework across the EU for IVD MDs and ensure a high level of safety and health while supporting innovation. Unlike the EU IVDD, the EU IVDR is directly applicable in all EU member states without the need for member states to implement into national law. This aims at increasing harmonization across the EU.

The EU IVDR became effective on May 26, 2022. In accordance with the recently amended provisions of the EU IVDR both (i) IVD MDs lawfully placed on the market pursuant to the EU IVDD prior to May 26, 2022 and (ii) IVD MDs lawfully placed on the market after May 26, 2022 in accordance with the transitional provisions of the EU IVDR may generally continue to be made available on the market or put into service provided that the requirements of the transitional provisions are fulfilled. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the EU IVDR, in particular the obligations described below.

The EU IVDR requires that before placing an IVD MD on the market, manufacturers (as well as other economic operators such as authorized representatives and importers) must register by submitting identification information to the electronic system (EUDAMED), unless they have already registered. The information to be submitted by manufacturers (and authorized representatives) also includes the name, address and contact details of the person or persons responsible for regulatory compliance. The new Regulation also requires that before placing a device on the market, manufacturers must assign a unique identifier to the device and provide it along with other core data to the unique device identifier, or UDI, database. These new requirements aim at ensuring better identification and traceability of the devices. Each device – and as applicable, each package – will have a UDI composed of two parts: a device identifier, or UDI-DI, specific to a device, and a production identifier, or UDI-

PI, to identify the unit producing the device. Manufacturers are also notably responsible for entering the necessary data on EUDAMED, which includes the UDI database, and for keeping it up to date. The obligations for registration in EUDAMED will become applicable at a later date (as EUDAMED is not yet fully functional). Until EUDAMED is fully functional, the corresponding provisions of the EU IVDD continue to apply for the purpose of meeting the obligations laid down in the provisions regarding exchange of information, including, and in particular, information regarding registration of devices and economic operators.

All manufacturers placing medical devices on the market in the EU must comply with the EU medical device vigilance system which has been reinforced by the EU IVDR. Under this system, serious incidents and Field Safety Corrective Actions, or FSCAs, must be reported to the relevant authorities of the EU member states. These reports will have to be submitted through EUDAMED – once functional – and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until EUDAMED is fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply. A serious incident is defined as any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect, which, directly or indirectly, might have led or might lead to the death of a patient or user or of other persons or to a temporary or permanent serious deterioration of a patient's, user's or other person's state of health or a serious public health threat. Manufacturers are required to take FSCAs defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical device that is made available on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a FSCA implemented or where the incidents are common and well documented, manufacturers may provide periodic summary reports instead of individual serious incident reports.

The advertising and promotion of medical devices are subject to some general principles set forth in EU legislation. According to the EU IVDR, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example, requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at a national level. EU member states' laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices (including IVD MDs), in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

In the EU, regulatory authorities have the power to carry out announced and, if necessary, unannounced inspections of companies, as well as suppliers and/or sub-contractors and, where necessary, the facilities of professional users. Failure to comply with regulatory requirements (as applicable) could require time and resources to respond to the regulatory authorities' observations and to implement corrective and preventive actions, as appropriate. Regulatory authorities have broad compliance and enforcement powers and if such issues cannot be resolved to their satisfaction can take a variety of actions, including untitled or warning letters, fines, consent decrees, injunctions, or civil or criminal penalties.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Brexit

Since the end of the Brexit transition period on January 1, 2021, Great Britain (England, Scotland and Wales) has not been directly subject to EU laws, however under the terms of the Protocol on Ireland/Northern Ireland, EU laws generally apply to Northern Ireland. On February 27, 2023, the United Kingdom, or UK Government and the European Commission reached a political agreement on the "Windsor Agreement" which is likely to lead to further amendments to the Protocol on Ireland/Northern Ireland in order to address some of the perceived shortcomings in its operation. These proposed changes need to be codified and agreed by the respective parliaments of the UK and EU before taking effect.

The EU laws that have been transposed into United Kingdom law through secondary legislation remain applicable in Great Britain. However, under the Retained EU Law (Revocation and Reform) Bill 2022, which is currently before the UK parliament, any retained EU law not expressly preserved and "assimilated" into domestic law or extended by ministerial regulations (to no later than June 23, 2026) will automatically expire and be revoked by December 31, 2023. In addition, new legislation such as the EU IVDR is not applicable in Great Britain.

The UK government has passed a new Medicines and Medical Devices Act 2021, which introduces delegated powers in favor of the Secretary of State or an 'appropriate authority' to amend or supplement existing regulations in the area of medicinal products and medical devices,

including IVD MDs. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

The EU-UK Trade and Cooperation Agreement, or TCA, came into effect on January 1, 2021. The TCA does not specifically refer to medical devices or IVD MDs but does provide for cooperation and exchange of information in the area of product safety and compliance, including market surveillance, enforcement activities and measures, standardization related activities, exchanges of officials, and coordinated product recalls (or other similar actions). For medical devices and IVD MDs that are locally manufactured but use components from other countries, the "rules of origin" criteria will need to be reviewed.

Since January 1, 2021, the Medicines and Healthcare Products Regulatory Agency, or MHRA, has become the sovereign regulatory authority responsible for Great Britain. New regulations require all medical devices and IVD MDs to be registered with the MHRA, and since January 1, 2022, manufacturers based outside the UK have been required to appoint a UK responsible person that has a registered place of business in the UK to register devices with the MHRA.

On June 26, 2022, the MHRA published its response to a 10-week consultation on the post-Brexit regulatory framework for medical devices and IVD MDs. The MHRA seeks to amend the UK Medical Devices Regulations 2002 (which are based on EU legislation, primarily the EU Medical Devices Directive 93/42/EEC and the EU IVDD), in particular to create a new access pathway to support innovation, create an innovative framework for regulating software and artificial intelligence as medical devices, reform IVD MD regulation and foster sustainability through the reuse and remanufacture of medical devices. Regulations implementing the new regime were originally scheduled to come into force in July 2023, but the Government has recently confirmed that this date has been postponed until July 2024. Devices which have valid a valid certificate issued by EU notified bodies under the EU IVDR or EU IVDD are subject to transitional arrangements. In its consultation response, the MHRA indicated that the future regulations in Great Britain will allow IVD MDs with valid certification to continue being placed on the market in Great Britain under the CE mark until either the certificate expires or for five years after the new regulations take effect, whichever is sooner. Following these transitional periods, it is expected that all IVD MDs will require a UK Conformity Assessment, or UKCA, mark. Manufacturers may choose to use the UKCA mark on a voluntary basis prior to the regulations coming into force. However, from July 2024, products which do not have existing and valid certification under the EU IVDD or EU IVDR and are therefore not subject to the transitional arrangements will be required to carry the UKCA mark if they are to be sold into the market in Great Britain. UKCA marking will not be recognized in the EU. The rules for placing IVD MDs on the market in Northern Ireland, which is part of the UK, differ from those in Great Britain and continues to be based on EU law.

Under the terms of the Ireland/Northern Ireland Protocol, Northern Ireland follows EU rules on IVD MDs, including the EU IVDR, and IVD MDs marketed in Northern Ireland require assessment according to the EU regulatory regime. Such assessment may be conducted by an EU Notified Body, in which case a CE mark is required before placing the device on the market in Northern Ireland. Alternatively, if a UK approved body conducts such assessment, a 'UKNI' mark is applied and the device may only be placed on the market in Northern Ireland and not the EU.

Other Healthcare Laws

Our current and future business activities are subject to healthcare regulation and enforcement by federal, state and local governments and the foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, data privacy and security and transparency laws and regulations regarding payments or other transfers of value made to physicians and other licensed healthcare professionals.

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing any 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. There are a number of statutory exceptions and regulatory safe harbors that the OIG has promulgated outlining certain categories of relationships between health care providers and persons or entities that may have a referral relationship that would be deemed not to violate the Anti-Kickback Statute. However, the exceptions and safe harbors are drawn narrowly to avoid inadvertently immunizing prohibited conduct. 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 Anti-Kickback Statute. 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 Anti-Kickback Statute has been violated. In addition, 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 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.

Additionally, the federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting or causing the presentation of a false or fraudulent claim for payment to, or approval by, the U.S. government. The False Claims Act defines the term "knowingly" broadly, and submitting a claim with reckless disregard to its truth or falsity can constitute the "knowing" submission of a false or fraudulent claim for the purposes of the False Claims Act. In addition to actions initiated by the government itself, the statute authorizes actions

to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud. Such "whistleblower" or "qui tam" provisions are being used with more frequency to challenge the reimbursement practices of providers and suppliers. 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 decides to intervene 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 monetary recovery. The federal government is using the False Claims Act, 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 Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act 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. Many states have enacted similar false claims acts as well.

The federal Health Insurance Portability and Accountability Act of 1996, as amended ("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 statements or representations in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, 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 Civil Monetary Penalties Law imposes penalties against any person or entity that, among other things, knowingly presents or causes 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.

Also, as stated above, many states have similar fraud and abuse laws that may be broader in scope and may apply regardless of payor.

Moreover, the Physician Payments Sunshine Act requires certain device manufacturers, among others, to report certain payments or "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives) and teaching hospitals, and to report ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. The statute 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 any covered payment or transfers of value within the Open Payments system 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.

We also may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH, through its implementing regulations, makes certain HIPAA privacy and security standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains or transmits protected health information for or on behalf of a covered entity for a function or activity regulated by HIPAA. In addition to HIPAA criminal penalties, HITECH created four new tiers of civil and monetary penalties and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws in certain circumstances and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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 penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Climate Change and Environmental Laws

The medical device industry is increasingly becoming subject of scrutiny, stringent regulation and the demand for green, sustainable products. We are focused on monitoring these increasing requirements for efficient and accurate processes for hazardous substance handling,

supplier disclosures, and regulatory reporting in order to comply with numerous global health and environmental regulatory requirements and restrictions.

We believe that we are in compliance in all material respects with all foreign, federal, state, and local environmental regulations applicable to our manufacturing facilities. The cost of ongoing compliance with such regulations does not have a material effect on our operations.

Coverage and Reimbursement

Maintaining and growing sales of our diagnostic tests 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, including clinical laboratory tests. 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. Third-party payors may deny coverage if they determine that our products are not cost-effective as determined by the payor, or are deemed by the third-party payor to be experimental or medically unnecessary. Decreases in third-party reimbursement for our products, product candidates, or services in which our products are used, or a decision by a third-party payor to not cover our tests, product candidates, or services in which our products are used could reduce physician utilization of our tests, if approved, and have a material adverse effect on our sales, results of operations and financial condition.

Hospitals, clinical laboratories and other healthcare provider customers that may purchase our products and/or product candidates 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 products and/or product candidates. The majority of our diagnostic tests are performed in a hospital inpatient setting, where governmental payors, such as Medicare, generally reimburse hospitals with a single bundled payment that is based on the patients' diagnosis under a classification system known as the Medicare severity diagnosis-related groups, or MS-DRGs, classification for all items and services provided to the patient during a single hospitalization, regardless of whether our diagnostic tests are performed during such hospitalization. In addition, new products may be eligible for an add-on payment for a time period up to three years if they meet certain criteria, including, among other things, demonstrating a substantial clinical improvement relative to services or technologies previously available. For fiscal years 2021 and 2022, hospitals paid under the Medicare Hospital Inpatient Prospective Payment System were eligible to receive a new technology add-on payment, or NTAP for T2Bacteria, which is incremental to the MS-DRG reimbursement for qualifying Medicare inpatient cases based on the cost of the case. Effective fiscal year 2023, T2Bacteria is no longer eligible for NTAP. To the extent that our diagnostic tests are performed in an outpatient setting, certain of our tests may be eligible for separate payment using existing Current Procedural Terminology, or CPT, codes, under the Clinical Laboratory Fee Schedule.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. EU member states and the UK impose controls on whether products are reimbursable by national or regional health service providers and on the prices at which devices are reimbursed under state-run healthcare schemes. More and more, local, product specific reimbursement law is applied as an overlay to medical device regulation, which has provided an additional layer of clearance requirement.

We are unable to predict at this time whether our products and/or product candidates, if approved, will be covered by third-party payors. Nor can we predict at this time the adequacy of payments, whether made separately in an outpatient setting or with a bundled payment amount in an inpatient setting. 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.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. By way of example, the ACA created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021, through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions of Medicare payments to providers, which will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020, through March 31, 2022. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows.

On January 1, 2018, CMS implemented certain provisions of the Protecting Access to Medicare Act of 2014, or PAMA, which made substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for "advanced diagnostics laboratory tests"), private payer payment rates and volumes for their tests. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. CMS uses the data to calculate a weighted median payment rate for each test, which is used to establish a revised Medicare reimbursement rate. Under PAMA, the revised Medicare reimbursement rates were scheduled to apply to clinical diagnostic laboratory tests furnished on or after January 1, 2018. The revised reimbursement methodology is expected to generally result in relatively lower reimbursement under Medicare for clinical diagnostic lab tests that has been historically available. Any reduction to payment rates resulting from the new methodology is limited to 10% per test per year in 2018 through 2020, and to 15% per test per year in 2021 through 2023 and 15% per test per year in 2024 through 2026. The CARES Act, which was signed into law on March 27, 2020, amended the timeline for reporting private payer payment rates and delayed by one year the payment reductions scheduled for 2021. On December 10, 2021, Congress passed the Protecting Medicare and American Farmers from Sequester Cuts Act, or PMAFSA, which delayed the next data reporting period by an additional year and prevented any reduction in payment amounts from commercial payer rate implementation in 2022. The Consolidated Appropriations Act, 2023, enacted on December 29, 2022, further revised the next data reporting period for certain tests and delayed the phase-in of payment reductions for an additional year, through 2026.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

For instance, in December 2021, the EU Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. This regulation which entered into force in January 2022 intends to boost cooperation among EU member states in assessing health technologies, including some medical devices and IVD MDs, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation foresees a three-year transitional period and will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

Research and Development

We have committed, and expect to commit, significant resources to developing new technologies and products, improving product performance and reliability and reducing costs. We have assembled an experienced research and development team with the scientific, engineering, software and process talent that we believe is required to successfully grow our business. We are currently focused on several product candidates and enhancements utilizing our proprietary technology. Major components of the research and development expenses were salaries and benefits, research-related facility and overhead costs, laboratory supplies, equipment and contract services. Research and development expenses can be impacted by services performed and expenses incurred under collaboration agreements and other research and development contracts.

We continuously seek to improve our proprietary technology. As we make improvements, we anticipate we will make available new and improved generations of our diagnostic instruments and panels. Our technology developmental efforts are focused on applying our proprietary technology to additional potential applications in the *in vitro* diagnostics area. We believe that technical advantage is important to sustain a

competitive advantage, and therefore our research and development efforts are focused on the continued enhancement of our proprietary technology. We are dedicated to ongoing innovation to our technology and expanding our pipeline of product candidates. Our goal is for our technology to become a standard of care by offering a rapid, sensitive and simple diagnostic alternative to existing methodologies for identifying sepsis, with a long-term objective of targeting the broader *in vitro* diagnostics market.

In September 2019, BARDA awarded us a milestone-based contract for the development of a next-generation diagnostic instrument, a comprehensive sepsis panel and a multi-target biothreat panel. In September 2020, BARDA exercised the first contract option valued at $10.5 million. In April 2021, BARDA agreed to modify the contract to accelerate product development by advancing future deliverables and adding a U.S. T2Resistance Panel into Option 1 of the contract. In September 2021, BARDA exercised Option 2A valued at approximately $6.4 million to further advance the new product development initiatives. In December 2021, we initiated the U.S. clinical trials for the T2Resistance Panel and T2Biothreat Panel. In March 2022, BARDA exercised Option 2B valued at approximately $4.4 million. In May 2022, BARDA exercised Option 3 valued at approximately $3.7 million to complete the U.S. clinical trials for the T2Resistance Panel and T2Biothreat Panel and subsequently submit applications to the FDA for U.S. regulatory clearance for those product candidates. In December 2022, the T2Biothreat clinical evaluation was completed. In May 2023, we submitted a 510(k) premarket notification to the FDA for the T2Biothreat Panel and in September 2023, we received 510(k) clearance from the FDA to market the T2Biothreat Panel. The BARDA contract expired in September 2023

We recorded research and contribution revenue of $0.4 million and $11.0 million for the years ended December 31, 2023 and 2022, respectively, under the BARDA contract.

Human Capital Resources

At T2 Biosystems, employees are integral to our success. Our key human capital management objectives are to attract, retain and develop talent needed to deliver on our strategy and advance our mission. As of December 31, 2023, we had a total of 113 employees, including 79 employees working on-site, and 34 employees working remotely or in the field. All of these employees were full-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We focus on the following areas in supporting our human capital:

Diversity and Inclusion. We recognize and appreciate the importance of creating an environment where all team members feel valued, included and empowered to do their best work and bring great ideas to the table. We recognize that each team member's unique experiences, perspectives, and viewpoints add value to our ability to develop and deliver innovative diagnostic products and make a meaningful impact on patient care. We strive to foster an organizational culture that ensures all employees are treated fairly and with respect, promotes inclusivity, and provides equal opportunities for professional growth and advancement based on merit. Our Code of Business Conduct and Ethics prohibits discrimination on the basis of race, color, religion, national origin, sex (including pregnancy), sexual orientation, age, disability, veteran status or other characteristic protected by law.

Health and Safety. Safety is a top priority at T2 Biosystems. We promote safety with a robust health and safety program, which includes employee orientation and training, regular safety meetings, contractor management, risk assessments, hazard identification and mitigation, incident reporting and investigation, and corrective and preventative action development.

Training and Development. We invest in training and development initiatives to ensure our employees have the skills and tools necessary to successfully contribute towards advancing progress on our strategic priorities and to prepare them to confidently take on new or expanded roles within the organization. Our on-going efforts are aimed at attracting, engaging, retaining, and developing employees in a thoughtful and meaningful way to support an inclusive culture.

Compensation and Benefits. We aim to provide fair, competitive compensation and a comprehensive benefits program that will attract, retain and motivate employees. To align individual performance with our short- and long-term corporate objectives, our compensation programs consist of base pay, short-term incentives and long-term incentives, including restricted stock unit grants. Our benefits program currently includes medical, dental, and vision insurance plans for employees and their families, in addition to life insurance and short and long-term disability plans, paid time off for holidays, vacation, sick and other personal leave, and health and dependent care savings accounts. We also provide our employees with a 401(k) plan that includes a competitive company match, and employees have access to several other programs, such as our Employee Stock Purchase Program (ESPP).

Available Information

We make available, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or the SEC. The address of the SEC's website is www.sec.gov. We also make these documents and certain public financial information available free of charge on our website, which is www.t2biosystems.com. Our SEC reports and other financial information can be accessed through the investor relations section of our website. The information on, or that can be accessed from, our website is not incorporated by reference into this Annual Report or any other report we file with or furnish to the SEC.

Item 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risk factors described below, as well as the other information in this prospectus, including our financial statements and the related notes and "Management's Discussion and Analysis of Results of Operations and Financial Condition," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. The occurrence of any of these risks may cause the trading price of our common stock to decline and you could lose all or part of your investment.

Risks Related to our Business and Strategy

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

Our cash, cash equivalents, and restricted cash as of December 31, 2023 was $16.2 million, which will not be sufficient to fund our current operating plan for at least a year from issuance of our financial statements included herein. The Company believes it will require additional financing during the first half of 2024. There can be no assurance that any financing by us can be realized, or if realized, what the terms of any such financing may be, or that any amount that we are able to raise will be adequate.

The Term Loan Agreement with CRG Servicing LLC ("CRG") (See Note 6 of the notes to our consolidated financial statements) has a minimum liquidity covenant which requires us to maintain a minimum cash balance of $0.5 million. As security for its obligations under the Term Loan Agreement, the Company entered into a security agreement with CRG whereby the Company granted a lien on substantially all of its assets, including intellectual property. We intend to continue to evaluate options to refinance the Term Loan Agreement, which becomes due on December 31, 2025. There can be no assurances that we will be able to refinance on terms favorable or at all.

These conditions, as well as those described below under "*Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock,*" raise substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that the financial statements for the year ended December 31, 2023 are issued. Our ability to fund working capital, make capital expenditures, and service our debt depends on our ability to generate cash from operating activities, which is subject to its future operating success, and obtain financing on reasonable terms, which is subject to factors beyond our control, including general economic, political, and financial market conditions. The capital markets have in the past experienced, are currently experiencing, and may in the future experience, periods of upheaval that could impact the availability and cost of financing and there can be no assurances that such financing will be available to the Company on satisfactory terms, or at all. Management's plans to alleviate the conditions that raise substantial doubt include raising additional capital, delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for us to continue as a going concern for a period of 12 months from the date these financial statements are issued. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of the financial statements for the year ended December 31, 2023.

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock.

On March 30, 2023, the Company received notice from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 555(a)(2) (the "Minimum Bid Price Rule"). On May 23, 2023, Nasdaq notified the Company that its securities were subject to delisting due to non-compliance with the Minimum Bid Price Rule and to maintain a minimum value of listed securities (the "MVLS Rule") of at least $35 million. The Company requested a hearing with Nasdaq and, on July 6, 2023, appealed to the Nasdaq Hearings Panel for an extension to the time period in which to regain compliance with the MVLS Rule and the Minimum Bid Price Rule. On July 26, 2023, we filed a definitive proxy statement to effect a reverse stock split of our common stock in connection with our annual meeting that occurred in September 2023 as required by the Nasdaq Hearings Panel. On August 9, 2023, the Company received written notice from Nasdaq informing the Company that it had regained compliance with the MVLS Rule. On September 15, 2023, at the Company's annual meeting of stockholders, the Company's stockholders approved an amendment to the Company's restated certificate of incorporation to effect a reverse stock split of the Company's common stock. On October 12, 2023, the Company announced that its board of directors had approved the reverse stock split at the ratio of 1 post-split share for every 100 pre-split shares, which was effective as of October 12, 2023.

On October 31, 2023, the Company received written notice from Nasdaq informing the Company that it has regained compliance with the Minimum Bid Price Rule. The Company will be subject to a Mandatory Panel Monitor for a period of one year. If, within that one-year monitoring period, the Company fails to comply with the Minimum Bid Price Rule, the Company will not be permitted additional time to regain compliance with the Minimum Bid Price Rule. However, the Company will have an opportunity to request a new hearing with the Nasdaq Hearings Panel prior to the Company's securities being delisted from Nasdaq.

On November 20, 2023, the Company received written notice from Nasdaq informing the Company that it no longer satisfied the MVLS Rule. In accordance with the terms of the Mandatory Panel Monitor, the Company was not granted a grace period but rather issued a delist determination, which will be stayed if the Company exercises its right to appeal by requesting a hearing and paying a non-refundable $20,000 fee. The Company has paid the $20,000 applicable fee and requested a new hearing, which will stay any further action by Nasdaq at least pending the issuance of its decision and the expiration of any extension that may be granted to the Company as a result of the hearing. The Company's common stock will remain listed and eligible to trade on Nasdaq pending the outcome of the hearing. On February 15, 2024, the Company appealed to the Nasdaq Hearings Panel for an extension to the time period in which to regain compliance with the MVLS Rule. On March 11, 2024, the Company received notice from the Nasdaq Hearings Panel that it had granted the Company's request for continued listing on Nasdaq, subject to the Company demonstrating compliance with Nasdaq's MVLS Rule on or before May 20, 2024.

The delisting of our common stock from Nasdaq may make it more difficult for us to raise capital on favorable terms in the future. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from Nasdaq, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities. Moreover, there is no assurance that any actions that we take to restore our compliance with the MVLS Rule would stabilize the market price or improve the liquidity of our common stock, prevent our common stock from falling below the minimum value of listed securities required for continued listing again, or prevent future non-compliance with Nasdaq's listing requirements.

We have incurred significant losses since inception and expect to incur losses in the future. We cannot be certain that we will achieve or sustain profitability.

We have incurred significant losses since inception through December 31, 2023 and expect to incur losses in the future. Our accumulated deficit as of December 31, 2023 was $584.3 million and we incurred net losses of $50.1 million and $62.0 million for the years ended December 31, 2023 and 2022, respectively. We expect that our losses will continue for at least the next few years as we will be required to invest significant additional funds toward the continued development and commercialization of our technology. Our ability to achieve or sustain profitability depends on numerous factors, many of which are beyond our control, including the market acceptance of our products and future product candidates, future product development, our ability to achieve marketing clearance from the FDA and international regulatory clearance or certification for future product candidates, our ability to compete effectively against an increasing number of competitors and new products, and our market penetration and margins. In spite of efforts to reduce expenses, we may never be able to generate sufficient revenue to achieve or sustain profitability. As noted above, management has identified conditions and events that raise doubt about our ability to continue as a going concern.

A reassessment of our sales demand forecast has recently resulted in impairment charges to certain long-lived assets, and we may recognize additional impairment charges in the future due to similar or other events.

We categorize our long-lived assets by two assets groups, our owned assets that are placed at customer sites as rental instruments and all other assets which support our product research and manufacturing. The value of these long-lived assets is driven in part by prospective demand for our products, and if demand for our products should fall, our return on these rental instruments and other assets could be diminished. In the third quarter of 2023, we determined that a triggering event occurred that required us to evaluate these long-lived assets for impairment. As a result of this evaluation, we recorded impairment charges for our owned non-lease instruments and reagent manufacturing assets totaling $2.5 million for the year ended December 31, 2023. We review the value of these long-lived assets for impairment when events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Should the markets for our products experience similar demand changes in the future or should other circumstances arise, it is possible that we will be required to record additional impairment charges in that could have a material adverse effect on our results of operations and financial condition.

We have relied on a few large customers for a significant portion of our business, and the loss of any of these customers has in the past and could in the future materially and adversely impact our results of operations and financial condition.

Our total revenues are concentrated among a small number of large customers. Sales to our two largest customers together represented 29% of our revenues for the fiscal year ended December 31, 2023. In September 2019, BARDA awarded us a milestone-based contract for the development of a next-generation diagnostic instrument, a comprehensive sepsis panel and a multi-target biothreat panel. BARDA exercised certain options under this contract, but it nonetheless expired in September 2023. Revenue associated with our BARDA contract represented 50% of our total revenue for the fiscal year ended December 31, 2022 and less than 10% of our total revenue for the fiscal year ended December 31, 2023. Our customer concentration and the loss of any such customers or changes in the amount of business we do with them has in the past and could in the future materially and adversely impact our results of operations and financial condition.

Failure to comply with the terms of our debt instruments may result in a default under their terms, and otherwise restrict our ability to pursue our business strategies.

If there is an event of default to our current credit facility, which includes if there is any change that has an material adverse effect on our business or our ability to perform our obligations under the credit facility documents, and such event of default is not cured or waived, the lender could terminate commitments to lend and cause all amounts outstanding with respect to the debt to be due and payable immediately, which in turn could result in cross defaults under other debt instruments. Our assets and cash flow will not be sufficient to fully repay borrowings under all of our outstanding debt instruments if some or all of these instruments are accelerated upon a default. As security for its obligations under the Term Loan Agreement, the Company entered into a security agreement with CRG whereby the Company granted a lien on substantially all of its assets, including intellectual property.

Our credit facility requires us, and any debt instruments we may enter into in the future may require us, to comply with various covenants that limit our ability to, among other things:

- convey, lease, sell, transfer, assign or otherwise dispose of assets;
- change the nature or location of our business;
- complete mergers or acquisitions;
- incur indebtedness;
- encumber assets;
- pay dividends or make other distributions to holders of our capital stock (other than dividends paid solely in common stock);
- make specified investments;
- change certain key management personnel; and
- engage in material transactions with our affiliates.

These restrictions could inhibit our ability to pursue our business strategies.

We may incur additional indebtedness in the future. The debt instruments governing such indebtedness could contain provisions that are as, or more, restrictive than our existing debt instruments. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral granted to them to secure such indebtedness or force us into bankruptcy or liquidation.

Servicing our debt will require a significant amount of cash. Our ability to generate sufficient cash to service our debt depends on many factors beyond our control.

Our ability to make payments on and to refinance our debt, to fund planned capital expenditures, and to maintain sufficient working capital depends on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control. We cannot assure you that our business will generate sufficient cash flow from operations or from other sources in an amount sufficient to enable us to service our debt or to fund our other liquidity needs. Our operations used $48.1 million in cash in 2023. If our cash flow and capital resources are insufficient to allow us to make scheduled payments on our debt, we may need to seek additional capital or restructure or refinance all or a portion of our debt on or before the maturity thereof, any of which could have a material adverse effect on our business, financial condition or results of operations. We cannot assure you that, if needed, we would be able to refinance any of our debt on commercially reasonable terms or at all, or that the terms of that debt will allow any of the above alternative measures or that these measures would satisfy our scheduled debt service obligations. If we are unable to generate sufficient cash flow to repay or refinance our debt on favorable terms, it could significantly adversely affect our financial condition. Our ability to restructure or refinance our debt will depend on the condition of the capital markets and our financial condition. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. There can be no assurance that we will be able to obtain any financing when needed, and if we are unable to do so, we would likely be forced to pursue a reorganization proceeding under applicable bankruptcy laws.

Our future capital needs are uncertain, and we may need to raise additional funds in the future.

We currently have limited cash and cash equivalents and in the future we will need to raise substantial additional capital to:

- expand our product offerings;
- expand our sales and marketing infrastructure;
- increase our manufacturing capacity;
- fund our operations; and
- continue our research and development activities.

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

- our ability to obtain marketing clearance from the FDA and international regulatory clearance or certification to market our future product candidates;
- market acceptance of our products and product candidates;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of our research and development activities;
- the ability of healthcare providers to obtain coverage and adequate reimbursement by third-party payors for procedures using our products and product candidates;
- the cost and timing of marketing clearance or regulatory clearances or certifications;
- the cost of goods associated with our products and product candidates;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for products or technology.

We cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may need to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our development programs.

If we do not have, or are not able to obtain, sufficient funds, we may be required to delay development or commercialization of our product candidates or license to third parties the rights to commercialize our product candidates or technologies that we would otherwise seek to commercialize ourselves. We also may need to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our operating results.

Adverse outcomes in legal proceedings could subject us to substantial damages and adversely affect our results of operations and profitability.

We may become party to legal proceedings, including matters involving personnel and employment issues, contract disputes, personal injury, environmental matters, and other proceedings. Some of these potential proceedings could result in substantial damages or payment awards that exceed our insurance coverage. We will estimate our exposure to any future legal proceedings and establish provisions for the estimated liabilities where it is reasonably possible to estimate and where an adverse outcome is probable. Assessing and predicting the outcome of these matters will involve substantial uncertainties. Furthermore, even if the outcome is ultimately in our favor, our costs associated with such litigation may be material. Adverse outcomes in future legal proceedings or the costs and expenses associated therewith could have an adverse effect on our results of operations.

In September 2021, we entered into a lease for office, research, laboratory and manufacturing space that would consolidate our existing operations into a single 70,000 square foot, state-of-the-art life sciences facility in Billerica, Massachusetts (the "Lease") with Farley White Concord Road, LLC (the "Landlord"). On January 17, 2023, the Landlord sent a Notice of Termination (the "Notice") of the Lease to us. The Notice provides that the Landlord terminated the Lease because of our alleged failure to perform our obligations under the Lease in a timely manner and our alleged breach of the covenant of good faith and fair dealing. Occupancy of the Premises was delayed due to disagreement between us and the Landlord as to the parties' obligations under the Lease. In connection with the Notice, on January 18, 2023, the Landlord filed a complaint in the Massachusetts Superior Court and has unilaterally deducted the $1.0 million security deposit for its alleged damages. In addition, the Landlord is seeking damages for unpaid rent, brokerage fees, transaction costs, attorney's fees and court costs. On March 1, 2023, we filed a response to the Landlord's complaint and a counterclaim alleging that the Landlord breached its obligations under the contract and unlawfully drew on the security deposit, in addition to breaching its covenants of good faith and fair dealing, making fraudulent misrepresentations, and engaging in deceptive and unfair trade practices.

We are an early stage commercial company and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets.

We applied the CE mark to the T2Dx Instrument and T2Candida Panel in July 2014 and received marketing authorization from the FDA for them on September 22, 2014 and began commercializing these products in the fourth quarter of 2014. We applied the CE mark to the T2Bacteria Panel in June 2017 and received marketing clearance from the FDA for it on May 24, 2018 and began commercializing it promptly thereafter. We applied the CE mark to the T2Resistance Panel in the EU on November 20, 2019. We received Emergency Use Authorization, or EUA, from the FDA for the T2SARS-CoV-2 Panel in August 2021. We received marketing authorization from the FDA for T2Biothreat on September 18, 2023. In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies early in their commercialization in competitive and rapidly evolving markets, particularly companies that develop and sell medical devices. These risks include our ability to:

- implement and execute our business strategy;
- expand and improve the productivity of our commercial infrastructure to grow sales of our products and product candidates;
- increase awareness of our brand;
- manage expanding operations;

- expand our manufacturing capabilities, including increasing production of current products efficiently while maintaining quality standards and adapting our manufacturing facilities to the production of new product candidates;
- respond effectively to competitive pressures and developments;
- enhance our existing products and develop new products;
- obtain and maintain regulatory clearance, approval or certification to commercialize product candidates and enhance our existing products;
- effectively perform clinical studies with respect to our proposed products;
- attract, retain and motivate qualified personnel in various areas of our business; and
- implement and maintain systems and processes that are compliant with applicable regulatory standards.

We may not have the institutional knowledge or experience to be able to effectively address these and other risks that may face our business. In addition, we may not be able to develop insights into trends that could emerge and negatively affect our business and may fail to respond effectively to those trends. As a result of these or other risks, we may not be able to execute key components of our business strategy, and our business, financial condition and operating results may suffer.

Until we achieve scale in our business model our revenue will be primarily generated from the T2Dx Instrument, T2Candida, T2Bacteria, T2Biothreat, and T2Resistance Panels, and research revenue, and any factors that negatively impact sales of these products may adversely affect our business, financial condition and operating results.

We began to offer our sepsis products for sale, including the T2Candida Panel and T2Dx Instrument, in the fourth quarter of 2014, T2Bacteria in 2018, T2Resistance in 2019 and T2Biothreat in 2023 and expect that we will be dependent upon the sales of these products for the majority of our revenue until we receive regulatory clearance, approval or certification for our other product candidates currently in development. Because we currently rely on a limited number of products to generate a significant portion of our revenue, any factors that negatively impact sales of these products, or result in sales of these products increasing at a lower rate than expected, could adversely affect our business, financial condition and operating results and negatively impact our ability to successfully launch future product candidates currently under development.

If our T2Dx Instrument, T2Candida, T2Bacteria, T2Biothreat and T2Resistance Panels or any of our other product candidates fail to achieve and sustain sufficient market acceptance, we will not generate expected revenue and our growth prospects, operating results and financial condition may be harmed.

The commercialization of our T2Dx Instrument, T2Candida, T2Bacteria, T2Biothreat and T2Resistance Panels and the future commercialization of our other product candidates in the United States and other jurisdictions in which we intend to pursue marketing clearance or certification are key elements of our strategy. If we are not successful in conveying to hospitals that our current products and future product candidates provide equivalent or superior diagnostic information in a shorter period of time compared to existing technologies, or that these products and future product candidates improve patient outcomes or decrease healthcare costs, we may experience reluctance, or refusal, on the part of hospitals to order, and third-party payors to pay for performing a test in which our product is utilized. For example, T2Candida is labeled for the presumptive diagnosis of candidemia. The results of the web-based survey we conducted of decision makers involved with laboratory purchasing may not be indicative of the actual adoption of T2Candida. In addition, our expectations regarding cost savings from using our products may not be accurate.

These hurdles may make it difficult to demonstrate to physicians, hospitals and other healthcare providers that our current diagnostic products and future product candidates are appropriate options for diagnosing sepsis, may be superior to available tests and may be more cost-effective than alternative technologies. Furthermore, we may encounter significant difficulty in gaining inclusion in sepsis treatment guidelines, gaining broad market acceptance by healthcare providers, third-party payors and patients using our technology and our related products and product candidates. Furthermore, healthcare providers may have difficulty in maintaining adequate reimbursement for sepsis treatment, which may negatively impact adoption of our products.

If we fail to successfully commercialize our products and product candidates, we may never receive a return on the significant investments in product development, sales and marketing, regulatory, manufacturing and quality assurance we have made and further investments we intend to make, and may fail to generate revenue and gain economies of scale from such investments.

If we are unable to expand, manage and maintain our direct sales and marketing organizations, or otherwise commercialize our products, our business may be adversely affected.

Because we applied the CE mark to the T2Dx Instrument and T2Candida Panel in the EU in June 2014 and received FDA authorizations to market them in the US in the third quarter of 2014, applied the CE mark to the T2Bacteria Panel in 2017 and received marketing authorization from the FDA in 2018, applied the CE mark to T2Resistance in 2019, and received marketing authorization from the FDA for the T2Biothreat Panel in 2023, we have limited experience marketing and selling our products. As of December 31, 2023, our commercial organization consisted of 27 people, including 11 people in sales and marketing. Our clinical and medical affairs teams are raising awareness by amplifying clinical value messaging for our products. Our financial condition and operating results are highly dependent upon the sales and marketing efforts of our sales and marketing employees with the assistance of the medical affairs team. If our sales and marketing efforts fail to adequately promote, market and sell our products, our sales may not increase at levels that are in line with our forecasts.

Our future sales growth will depend in large part on our ability to successfully expand the size and geographic scope of our direct sales force and medical affairs team in the United States. Accordingly, our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled sales, marketing, and medical affairs personnel. Because the competition for individuals with their skillset is high, there is no assurance we will be able to hire and retain additional personnel on commercially reasonable terms. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our products and our business and operating results may be adversely affected.

Outside of the United States, we sell our products through distribution partners and there is no guarantee that we will be successful in attracting or retaining desirable distribution partners for these markets or that we will be able to enter into such arrangements on favorable terms. Distributors may not commit the necessary resources to market and sell our products effectively or may choose to favor marketing the products of our competitors. If distributors do not perform adequately, or if we are unable to enter into effective arrangements with distributors in particular geographic areas, we may not realize international sales and growth.

The sales cycle and implementation and adoption timeline are lengthy and variable, which makes it difficult for us to forecast revenue and other operating results.

Our sales process involves numerous interactions with multiple individuals within an organization and often includes in-depth analysis by potential customers of our products, performance of proof-of-principle studies, preparation of extensive documentation and a lengthy review process. As a result of these factors and the budget cycles of our potential customers, the time from initial contact with a potential customer to our receipt of a purchase order from such potential customer and then implementation and adoption of our products, varies significantly and can be up to 12 months or longer. Given the length and uncertainty of our anticipated sales cycle and implementation and adoption timeline, we likely will experience fluctuations in our product sales on a period-to-period basis. Expected revenue streams are highly dependent on hospitals' adoption of our consumables-based business model, and we cannot assure you that our potential hospital clients will follow a consistent purchasing pattern. Moreover, it is difficult for us to forecast our revenue as it is dependent upon our ability to convince the medical community of the clinical utility and economic benefits of our products and their potential advantages over existing diagnostic tests, the willingness of hospitals to utilize our products and the cost of our products to hospitals.

We may not be able to gain and retain the ongoing support of hospitals and key thought leaders, or to continue the publication of the results of new clinical studies in peer-reviewed journals, which may make it difficult to establish our technology as a standard of care and may limit our revenue growth and ability to achieve profitability.

Our strategy includes developing relationships with hospitals and key thought leaders in the industry. If these hospitals and key thought leaders determine that our technology and related products are not clinically effective or that alternative technologies are more effective, or if we encounter difficulty promoting adoption or establishing our technology as a standard of care, our revenue growth and our ability to achieve profitability could be significantly limited.

We believe that the publication of scientific and medical results in peer-reviewed journals and presentation of data at leading conferences are critical to the broad adoption of our technology. Publication in leading medical journals is subject to a peer-review process, and peer reviewers may not consider the results of studies involving our technology sufficiently novel or worthy of publication.

If we are unable to successfully manage our growth, our business will be harmed.

During the past few years, we have expanded our operations. We expect this expansion to continue to an even greater degree as we continue to commercialize our sepsis products, build a targeted sales force, and seek marketing clearance or certification from the FDA, international regulatory authorities and notified bodies for our future product candidates. Our growth has placed, and will continue to place, a significant strain on our management, operating and financial systems and our sales, marketing and administrative resources. As a result of our growth, operating costs may escalate even faster than planned, and some of our internal systems and processes, including those relating to manufacturing our products, may need to be enhanced, updated or replaced. Additionally, our anticipated growth will increase demands placed on our suppliers, resulting in an increased need for us to manage our suppliers and monitor for quality assurance. If we cannot effectively manage our expanding operations, manufacturing capacity and costs, including scaling to meet increased demand and properly managing suppliers, we may not be able to continue to grow or we may grow at a slower pace than expected and our business could be adversely affected.

Our future success is dependent upon our ability to create and expand a customer base for our products in hospitals and to increase adoption at our existing hospital accounts.

We market and sell our sepsis products to hospitals world-wide. We may not be successful in promoting adoption of our technologies in those targeted hospitals or increasing adoption at our existing hospital accounts, which may make it difficult for us to achieve broader market acceptance of these products and increase revenue.

We may be adversely affected by fluctuations in demand for, and prices of, raw materials and other supplies.

We use various raw materials and other supplies in our business. Although there are currently multiple suppliers for these materials and supplies, changes in demand for, and the market price of, these raw materials and supplies could significantly affect our ability to manufacture our diagnostic instruments and, consequently, our profitability. The prices of these raw materials and supplies may fluctuate and are affected by numerous factors beyond our control such as interest rates, exchange rates, inflation or deflation, global and regional supply and demand, and the political and economic conditions of countries that produce rare earth minerals and products.

In addition, our agreements with our third party suppliers are non-exclusive. Our suppliers may dedicate more resources to other companies. We may in the future experience shortages and price fluctuations of certain key components and raw materials required in the manufacturing of our products, and the predictability of the availability and pricing of these components and raw materials may be limited. Current or future supply chain interruptions that could be exacerbated by global political tensions, such as the situation in Ukraine and the Middle East, and government responses could negatively impact our ability to acquire such key components or materials. Component and raw material shortages or pricing fluctuations could be material in the future. In the event of a component or raw material shortage, supply interruption or material pricing change from suppliers of these components or raw materials, we may not be able to develop alternate sources in a timely manner or at all in the case of sole or limited sources. During 2023, we experienced process and raw material challenges that impacted our ability to timely deliver our sepsis test panels to our global customers. We took a variety of actions to address these challenges, including the hiring of a new Vice President of Operations, advanced procurement of raw materials, process improvements, and investments in equipment. As of the end of December 2023, we had resolved the backorders for T2Bacteria and T2Candida, and as of the end of January 2024, we had resolved the backorder for T2Resistance. While we have resolved these challenges, there can be no assurance that we will not experience similar issues in the future, and, if we do face such challenges, they could limit our ability to meet customer demand.

Developing alternate sources of supply for these components or raw materials may be time consuming, difficult, and costly and we may not be able to source these components or raw materials on terms that are acceptable to us, or at all, which may undermine our ability to meet our requirements or to fill user orders in a timely manner. Any interruption or delay in the supply of any of these parts or components, or the inability to obtain these components or raw materials from alternate sources at acceptable prices and within a reasonable amount of time, would adversely affect our ability to meet scheduled product deliveries to users. This could adversely affect our relationships with our users and could cause delays in our ability to expand our operations. Even where we are able to pass increased component or raw material costs along to our users, there may be a lapse of time before we are able to do so such that we must absorb the increased cost initially. If we are unable to buy these components or raw materials in quantities sufficient to meet our requirements on a timely basis, we will not be able to have sufficient ability to meet user demand, which may have a negative impact on our operations and financial results.

If we are unable to recruit, train and retain key personnel, we may not achieve our goals.

Our future success depends on our ability to recruit, develop, retain and motivate key personnel, including individual on our senior management, research and development, science and engineering, manufacturing and sales and marketing teams. In particular, we are highly dependent on the management and business expertise of John Sperzel, our President and Chief Executive Officer. We do not maintain fixed-term employment contracts or key man life insurance with any of our employees. Competition for qualified personnel is intense, particularly in the Boston, Massachusetts area. Our growth depends, in particular, on attracting, retaining and motivating highly skilled sales personnel with the necessary clinical background and ability to understand our systems at a scientific and technical level. In addition, we may need to hire additional employees at our manufacturing facilities to meet demand for our products as we scale up our sales and marketing operations. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract, develop, retain and motivate qualified personnel could materially harm our operating results and growth prospects.

If our diagnostics do not perform as expected, our operating results, reputation and business will suffer.

Our future success will depend on the market's confidence that our technologies can provide reliable, high-quality diagnostic results. We believe that our customers are likely to be particularly sensitive to any defects or errors in our products. If our technology fails to detect the presence of *Candida* or bacterial pathogens that our technology is designed to detect and a patient subsequently suffers from sepsis, then we could face claims against us or our reputation could suffer as a result of such failures. The failure of our current products or planned diagnostic product candidates to perform reliably or as expected could significantly impair our reputation and the public image of our products, and we may be subject to legal claims arising from any defects or errors.

The diagnostics market is highly competitive. If we fail to compete effectively, our business and operating results will suffer.

While the technology of our products and product candidates is different than other products currently available, we compete with commercial diagnostics companies for the limited resources of our customers. In this regard, our principal competition is from a number of companies that offer platforms and applications in our target markets, most of which are more established commercial organizations with considerable name recognition and significant financial resources.

Other than our products, we are not aware of any other FDA-cleared or CE marked products available in the market that are able to detect sepsis causing pathogens and antibiotic resistant genes directly from whole blood. However, since hospitals continue to rely on blood culture based diagnostics as the standard of care for the detection of sepsis causing pathogens, we compete with companies that currently provide traditional blood culture-based diagnostics, including Becton Dickinson & Co., bioMerieux, Inc. (and its affiliate, BioFire Diagnostics, Inc.) Bruker Corporation, Accelerate Diagnostics, Luminex, Roche, Cepheid and Beckman Coulter, a Danaher company.

Most of our expected competitors are either publicly traded, or are divisions of publicly traded companies, and have a number of competitive advantages over us, including:

- greater name and brand recognition, financial and human resources;
- established and broader product lines;
- larger sales forces and more established distribution networks;
- substantial intellectual property portfolios;
- larger and more established customer bases and relationships; and
- better established, larger scale and lower-cost manufacturing capabilities.

We believe that the principal competitive factors in all of our target markets include:

- impact of products on the health of the patient;
- impact of the use of products on the cost of treating patients in the hospital;
- cost of capital equipment;
- reputation among physicians, hospitals and other healthcare providers;
- innovation in product offerings;
- flexibility and ease-of-use;
- speed, accuracy and reproducibility of results; and

- ability to implement a consumables-based model for panels.

We believe that additional competitive factors specific to the diagnostics market include:

- breadth of clinical decisions that can be influenced by information generated by diagnostic tests;
- volume, quality and strength of clinical and analytical validation data;
- availability of adequate reimbursement for testing services and procedures for healthcare providers using our products; and
- economic benefit accrued to hospitals based on the total cost to treat a patient for a health condition.

We cannot assure you that we will effectively compete or that we will be successful in the face of increasing competition from new products and technologies introduced by our existing competitors or new companies entering our markets. In addition, we cannot assure you that our future competitors do not have or will not develop products or technologies that enable them to produce competitive products with greater capabilities or at lower costs than our products and product candidates. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

Undetected errors or defects in our products or product candidates could harm our reputation, decrease market acceptance of our products or expose us to product liability claims.

Our products or product candidates may contain undetected errors or defects. Disruptions or other performance problems with our products or product candidates may damage our customers' businesses and could harm our reputation. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted or other significant customer relations problems may arise. We may also be subject to warranty and liability claims for damages related to errors or defects in our products or product candidates. A material liability claim or other occurrence that harms our reputation or decreases market acceptance of our products or product candidates could harm our business and operating results.

The sale and use of products or product candidates or services based on our technologies, or activities related to our research and clinical studies, could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure you that our product liability insurance would adequately protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

We may not be able to develop new product candidates or enhance the capabilities of our systems to keep pace with our industry's rapidly changing technology and customer requirements, which could have a material adverse impact on our revenue, results of operations and business.

Our industry is characterized by rapid technological changes, frequent new product introductions and enhancements and evolving industry standards. Our success depends on our ability to develop new product candidates and applications for our technology in new markets that develop as a result of technological and scientific advances, while improving the performance and cost-effectiveness of our existing product candidates. New technologies, techniques or products could emerge that might offer better combinations of price and performance than the products and systems that we plan to sell. Existing markets for our intended diagnostic product candidates are characterized by rapid technological change and innovation. It is critical to our success that we anticipate changes in technology and customer requirements and physician, hospital and healthcare provider practices and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis. At the same time, however, we must carefully manage our introduction of new products. If potential customers believe that such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory of older products as we transition to new products, and we have no experience in managing product transitions. If we do not successfully innovate and introduce new technology into our anticipated product lines or manage the transitions of our technology to new product offerings, our revenue, results of operations and business will be adversely impacted.

Competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. We anticipate that we will face strong competition in the future as expected competitors develop new or improved products and as new companies enter the market with new technologies and products.

We are developing additional product candidates and we may have problems applying our technologies to other areas and our new applications may not be as effective in detection as our initial applications. Any failure or delay in creating a customer base or launching new applications may compromise our ability to achieve our growth objectives.

Manufacturing risks may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our operating results.

Our business strategy depends on our ability to manufacture and assemble our current and proposed products in sufficient quantities and on a timely basis so as to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks relating to our manufacturing capabilities, including:

- Highly accurate levels of detection which require raw materials free of contamination lest test results include false positives for contaminants and not actual patient borne pathogens making paramount quality or reliability defects in product components that we source from third party suppliers;
- our inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms;
- our failure to increase production of products to meet demand;
- the challenge of implementing and maintaining acceptable quality systems while experiencing rapid growth;
- our inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements; and
- difficulty identifying and qualifying alternative suppliers for components in a timely manner.

As demand for our products increases, we will need to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes and quality systems. If we fail to increase our production capacity efficiently while also maintaining quality requirements, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. In addition, although we expect some of our product candidates to share product features and components with the T2Dx Instrument and T2Candida, T2Bacteria, T2Biothreat, and T2Resistance Panels manufacturing of these products may require the modification of our production lines, the hiring of specialized employees, the identification of new suppliers for specific components, or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable. Any future interruptions we experience in the manufacturing or shipping of our products could delay our ability to recognize revenues in a particular quarter and could also adversely affect our relationships with our customers.

We currently develop, manufacture and test our products and product candidates and some of their components in two facilities. If these or any future facility or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.

We currently develop our diagnostic products exclusively in a facility in Lexington, Massachusetts and manufacture and test some components of our products and product candidates in both Wilmington and Lexington, Massachusetts. If these or any future facility were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages, or otherwise, or if our business is disrupted for any other reason, we may not be able to develop or test our products and product candidates as promptly as our potential customers expect, or possibly not at all.

The manufacture of components of our products and product candidates at our Wilmington facility involves complex processes, sophisticated equipment and strict adherence to specifications and quality systems procedures. Any unforeseen manufacturing problems, such as contamination of our facility, equipment malfunction, or failure to strictly follow procedures or meet specifications, could result in delays or shortfalls in production of our products. Identifying and resolving the cause of any manufacturing issues could require substantial time and resources. If we are unable to keep up with future demand for our products by successfully manufacturing and shipping our products in a timely manner, our revenue growth could be impaired and market acceptance of our product candidates could be adversely affected.

We maintain insurance coverage against damage to our property and equipment, subject to deductibles and other limitations that we believe is adequate. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.

We may be adversely affected by fluctuations in demand for, and prices of, raw materials and other supplies.

We use various raw materials and other supplies in our business. Although there are currently multiple suppliers for these materials and supplies, changes in demand for, and the market price of, these raw materials and supplies could significantly affect our ability to manufacture our diagnostic instruments and, consequently, our profitability. The prices of these raw materials and supplies may fluctuate and are affected by numerous factors beyond our control such as interest rates, exchange rates, inflation or deflation, global and regional supply and demand, and the political and economic conditions of countries that produce rare earth minerals and products.

As part of our current business model, we may enter into strategic relationships with third parties to develop and commercialize diagnostic products.

We may enter into strategic relationships with third parties for future diagnostic products. However, there is no assurance that we will be successful in doing so. Establishing strategic relationships can be difficult and time-consuming. Discussions may not lead to agreements on favorable terms, if at all. To the extent we agree to work exclusively with a party in a given area, our opportunities to collaborate with others or develop opportunities independently could be limited. Potential collaborators or licensors may elect not to work with us based upon their assessment of our financial, regulatory or intellectual property position. Even if we establish new strategic relationships, they may never result in the successful development or commercialization of future products.

Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We have not made any acquisitions to date, and our ability to do so successfully is unproven. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- diversion of management time and focus from operating our business to acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- possible write-offs or impairment charges relating to acquired businesses; and
- inability to develop a sales force for any additional product candidates.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any acquisition may not materialize. 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.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2023, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of $273.7 million, which are available to offset future taxable income, if any, of which $10.4 million begin to expire in 2026 and $263.3 million carry forward indefinitely. Since 2020 and through 2023, we have conducted and updated studies of our historic ownership changes pursuant to Internal Revenue Code Sections 382 and 383 (the “382 study”) of our cumulative net operating loss and tax credit carryforwards. From the results of these studies, we determined there are limitations on the use of our loss and credit carryforwards. Future changes in our stock ownership, as well as other changes that may be outside of our control, could result in additional ownership changes under Section 382 of the Code. As a result, even if we achieve profitability, we may not be able to use a material portion of our NOLs. We have recorded a full valuation allowance related to our NOLs due to the uncertainty of the ultimate realization of the future benefits of those assets.

We face risks related to handling hazardous materials and other regulations governing environmental safety.

Our operations are subject to complex and stringent environmental, health, safety and other governmental laws and regulations that both public officials and private individuals may seek to enforce. Our activities that are subject to these regulations include, among other things, our use of hazardous materials and the generation, transportation and storage of waste. We may not be in material compliance with these regulations. Existing laws and regulations may also be revised or reinterpreted, or new laws and regulations may become applicable to us, whether retroactively or prospectively, that may have a negative effect on our business and results of operations. It is also impossible to eliminate completely the risk of accidental environmental contamination or injury to individuals. In such an event, we could be liable for any damages that result, which could adversely affect our business.

We generate a portion of our revenue internationally and are subject to various risks relating to our international activities which could adversely affect our operating results.

A portion of our revenue comes from international sources. Engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign healthcare and other regulatory requirements and laws, such as those relating to patient privacy or handling of bio-hazardous waste;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act, data privacy requirements, labor laws and anti-competition regulations;
- export or import restrictions;
- various reimbursement and insurance regimes;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- foreign exchange controls;
- difficulties and costs of staffing and managing foreign operations;
- difficulties protecting or procuring intellectual property rights; and
- pandemics and public health emergencies, such as the coronavirus (COVID-19), could result in disruptions to travel and distribution in geographic locations where our products are sold.

As we expand internationally, our results of operations and cash flows may become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our expenses are generally denominated in the currencies in which our operations are located, which is in the United States. If the value of the U.S. dollar increases relative to foreign currencies in the future, in the absence of a corresponding change in local currency prices, our future revenue could be adversely affected in the event we convert future revenue from local currencies to U.S. dollars.

If we dedicate resources to our international operations and are unable to manage these risks effectively, our business, operating results and prospects will suffer.

Our employees, independent contractors, principal investigators, consultants, commercial partners, distributors and vendors 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, independent contractors, principal investigators, consultants, commercial partners, distributors and vendors. Misconduct by these parties could include intentional, reckless or negligent failures to: comply with the regulations of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar regulatory authorities or notified bodies; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws and regulations in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately, or disclose unauthorized activities to us. These laws may impact, among other things, our activities with principal investigators and research subjects, as well as our sales, marketing and education programs. In particular, the promotion, 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 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 the 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 have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Any of these actions or investigations could result in substantial costs to us, including legal fees, and divert the attention of management from operating our business.

We depend on our information technology systems, and any failure of these systems could harm our business.

We depend on information technology systems for significant elements of our operations, including the storage of data and retrieval of critical business information. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including systems handling human resources, financial controls and reporting, contract management, regulatory compliance, sales management and other infrastructure operations. These information technology systems may support a variety of functions, including laboratory operations, test validation, quality control, customer service support, billing and reimbursement, research and development activities and general administrative activities. Our clinical trial data is currently stored on a third party's servers.

Information technology systems are vulnerable to damage from a variety of sources, including network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology systems, failures or significant downtime of our information technology systems or those used by our third-party service providers could prevent us from conducting our general business operations. Any disruption or loss of information technology systems on which critical aspects of our operations depend could have an adverse effect on our business. Further, we store highly confidential information on our information technology systems, including information related to clinical data, product designs and plans to create new products. If our servers or the servers of the third party on which our clinical data is stored are attacked by a physical or electronic break-in, computer virus or other malicious human action, our confidential information could be stolen or destroyed.

Our internal computer systems, or those used by our third-party research institution collaborators, vendors or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our vendors and other contractors and consultants may be vulnerable to security breaches and damage from computer viruses and unauthorized access, including the unauthorized encryption of data stored on our computer network. If such an event were to occur again and cause interruptions in our operations, it could result in a material disruption of our business operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed, which could adversely affect our business, results of operations and financial condition.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we store sensitive data, including intellectual property, our proprietary business information and that of our customers, and personally identifiable information of our employees, in our data centers and on our networks. The secure maintenance and transmission of this information is critical to our operations. We face risks related to the protection of information that we maintain—or engage a third-party to maintain on our behalf—including unauthorized access, acquisition, use, disclosure, or modification of such information. Despite our security measures and data backup, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Cyberattacks are increasing in their frequency, sophistication and intensity and have become increasingly difficult to detect. Cyberattacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties, disrupt our operations and damage our reputation, which could adversely affect our business/operating margins, revenues and competitive position.

Risks Related to Government Regulation and Diagnostic Product Reimbursement

Approval, clearance and certification by the FDA and foreign regulatory authorities or notified bodies for our diagnostic tests takes significant time and requires significant research, development and clinical study expenditures and ultimately may not succeed.

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. The regulations are very complex and are subject to rapid change and varying interpretations. Regulatory restrictions or changes could limit our ability to carry on or expand our operations or result in higher than anticipated costs or lower than anticipated sales. The FDA, other U.S. governmental agencies and foreign regulatory bodies regulate numerous elements of our business, including:

- product design and development;
- pre-clinical and clinical testing and trials;
- product safety;

- establishment registration and product listing;
- labeling and storage;
- marketing, manufacturing, sales and distribution;
- pre-market clearance, approval or certification;
- servicing and post-market surveillance;
- advertising and promotion; and
- recalls and field safety corrective actions.

Before we begin to label and market our product candidates for use as clinical diagnostics in the United States, we are required to obtain clearance from the FDA under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or FDCA, approval of a *de novo* classification request for our product, or approval of pre-market approval, or PMA, application from the FDA, unless an exemption from pre-market review applies. The process of obtaining regulatory clearances or approvals, or completing the *de novo* classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre-market reviews on a timely basis, if at all.

The FDA and other regulators or bodies can delay, limit or deny authorization or certification 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 products are substantially equivalent to a predicate device or are safe and effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical studies or the interpretation of data from preclinical studies or clinical studies;
- the data from our preclinical studies and clinical studies may be insufficient to support clearance, *de novo* classification, approval or certification, 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 marketing authorization or certification policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for marketing authorization or certification.

Any delay in, or failure to receive or maintain, clearance, certification or approval for our product candidates could prevent us from generating revenue from these product candidates and adversely affect our business operations and financial results.

Obtaining FDA clearance, *de novo* classification, or approval for diagnostics can be expensive and uncertain, and generally takes from several months to several years, and may require detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in the receipt of FDA marketing authorization. Even if we were to obtain such marketing authorizations for our products, it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those uses. Any delay in, or failure to receive or maintain, marketing authorization for our products could prevent us from generating revenue from these products and adversely affect our business operations and financial results.

The EU regulatory landscape concerning in vitro diagnostic medical devices is evolving. On May 26, 2022, the EU In Vitro Diagnostic Medical Devices Regulation, or IVDR, entered into force, which repealed and replaced the EU In Vitro Diagnostic Medical Devices Directive (*See – International Regulation - Regulation of Medical Devices in the European Union*) and these modifications will have an effect on the way we conduct our business in the EU and the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Subject to the transitional provisions (i.e., a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the regulation) and in order to sell our products in the member states of the EU our products must comply with the general safety and performance requirements of the IVDR. Compliance with these requirements is a prerequisite to be able to affix the European Conformity, or CE, mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the IVDR including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

To demonstrate compliance with the general safety and performance requirements we must undergo a conformity assessment procedure, which varies according to the type of in vitro diagnostic medical device and its (risk) classification. A conformity assessment procedure generally requires the intervention of a notified body. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to comply with applicable EU laws and regulations, and corresponding EU member state laws, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU.

If we fail to comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU. The aforementioned EU rules are generally applicable in the EEA. Non-compliance with the above requirements would also prevent us from selling our products in these three countries.

Following Brexit, EU laws no longer apply directly in Great Britain. The regulations on medical devices and in vitro diagnostic medical devices in Great Britain continue to be based largely on the three EU Directives which preceded the EU Medical Devices Regulation, or MDR and the (EU) IVDR, as implemented into national law. However under the terms of the Protocol on Ireland/Northern Ireland, the (EU) MDR and (EU) IVDR do apply to Northern Ireland. Consequently, there are currently different regulations in place in Great Britain as compared to both Northern Ireland and the EU, respectively. Ongoing compliance with both sets of regulatory requirements may result in increased costs for our business.

Furthermore, the UK Government is currently drafting amendments to the existing legislation which is likely to result in further changes to the Great Britain regulations in the near future. For example, subject to transitional periods for validly-certified devices, the new Great Britain regulations are likely to require medical devices and in vitro diagnostic medical devices placed on the Great Britain market to be "UKCA" certified by a UK Approved Body in order to be lawfully placed on the market. The UK Government has stated that the amended regulations are likely to apply from July 2024; understanding and ensuring compliance with any new such requirements is likely to lead to further complexity and increased costs to our business. If there is insufficient UK Approved Body capacity, there is a risk that our product certification could be delayed which might impact our ability to market products in Great Britain after the respective transition periods.

Even if granted, a 510(k) clearance, *de novo* classification, PMA approval, or similar authorization or certification from other regulators or notified bodies for any future product would likely place substantial restrictions on how our device is marketed or sold, and the FDA and other regulatory authorities or bodies will continue to place considerable restrictions on our products and operations. For example, the manufacture of medical devices in the United States must comply with the FDA's Quality System Regulation, or QSR. In addition, manufacturers must register their manufacturing facilities, list the products with the FDA, and comply with requirements relating to labeling, marketing, complaint handling, adverse event and medical device reporting, reporting of corrections and removals, and import and export. The FDA monitors compliance with the QSR and these other requirements through periodic inspections. If our facilities or those of our manufacturers or suppliers are found to be in violation of applicable laws and regulations, or if we or our manufacturers or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the FDA and other regulatory authorities could take enforcement action, including any of the following sanctions:

- adverse publicity, untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) clearance or PMA approvals or foreign regulatory authorizations or certifications of new products or modified products;
- withdrawing 510(k) clearances, PMA approvals or foreign regulatory authorizations or certifications that have already been granted;
- refusing to issue certificates to foreign governments needed to export products for sale in other countries;

- refusing to grant export approval for our products; or
- pursuing criminal prosecution.

Any of these sanctions could impair our ability to produce our products and product candidates in a cost-effective and timely manner in order to meet our customers' demands, and could have a material adverse effect on our reputation, business, results of operations and financial condition. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

In addition, the EU regulatory landscape concerning in vitro diagnostic medical devices recently evolved and a new regulation governing in vitro diagnostic medical devices became applicable on May 26, 2022 (*See – International Regulation - Regulation of Medical Devices in the European Union*) and these modifications may have an effect on the way we conduct our business in the EU and the EEA. For example, as a result of the transition towards the new regime, notified body review times have lengthened, and product introductions could be delayed or canceled, which could adversely affect our ability to grow our business.

In addition, FDA and foreign regulations and guidance are often revised or reinterpreted by the FDA and foreign regulatory authorities in ways that may significantly affect our business and our products. For example, on January 31, 2024, the FDA issued a final rule to amend the QSR to align more closely with ISO:13485 (2016), as established by the International Organization for Standardization. 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. 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 as a result of a changing regulatory landscape, we may lose any marketing authorizations that we have already obtained or fail to obtain new marketing approvals or clearances, and we may not be able to achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Our products could become subject to more onerous regulation by the FDA or other regulatory agencies in the future, which could increase our costs and delay or prevent commercialization of our products, thereby materially and adversely affecting our business, financial condition, results of operations and prospects.

We make certain of our products, including our T2Resistance Panel and T2Cauris Panel, available to customers as research use only, or RUO, products. RUO products include *in vitro* diagnostic products in the laboratory research phase of development that are being shipped or delivered for an investigation that is not subject to the FDA's investigational device exemption requirements. Products that are intended for RUO and are labeled as RUO are exempt from compliance with most FDA requirements, including premarket clearance or approval, manufacturing requirements, and others. A product labeled RUO but which is actually intended for clinical diagnostic use may be subject to FDA enforcement action as an adulterated and misbranded device. The FDA will consider the totality of the circumstances surrounding distribution and use of the product, including how the product is marketed and to whom, when determining the intended use of a product labeled RUO. The FDA could disagree with our assessment that our products are properly marketed as RUOs, or could conclude that products labeled as RUO are actually intended for clinical diagnostic use, and could take enforcement action against us, including requiring us to stop distribution of and recalling our products, which would reduce our revenue, increase our costs and adversely affect our business, prospects, results of operations and financial condition. In the event that the FDA requires us to obtain marketing authorization of our RUO products in the future, there can be no assurance that the FDA will grant any such marketing authorization requested by us in a timely manner, or at all.

Modifications to our products, if cleared, approved or certified, may require new 510(k) clearances or pre-market approvals or certifications, or may require us to cease marketing or recall the modified products until clearances or certifications are obtained.

Any modification to a device authorized for marketing that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA or *de novo* classification. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications, *de novo* classification requests or PMAs for modifications to previously cleared products for which we conclude that new marketing authorizations are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our business.

In the EU, in vitro diagnostic medical devices lawfully placed on the market pursuant to the IVDD prior to May 26, 2026 may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid and no substantial change must be made to the device as such a modification would trigger the obligation to obtain a new certification under the IVDR and therefore to have a notified body conducting a new conformity assessment of the devices. Once our devices will be certified under the IVDR, we must inform the notified body that carried out the conformity assessment of the devices that we market or sell in the EU and EEA of any planned substantial changes to our quality system or substantial changes to our in vitro diagnostic medical devices that could affect compliance with the general safety and performance requirements laid down in Annex I to IVDR or cause a substantial change to the intended use for which the device has been CE marked. The notified body will then assess the planned changes and verify whether they affect the products' ongoing conformity with the IVDR. If the assessment is favorable, the notified body will issue a new certificate of conformity or an addendum to the existing certificate attesting compliance with the essential requirements and quality system requirements laid down in the Annexes to the IVDR. The notified body may disagree with our proposed changes and product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

A recall of our products, either voluntarily or at the direction of the FDA or foreign regulatory authorities, or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities 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. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. We are subject to similar requirements under foreign regulations. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA or foreign regulatory authorities may require, or we may decide, that we will need to obtain new approvals, clearances or certifications for the device before we may market or distribute the corrected device. Seeking such approvals, clearances or certifications 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. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

The clinical study process is lengthy and expensive with uncertain outcomes, and the results of earlier studies may not be predictive of future clinical trial results.

Clinical testing is difficult to design and implement, can be a lengthy and expensive process and carries uncertain outcomes. 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 institutional review boards, or IRBs, or ethics committees, at the medical institutions where the clinical studies are conducted. Clinical studies must be conducted with supplies of our devices produced under current good manufacturing practice requirements and other applicable regulations. Furthermore, we rely on contract research organizations, or CROs, and clinical study sites to ensure the proper and timely conduct of our clinical studies and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical studies in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical studies, 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.

The results of preclinical studies and clinical studies of our products conducted to date and ongoing or future studies of our current, planned or future products may not be predictive of the results of later clinical studies, and interim results of a clinical study 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 studies. 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 studies have nonetheless failed to replicate results in later clinical studies. Products in later stages of clinical studies may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical studies. Failure can occur at any stage of clinical testing. The initiation and completion of any of clinical studies may be prevented, delayed, or halted for numerous reasons. We may experience delays in our ongoing clinical studies for a number of reasons, which could adversely affect the costs, timing or successful completion of our clinical studies, including related to the following:

- we may be required to submit an investigational device exemption application, or IDE, to the FDA, which must become effective prior to commencing certain human clinical studies of medical devices, and FDA may not approve our IDE 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 studies;
- regulators and/or IRBs or other reviewing bodies may not authorize us or our investigators to commence a clinical study, or to conduct or continue a clinical study at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the number of subjects or patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, and the number of clinical studies being conducted at any given time may be high and result in fewer available patients for any given clinical study, or patients may drop out of these clinical studies at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing products or conducting clinical studies 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 studies for various reasons;
- we may have to amend clinical study 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 studies may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical study;
- we may be unable to recruit a sufficient number of clinical study sites; and/or
- 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 studies may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply.

Any of these occurrences may significantly harm our business, financial condition and prospects.

Furthermore, patient enrollment in clinical studies and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the study protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical study, patient compliance, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical studies if the study protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product candidate. In addition, patients participating in our clinical studies may drop out before completion of the study or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical study may delay commencement or completion of the clinical study, cause an increase in the costs of the clinical study and delays, or result in the failure of the clinical study.

Disruptions at the FDA, other government agencies and notified bodies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared, approved, certified or commercialized in a timely manner, or at all, which could negatively impact our business.

The ability of the FDA, other government agencies, and notified bodies to review, and authorize or certify new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, their ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency's or notified bodies' ability to perform routine functions. Average review times at the FDA, other government agencies and notified bodies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, other agencies and notified bodies may also slow the time necessary for new medical devices or modifications to authorized or certified medical devices to be reviewed and/or cleared or approved or certified by necessary government agencies or notified bodies, which would adversely affect our business. For example, over the last several years, the United States government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

For instance, in the EU, notified bodies must be officially designated to certify products and services in accordance with the IVDR. Only a few notified bodies have been designated so far. Without IVDR designation, notified bodies may not yet start certifying devices in accordance with the new regulation. As only a few notified bodies have been IVDR-designated they are facing a heavy workload and their review times have lengthened. This situation could impact the way we are conducting our business in the EU and the EEA, and the ability of our notified body to timely review and process our regulatory submissions and perform its audits.

Our customers are highly dependent on payment from third-party payors, and inadequate coverage and/or reimbursement for diagnostic tests using our technology or for procedures using our products and product candidates would compromise our ability to successfully commercialize our diagnostic products and product candidates.

Successful commercialization of our diagnostic products and product candidates depends, in large part, on the extent to which the costs of our products and product candidates purchased by our customers are reimbursed, either separately or through bundled payment, by third-party private and governmental payors, including Medicare, Medicaid, managed care organizations and private insurance plans. There is significant uncertainty surrounding third-party coverage and reimbursement for the use of tests that incorporate new technology, such as our technology. There may be significant delays in obtaining coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Third-party payors may deny coverage if they determine that our diagnostic tests are not cost-effective compared to the use of alternative testing methods as determined by the payor, or is deemed by the third-party payor to be experimental or medically unnecessary. Even if third-party payors make coverage and reimbursement available, such reimbursement may not be adequate or these payors' reimbursement policies may have an adverse effect on our business, results of operations, financial condition and cash flows. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Hospitals, clinical laboratories and other healthcare provider customers that may purchase our products and 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 products and product candidates. The majority of our diagnostic tests are performed in a hospital inpatient setting, where governmental payors, such as Medicare, generally reimburse hospitals a single bundled payment that is based on the patients' diagnosis under a classification system known as the Medicare severity diagnosis-related groups, classification for all items and services provided to the patient during a single hospitalization, regardless of whether our diagnostic tests are performed during such hospitalization. In addition, new products may be eligible for a new technology add-on payment, or NTAP, for up to three years under the Medicare Hospital Inpatient Prospective Payment System, or IPPS, if they meet certain criteria, including, among other things, demonstrating a substantial clinical improvement relative to services or technologies previously available. For fiscal years 2021 through 2022, hospitals paid under the IPPS were eligible to receive a NTAP for T2Bacteria, which was incremental to the MS-DRG reimbursement for qualifying Medicare inpatient cases based on the cost of the case. Effective fiscal year 2023, T2Bacteria is no longer eligible for NTAP. To the extent that our diagnostic tests are performed in an outpatient setting, certain of our tests may be eligible for separate payment under the Clinical Laboratory Fee Schedule using existing Current Procedural Terminology, or CPT, codes.

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for various products. Our customers' access to adequate coverage and reimbursement for inpatient procedures and diagnostic tests, including our products, 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.

In many countries outside of the United States, various coverage, pricing and reimbursement approvals are required and vary from country to country. We expect that it will take several years to establish broad coverage and reimbursement for testing services based on our products with payors in countries outside of the United States, and our efforts may not be successful.

We are subject to federal, state and foreign healthcare fraud and abuse laws and other federal, state and foreign healthcare laws applicable to our business activities. If we are unable to comply, or have not complied, with such laws, we could face substantial penalties.

Our operations are, and will continue to be, directly or indirectly subject to various federal, state and foreign fraud and abuse laws, including, without limitation, the federal and state anti-kickback statutes, false claims laws and transparency laws regarding payments and other transfers of value made to physicians and other licensed healthcare professionals. These laws impact, among other things, our sales and marketing and education programs and require us to implement additional internal systems for tracking certain marketing expenditures and reporting them to government authorities. In addition, we may be subject to patient data privacy and security regulation by both the federal government and the states in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly or willfully soliciting, receiving, offering or paying any 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, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to commit a violation;
- federal false claims laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from or approval by a governmental payor program that are false or fraudulent. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established additional federal crimes for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the Anti-Kickback Statute, 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and imposes obligations, including mandatory contractual terms, on certain types of people and entities regarding the security and privacy of protected health information;
- the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologicals, 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 CMS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and
- state or foreign 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; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require manufacturers to report information related to payments and other transfers of value to physicians, hospitals and other healthcare providers, marketing expenditures, or pricing; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including significant administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, the curtailment or restructuring of our operations, integrity reporting obligations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

Healthcare policy changes, including legislation reforming the United States healthcare system, may have a material adverse effect on our financial condition and results of operations.

The Affordable Care Act, or ACA, enacted in March 2010, made changes that significantly impacted the pharmaceutical and medical device industries and clinical laboratories. Other significant measures for our industry contained in the ACA included coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures; initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians; and initiatives to promote quality indicators in payment methodologies. To the extent that the reimbursement amounts for sepsis decrease, it could adversely affect the market acceptance and hospital adoption of our technologies.

The ACA also mandated a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule, or CLFS, of 1.75% for the years 2011 through 2015 and a productivity adjustment to the CLFS, further reducing payment rates. Some commercial payors are guided by the CLFS in establishing their reimbursement rates. Clinicians may decide not to order clinical diagnostic tests if third-party payments are inadequate, and we cannot predict whether third-party payors will offer adequate reimbursement for procedures utilizing our products and product candidates to make them commercially attractive. To the extent that the diagnostic tests using our products and product candidates are performed on an outpatient basis, these or any future proposed or mandated reductions in payments under the CLFS may apply to some or all of the clinical laboratory tests that our diagnostics customers may use our technology to deliver to Medicare beneficiaries and may indirectly reduce demand for our diagnostic products and product candidates.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011 resulted in aggregate reductions of Medicare payments to providers, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the temporary suspension from May 1, 2020 through March 31, 2022, unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations.

On January 1, 2018, CMS implemented certain provisions of the Protecting Access to Medicare Act of 2014, or PAMA, which made substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for "advanced diagnostics laboratory tests"), private payer payment rates and volumes for their tests. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. CMS uses the data to calculate a weighted median payment rate for each test, which is used to establish a revised Medicare reimbursement rate. Under PAMA, the revised Medicare reimbursement rates were scheduled to apply to clinical diagnostic laboratory tests furnished on or after January 1, 2018. The revised reimbursement methodology is expected to generally result in relatively lower reimbursement under Medicare for clinical diagnostic lab tests that has been historically available. Any reduction to payment rates resulting from the new methodology is limited to 10% per test per year in 2018 through 2020, 0% per test per year in 2021 through 2023, and 15% per test per year in 2024 through 2026. The CARES Act, which was signed into law on March 27, 2020, amended the timeline for reporting private payer payment rates and delayed by one year the payment reductions scheduled for 2021. On December 10, 2021, Congress passed the Protecting Medicare and American Farmers from Sequester Cuts Act, or PMAFSA, which delayed the next data reporting period by an additional year and prevented any reduction in payment amounts from commercial payer rate implementation in 2022. The Consolidated Appropriations Act, 2023, enacted on December 29, 2022, further revised the next data reporting period for certain tests and delayed the phase-in of payment reductions for an additional year, through 2026.

In the EU, similar developments may affect our ability to profitably commercialize our products, if certified. In December 2021, the EU Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once the regulation becomes applicable, it will have a phased implementation depending on the concerned products. This regulation intends to boost cooperation among EU member states in assessing health technologies, including some high-risk medical devices and in vitro diagnostic medical devices, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement

We expect that additional state, federal and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal, state and foreign governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure. We 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, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation and the expansion in government's effect on the United States healthcare industry may result in decreased profits to us, lower reimbursements by payors for our products and product candidates or reduced medical procedure volumes, any of which may adversely affect our business, financial condition and results of operations.

Risks Related to Intellectual Property

If we are unable to protect our intellectual property effectively, our business would be harmed.

We rely on patent protection as well as trademark, copyright, trade secret protection and confidentiality agreements to protect the intellectual property rights related to our proprietary technologies. The strength of patents in our field involves complex legal and scientific questions. Uncertainty created by these questions means that our patents may provide only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We own or exclusively license over 40 issued U.S. patents and patent applications. We also own or license over 50 pending or granted counterpart applications worldwide. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

We cannot assure you that any of our currently pending or future patent applications will result in issued patents with claims that cover our products and technologies in the United States or in other foreign countries, and we cannot predict how long it will take for such patents to be issued. Further, issuance of a patent is not conclusive as to its inventorship or scope, and there is no guarantee that our issued patents will include claims that are sufficiently broad to cover our technologies or to provide meaningful protection of our products from our competitors. Further, we cannot be certain that all relevant prior art relating to our patents and patent applications has been found. Accordingly, there may be prior art that can invalidate our issued patents or prevent a patent from issuing from a pending patent application, at all or with claims that have a scope broad enough to provide meaningful protection from our competitors.

Even if patents do successfully issue and even if such patents cover our products and technologies, we cannot assure you that other parties will not challenge the validity, enforceability or scope of such issued patents in the United States and in foreign countries, including by proceedings such as re-examination, inter partes review, interference, opposition, or other patent office or court proceedings. Moreover, we cannot assure you that if such patents were challenged in court or before a regulatory agency that the patent claims will be held valid, enforceable, or be sufficiently broad to cover our technologies or to provide meaningful protection from our competitors. Nor can we assure you that the applicable court or agency will uphold our ownership rights in such patents. Accordingly, we cannot guarantee that we will be successful in defending challenges made against our patents and patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents, or narrowing of claim scope, such that we could be deprived of patent protection necessary for the successful commercialization of our products and technologies, which could adversely affect our business.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our products and technologies or prevent others from designing around our claims. Others may independently develop similar or alternative products and technologies or duplicate any of our products and technologies. These products and technologies may not be covered by claims of issued patents owned by our company. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of the protections provided by our intellectual property rights. If our intellectual property, including licensed intellectual property, does not adequately protect our market position against competitors' products and methods, our competitive position could be adversely affected, as could our business.

Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product or product candidate under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to make the inventions covered by our pending patent applications, or that we were the first to file any patent application related to a product or product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. For example, recent decisions raise questions regarding the award of patent term adjustment ("PTA") for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will/will not be viewed in the future and whether patent expiration dates may be impacted.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

We depend on certain technologies that are licensed to us. We do not control the intellectual property rights covering these technologies and any loss of our rights to these technologies or the rights licensed to us could prevent us from selling our products.

We are a party to a number of license agreements under which we are granted rights to intellectual property that is important to our business and we expect that we may need to enter into additional license agreements in the future. We rely on these licenses in order to be able to use various proprietary technologies that are material to our business, including an exclusive license to patents and patent applications from Massachusetts General Hospital, or MGH, and non-exclusive licenses from other third parties related to materials used currently in our research and development activities, and which we use in our commercial activities. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to the continuation of and our compliance with the terms of those licenses. Our existing license agreements impose, and we expect that future license agreements will impose on us, various diligence obligations, payment of milestones or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

As we have done previously, we may need to obtain licenses from third parties to advance our research or allow commercialization of our products and technologies, and we cannot provide any assurances that third-party patents do not exist which might be enforced against our current products and technologies or future products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. 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, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products and technologies, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation.

In some cases, we do not control the prosecution, maintenance, or filing of the patents that are licensed to us, or the enforcement of these patents against infringement by third parties. Some of our patents and patent applications were not filed by us, but were either acquired by us or are licensed from third parties. Thus, these patents and patent applications were not drafted by us or our attorneys, and we did not control or have any input into the prosecution of these patents and patent applications either prior to our acquisition of, or entry into a license with respect to, such patents and patent applications. With respect to the license from MGH, although we have rights under our agreement to provide input into prosecution and maintenance activities, and are actively involved in such ongoing prosecution, MGH retains ultimate control over such prosecution and maintenance. We therefore cannot be certain that the same attention was given, or will continue to be given, to the drafting and prosecution of these patents and patent applications as we may have exercised if we had control over the drafting and prosecution of such patents and patent applications, or that we will agree with decisions taken by MGH in relation to ongoing prosecution activities. We also cannot be certain that drafting or prosecution of the patents and patent applications licensed to us have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Further, as MGH retains the right to enforce any licensed patent against third-party infringement, we cannot be certain that MGH will elect to enforce the patent to the extent that we would choose to do so, or in a way that will ensure that we retain the rights we currently have under our license with MGH. If MGH fails to properly enforce the patent subject to our license in the event of third-party infringement, our ability to retain our competitive advantage with respect to our products and product candidates may be materially affected.

In addition, certain of the patents we have licensed relate to technology that was developed with U.S. government grants. Federal regulations impose certain domestic manufacturing requirements and other obligations with respect to some of our products embodying these patents.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products and technologies, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

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 products and technologies.

We may be involved in lawsuits to protect or enforce our patents and proprietary rights, to determine the scope, enforceability and validity of others' proprietary rights, or to defend against third-party claims of intellectual property infringement, any of which could be time-intensive and costly and may adversely impact our business or stock price.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the medical device and diagnostics industries, including patent infringement lawsuits, interferences, oppositions and inter partes review proceedings before the U.S. Patent and Trademark Office, or U.S. PTO, and corresponding foreign patent offices.

We have received a notice of claims of infringement or misappropriation or misuse of other parties' proprietary rights in the past, and we may from time to time receive such additional notices in the future. Some of these claims may lead to litigation. Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, methods of manufacture or methods of use of our products and technologies. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that our products and technologies may infringe, or which such third parties claim are infringed by the use of our technologies. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets or infringement by us of third-party patents, trademarks or other rights, or challenging the validity of our patents, trademarks or other rights, will not be asserted against us.

Litigation may be necessary for us to enforce our patent and proprietary rights or to determine the scope, enforceability or validity of the proprietary rights of others. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the medical diagnostics industry. Third parties may assert that we are employing their proprietary technology without authorization. Many of our competitors have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Parties making claims against us for infringement of their intellectual property rights may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products and technologies. Further, defense of such claims in litigation, regardless of merit, could result in substantial legal fees and could adversely affect the scope of our patent protection, and would be a substantial diversion of employee, management and technical personnel resources from our business. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us. In the event of a successful claim of infringement against us, we could be required to redesign our infringing products or obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. 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. We could therefore incur substantial costs for licenses obtained from third parties, if such licenses were available at all, which could negatively affect our gross margins, or prevent us from commercializing our products and technologies. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products to avoid infringing third-party rights. In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, enforceability or scope of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. Any litigation that may be necessary in the future could result in substantial costs and the diversion of our resources and could have a material adverse effect on our business, operating results or financial condition. Further, if the scope of protection provided by our patents or patent applications is threatened or reduced as a result of litigation, it could discourage third parties from entering into collaborations with us that are important to the commercialization of our products.

We cannot guarantee that we have identified all relevant third-party intellectual property rights that may be infringed by our technology, nor is there any assurance that patents will not issue in the future from currently pending applications that may be infringed by our technology or products or product candidates. We are aware of third parties that have issued patents and pending patent applications in the United States, EU, Canada, and other jurisdictions in the field of magnetic resonance devices and methods for analyte detection, including the preparation and use of reagents. While we continue to evaluate third-party patents in this area on an ongoing basis, we cannot guarantee that patents we currently are aware of will be found invalid or not infringed if we are accused of infringing them, or if our products are found to infringe, that we will be able to modify our products to cause them to be non-infringing on a timely or cost-effective basis, or at all. We currently monitor the intellectual property positions of some companies in this field that are potential competitors or are conducting research and development in areas that relate to our business and will continue to do so as we progress the development and commercialization of our products or product candidates. While we continue to evaluate third-party patents in this area on an ongoing basis, we cannot assure you that third parties do not currently have or will not in the future have issued patents or other intellectual property rights that may be infringed by the practice of our technology or the commercialization of our products or product candidates.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or you perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, certain of our agreements with suppliers, distributors, customers and other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims relating to our technologies or products, or rights licensed to them by us. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify any of these third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

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

In addition to pursuing patents on our technology, we also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our products and technologies and discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents, in order to maintain our competitive position. We take steps to protect our intellectual property, proprietary technologies and trade secrets, in part, by entering into confidentiality agreements with our employees, consultants, corporate partners, 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 assign to us any inventions developed in the course of their work for us. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Our agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable. 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, courts outside the United States may be less willing to protect trade secrets. If any of the technology or information that we protect as trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

We may be subject to damages resulting from claims that we or our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at universities or other medical device companies, including our competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of our employees' former employers, or we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our products and technologies. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could hamper our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our products and technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. 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.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The U.S. PTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, were enacted March 16, 2013. However, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the U.S. PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, however there are situations in which noncompliance 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, competitors might be able to enter the market earlier than would otherwise have been the case.

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.

We have not yet registered certain of our trademarks in all of our potential markets, including in international markets. If we apply to register these trademarks, our applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

We may not be able to protect our intellectual property rights throughout the world.

The laws of some non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to technologies relating to biotechnology, which could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Also, because we have not pursued patents in all countries, there exist jurisdictions where we are not protected against third parties using our proprietary technologies. Further, compulsory licensing laws or limited enforceability of patents against government agencies or contractors in certain countries may limit our remedies or reduce the value of our patents in those countries.

We use third-party software that may be difficult to replace or cause errors or failures of our products that could lead to lost customers or harm to our reputation.

We use software licensed from third parties in our products. In the future, this software may not be available to us on commercially reasonable terms, or at all. Any loss of the right to use any of this software could result in delays in the production of our products until equivalent technology is either developed by us, or, if available, is identified, obtained and integrated with our technologies and products, which could harm our business. In addition, any errors or defects in, or failures of, such third-party software could result in errors or defects in the operation of our products or cause our products to fail, which could harm our business and reputation and be costly to correct. Many of the licensors of the software we use in our products attempt to impose limitations on their liability for such errors, defects or failures. If enforceable, such limitations would require us to bear the liability for such errors, defects or failures, which could harm our reputation and increase our operating costs.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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. The following examples are illustrative:

- others may be able to make diagnostic products and technologies that are similar to our products or product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our 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 will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Our Common Stock

A consistent, stable and active market for our common stock may not be sustained.

Since our initial listing on The Nasdaq Global Market in August 2014 and our transfer to the Nasdaq Capital Market in 2022, the trading market in our common stock has experienced periods of volatility. The listing of our common stock on The Nasdaq Capital Market does not assure that a meaningful, consistent and liquid trading market will exist or continue. We cannot predict whether an active market for our common stock will be sustained in the future.

The absence of an active trading market could adversely affect our stockholders' ability to sell our common stock at current market prices in short time periods, or possibly at all. Additionally, market visibility for our common stock may be limited and such lack of visibility may have a depressive effect on the market price for our common stock.

The price of our common stock has been volatile and is likely to continue to be volatile, which could result in substantial losses for purchasers of our common stock.

Our stock price has been and is likely to continue be volatile. The stock market in general has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the current market price. The market price for our common stock may be influenced by many factors, including:

- the composition of our stockholders, particularly the presence of short sellers or day traders trading in our stock;
- actual or anticipated fluctuations in our financial condition and operating results;
- announcements by us relating to the timing of regulatory clearance for our product candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- development of new technologies that may address our markets and may make our technology less attractive;
- changes in physician, hospital or healthcare provider practices that may make our products or product candidates less useful;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes to reimbursement levels by commercial third-party payors and government payors, including Medicare, and any announcements relating to reimbursement levels;
- technical factors in the public trading market for our stock that may produce price movements that may or may not comport with macro, industry or company-specific fundamentals, including, without limitation, the sentiment of retail investors (including as may be expressed on financial trading and other social media sites), the amount and status of short interest in our securities, access to margin debt, trading in options and other derivatives on our common stock and other technical trading factors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

We continue to incur significant costs as a result of operating as a public company, and our management continues to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting, insurance and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Capital Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We continue to be subject to applicable securities rules and regulations. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain a non-accelerated filer, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the Securities and Exchange Commission or Section 404. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, the Company's disclosure controls and procedures were not effective due to material weaknesses in our internal control over financial reporting. The material weaknesses remain unremediated as of December 31, 2023. The Company will establish enhanced evaluation and review procedures to prevent future occurrences.

Provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board of Directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Among other things, these provisions include those establishing:

- a classified Board of Directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our Board of Directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- the exclusive right of our Board of Directors to elect a director to fill a vacancy created by the expansion of the Board of Directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our Board of Directors;
- the ability of our Board of Directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our Board of Directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chief executive officer, the president or the Board of Directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our Board of Directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. In the event any of the analysts who cover us, or any investors who have taken a short position in our stock, issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our regulatory clearance timelines, clinical trial results or operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Our ability to pay cash dividends is prohibited by the terms of our existing credit facility. Any future debt agreements may also preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 1C. CYBERSECURITY

Risk management and strategy

We rely on our information technology to operate our business and understand the importance of preventing, assessing, identifying, and managing material risks associated with cybersecurity threats. Cybersecurity processes to assess, identify and manage risks from cybersecurity threats have been incorporated as a part of our overall risk assessment process and have been embedded in our operating procedures, internal controls and information systems. On a regular basis, we implement into our operations these cybersecurity processes, technologies, and controls to assess, identify and manage material risks.

As part of our broader risk management framework, we have identified potential cybersecurity risks to our business. We have designed our business applications and hosting services to minimize the impact that cybersecurity incidents could have on our business and have identified back-up systems where appropriate. We seek to further mitigate cybersecurity risks through a combination of monitoring and detection activities, use of anti-malware applications, employee training, quality audits and communication and reporting structures, among other processes. We have an incident response plan in place that outlines containment, eradication and recovery plans in the event of a cybersecurity threat or incident.

We engage a third-party consultant to assist us with designing controls and our cybersecurity risk management framework, and we are engaging with a third party to perform penetration testing. We also retain third parties to assist with the monitoring and detection of cybersecurity threats and responding to any cybersecurity threats or incidents.

With respect to third parties that manage or use our information technology or data, we obtain reports to assess the security of their systems and processes. We engage in ongoing monitoring of all critical third-party providers to help ensure compliance with our cybersecurity standards.

We have not encountered cybersecurity threats or incidents that have had a material impact on our business.

Governance

Our Board of Directors has assigned specific oversight responsibility for cybersecurity to our Audit Committee. The Audit Committee reviews and discusses with management our policies, practices and risks related to information security and cybersecurity.

Our General Counsel has primary responsibility for assessing, monitoring and managing cybersecurity risks.

Our General Counsel provides an update to the Audit Committee on any risks related to cybersecurity on a quarterly basis. Our incident response plan includes notifying the Audit Committee, and then the Board of Directors, of any material threats or incidents that arise.

Item 2. PROPERTY

Our corporate headquarters is located in Lexington, Massachusetts, where we currently lease approximately 23,200 square feet of space of which 12,200 square feet is laboratory space and 11,000 square feet is manufacturing space. Our base rent for leases at our corporate headquarters is between $2.2 million and $2.4 million annually for the duration of the leases. In addition, we lease approximately 7,600 square feet in Wilmington, Massachusetts for our manufacturing facility, for $0.1 million of base rent annually for the duration of the lease.

Item 3. LEGAL PROCEEDINGS

On September 8, 2021, the Company entered into a 10-year lease agreement (the “Lease”) with Farley White Concord Road, LLC (the “Landlord”), pursuant to which the Company leased approximately 70,125 square feet for its occupancy and use as office, laboratory and commercial manufacturing space at 290 Concord Road, Billerica, Massachusetts (the “Premises").

On January 17, 2023, the Landlord sent a Notice of Termination (the “Notice”) of the Lease to the Company. The Notice provides that the Landlord terminated the Lease because of the Company’s alleged failure to perform its obligations under the Lease in a timely manner and the Company’s alleged breach of the covenant of good faith and fair dealing. In connection with the Notice, on January 18, 2023, the Landlord filed a complaint in the Massachusetts Superior Court and has unilaterally deducted the Company’s $1,000,000 security deposit for its alleged damages. In addition, the Landlord is seeking damages for unpaid rent, brokerage fees, transaction costs, attorney's fees and court costs.

On March 1, 2023, the Company filed a response to the Landlord’s complaint and a counterclaim alleging that the Landlord breached its obligations under the contract and unlawfully drew on the security deposit, in addition to breaching its covenants of good faith and fair dealing, making fraudulent misrepresentations, and engaging in deceptive and unfair trade practices.

The Company intends to pursue legal remedies available under applicable laws.

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 and Holders

Our common stock is quoted on The Nasdaq Capital Market under the symbol "TTOO" and has been trading since August 7, 2014. On March 28, 2024, there were 13 holders of record of our common stock. This number does not include stockholders whose shares may be held in trust by other entities or stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and do not expect to pay any dividends for the foreseeable future. We currently intend to retain any future earnings to fund the operation, development and expansion of our business. Any future determination to pay dividends will be at the sole discretion of our Board of Directors and will depend upon a number of factors, including our results of operations, capital requirements, financial condition, future prospects, contractual arrangements, restrictions imposed by applicable law, any limitations on payments of dividends present in our current and future debt arrangements, and other factors our Board of Directors may deem relevant.

Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Sales of Unregistered Securities

None.

Item 6. [RESERVED]

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our consolidated financial condition and results of operations together with our consolidated financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, 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 "Item 1A.—Risk Factors" section of this Annual Report on Form 10-K, 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.

Business Overview

We are an in vitro diagnostics company and leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes. We are dedicated to improving patient care and reducing the cost of care by helping clinicians effectively treat patients faster than ever before. We have developed innovative products that offer a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are developing a broad set of applications aimed at improving patient outcomes, reducing the cost of healthcare, and lowering mortality rates by helping medical professionals make earlier targeted treatment decisions. Our technology enables rapid detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, plasma, serum, saliva, sputum and urine, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter, or CFU/mL. We are currently targeting a range of critically underserved healthcare conditions, focusing initially on those for which a rapid diagnosis will serve an important dual role – saving lives and reducing costs. Our current development efforts primarily target sepsis, bioterrorism, and Lyme disease, which are areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics.

Our primary commercial products include the T2Dx® Instrument, the T2Candida® Panel, the T2Bacteria® Panel, the T2Resistance® Panel, and the T2Biothreat Panel.

We have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit on December 31, 2023 was $584.3 million and we have experienced cash outflows from operating activities since inception. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs, from selling, general and administrative costs associated with our operations, and costs of product revenue. We have incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution of our FDA-cleared products, the T2Dx Instrument, T2Candida Panel, T2Bacteria Panel, and T2Biothreat Panel. In addition, we will continue to incur significant costs and expenses as we continue to develop other product candidates, improve existing products and maintain, expand and protect our intellectual property portfolio. We may seek to fund our operations through public equity or private equity or debt financings, as well as other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on our business, results of operations and financial condition and our ability to develop, commercialize and drive adoption of the T2Dx Instrument and the T2Candida, T2Bacteria, T2Resistance and T2Biothreat Panels and future products.

We are subject to a number of risks similar to other early commercial stage life science companies, including, but not limited to commercially launching our products, development and market acceptance of our product candidates, development by our competitors of new technological innovations, protection of proprietary technology, and raising additional capital.

We believe that our cash, cash equivalents, and restricted cash of $16.2 million on December 31, 2023 will not be sufficient to fund our current operating plan at least a year from issuance of our financial statements for the year ended December 31, 2023 unless additional funds are raised in the first half of 2024. Certain elements of our operating plan cannot be considered probable. During the year ended December 31, 2023, we reduced our overall cost structure, including reductions in headcount and operating expenses, with a focus on lowering overall operating expenses and improving cost of goods sold.

The Company's Term Loan Agreement (the "Term Loan Agreement") with certain CRG entities (collectively, "CRG") (See Note 6 of the notes to our consolidated financial statements) has a minimum liquidity covenant, which initially required the Company to maintain a minimum cash balance of $5.0 million. In May 2023, CRG reduced the minimum liquidity covenant under the Term Loan Agreement from $5.0 million to $500,000 until December 31, 2023. In July 2023, the Company also converted $10.0 million of the outstanding debt with CRG to equity. In October 2023, the Term Loan Agreement was amended to extend both the interest-only period and the maturity date by one year from December 30, 2024 to December 31, 2025, and permanently reduce the minimum liquidity covenant from $5.0 million to $500,000. There can be no assurances that the Company will continue to be in compliance with the cash covenant in future periods without additional funding.

On March 30, 2023, the Company received notice from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 555(a)(2) (the "Minimum Bid Price Rule"). On May 23, 2023, Nasdaq notified the Company that its securities were subject to delisting due to non-compliance with the Minimum Bid Price Rule and to maintain a minimum value of listed securities (the "MVLS Rule") of at least $35 million. The Company requested a hearing with Nasdaq and, on July 6, 2023, appealed to the Nasdaq Hearings Panel for an extension to the time period in which to regain compliance with the MVLS Rule and the Minimum Bid Price Rule. On July 26, 2023, we filed a definitive proxy statement to effect a reverse stock split of our common stock in connection with our annual meeting that occurred in September 2023 as required by the Nasdaq Hearings Panel. On August 9, 2023, the Company received written notice from Nasdaq informing the Company that it had regained compliance with the MVLS Rule. On September 15, 2023, at the Company's annual meeting of stockholders, the Company's stockholders approved an amendment to the Company's restated certificate of incorporation to effect a reverse stock split of the Company's common stock. On October 12, 2023, the Company announced that its board of directors had approved the reverse stock split at the ratio of 1 post-split share for every 100 pre-split shares, which was effective as of October 12, 2023.

On October 31, 2023, the Company received written notice from Nasdaq informing the Company that it has regained compliance with the Minimum Bid Price Rule. The Company will be subject to a Mandatory Panel Monitor for a period of one year. If, within that one-year monitoring period, the Company fails to comply with the Minimum Bid Price Rule, the Company will not be permitted additional time to regain compliance with the Minimum Bid Price Rule. However, the Company will have an opportunity to request a new hearing with the Nasdaq Hearings Panel prior to the Company's securities being delisted from Nasdaq.

On November 20, 2023, the Company received written notice from Nasdaq informing the Company that it no longer satisfied the MVLS Rule. In accordance with the terms of the Mandatory Panel Monitor, the Company was not granted a grace period but rather issued a delist determination, which will be stayed if the Company exercises its right to appeal by requesting a hearing and paying a non-refundable $20,000 fee. The Company has paid the $20,000 applicable fee and requested a new hearing, which will stay any further action by Nasdaq at least pending the issuance of its decision and the expiration of any extension that may be granted to the Company as a result of the hearing. The Company's common stock will remain listed and eligible to trade on Nasdaq pending the outcome of the hearing. On February 15, 2024, the Company appealed to the Nasdaq Hearings Panel for an extension to the time period in which to regain compliance with the MVLS Rule. On March 11, 2024, the Company received notice from the Nasdaq Hearings Panel that it had granted the Company's request for continued listing on Nasdaq, subject to the Company demonstrating compliance with Nasdaq's MVLS Rule on or before May 20, 2024.

These conditions raise substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that the financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt include raising additional funding, delaying certain research projects and capital expenditures, and eliminating certain future operating expenses in order to fund operations at reduced levels in order to continue as a going concern for a period of 12 months from the date these audited consolidated financial statements are issued. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources or maintain reduced expenditures, while reasonably possible, is less than probable. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of these financial statements.

Financial Overview

Revenue

We generate revenue from the sale of our products, related services, reagent rental agreements and government contributions.

Grants received, including cost reimbursement agreements, are assessed to determine if the agreement should be accounted for as an exchange transaction or a contribution. An agreement is accounted for as a contribution if the resource provider does not receive commensurate value in return for the assets transferred.

Product revenue is generated by the sale of instruments and consumable diagnostic tests predominantly through our direct sales force in the United States and distributors in geographic regions outside the United States. We generally do not offer product returns or exchange rights (other than those relating to defective goods under warranty) or price protection allowances to our customers, including our distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors' receipt of payment from their end-user customers. We either sell instruments to customers and international distributors, or retain title and place the instrument at the customer site pursuant to a reagent rental agreement. When the instrument is placed under a reagent rental agreement, our customers generally agree to fixed term agreements, which can be extended, and incremental charges on each consumable diagnostic test purchased. Shipping and handling costs are billed to customers in connection with a product sale.

Fees paid to member-owned group purchasing organizations ("GPOs") are deducted from related product revenues.

Direct sales of instruments include warranty, maintenance and technical support services typically for one year following the installation of the purchased instrument ("Maintenance Services"). Maintenance Services are separate performance obligations as they are service based warranties and are recognized on a straight-line basis over the service delivery period. After the completion of the initial Maintenance Services period, customers have the option to renew or extend the Maintenance Services typically for additional one-year periods in exchange for additional consideration. The extended Maintenance Services are also service based warranties that represent separate purchasing decisions.

We warrant that consumable diagnostic tests will be free from defects, when handled according to product specifications, for the stated life of the product. To fulfill valid warranty claims, we provide replacement product free of charge.

Our current sales strategy is to drive adoption of our test platform installed base in hospitals and to increase test use by our existing hospital customers. Accordingly, we expect the following to occur:

- recurring revenue from our consumable diagnostic tests will increase; and
- become a more predictable and significant component of total revenue; and
- we will gain manufacturing economies of scale through the growth in our sales, resulting in improving gross margins and operating margins.

In September 2023, the Company's milestone-based product development contract with the Biomedical Advanced Research and Development Authority ("BARDA") (See Note 16 of the notes to our consolidated financial statements) expired.

Cost of product revenue

Cost of product revenue includes the cost of materials, direct labor and manufacturing overhead costs used in the manufacture of our consumable diagnostic tests sold to customers and related license and royalty fees. Cost of product revenue also includes depreciation on the revenue-generating T2Dx instruments that have been placed with our customers under reagent rental agreements; costs of materials, direct labor and manufacturing overhead costs on the T2Dx instruments sold to customers; and other costs such as customer support costs, warranty and repair and maintenance expense on the T2Dx instruments that have been placed with our customers under reagent rental agreements. We manufacture the T2Dx instruments and part of our consumable diagnostic tests in our facilities. We outsource the manufacturing of components of our consumable diagnostic tests to contract manufacturers. We expect cost of product revenue to decrease as a percentage of revenue as a result of the cost of product revenue improvement initiatives.

Research and development expenses

Our research and development expenses consist primarily of costs incurred for the development of our technology and product candidates, technology improvements and enhancements, clinical trials to evaluate the clinical utility of our product candidates, and laboratory development and expansion, and include salaries and benefits, including stock-based compensation, research related facility and overhead costs, laboratory supplies, equipment, depreciation on T2Dx instruments used in research and development activities and contract services. Research and development expenses also include costs of delivering products or services associated with contribution revenue. We expense all research and development costs as incurred.

We anticipate our overall research and development expenses to remain consistent. We expect to continue developing additional product candidates, improving existing products, and conducting ongoing and new clinical trials.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of costs for our sales, marketing, service, medical affairs, finance, legal, human resources, information technology, and general management functions, as well as professional services, such as legal, consulting and accounting services. Other selling, general and administrative expenses include commercial support activity, facility-related costs, fees and expenses associated with obtaining and maintaining patents, clinical and economic studies and publications, marketing expenses, and travel expenses. We expense the majority of selling, general and administrative expenses as incurred. We expect selling, general and administrative expenses to decrease as a percentage of revenue in future periods.

Impairment of property and equipment

Impairment of property and equipment relates to loss recorded when the carrying value of property and equipment is written down to its estimated fair value when indicators of impairment exist.

Interest expense to related party

Interest expense to related party consists primarily of interest expense on our notes payable, the amortization of deferred financing costs and debt discount.

Change in fair value of derivative related to Term Loan with related party

The change in fair value of the derivative consists of the change in fair value of the derivative associated with the CRG Term Loan Agreement.

Change in fair value of warrant liabilities

The change in fair value of the derivative warrant liability consists of the change in fair value of the derivative warrant liability associated with the Securities Purchase Agreement.

Other, net

Other, net consists of dividend income, other investment income, interest income earned on our cash and cash equivalents, non-recurring expenses including issuance costs allocated to the derivative warrant liability, and non-recurring gains and losses including the initial loss on issuance of Series A redeemable convertible preferred stock and derivative warrant liability.

Results of Operations for the Years Ended December 31, 2023 and 2022

	Year Ended December 31,		
	2023	2022	Change
		(in thousands)	
Revenue:			
Product revenue	$ 6,770	$ 11,259	$ (4,489)
Contribution revenue	423	11,046	(10,623)
Total revenue	7,193	22,305	(15,112)
Costs and expenses:			
Cost of product revenue	15,363	21,010	(5,647)
Research and development	14,153	25,715	(11,562)
Selling, general and administrative	24,830	30,625	(5,795)
Impairment of property and equipment	2,511	151	2,360
Total costs and expenses	56,857	77,501	(20,644)
Loss from operations	(49,664)	(55,196)	5,532
Other income (expense):			
Interest expense to related party	(5,343)	(6,084)	741
Change in fair value of derivative related to Term Loan with related party	(466)	(1,088)	622
Change in fair value of warrant liabilities	5,891	326	5,565
Other, net	(495)	39	(534)
Total other expense	(413)	(6,807)	6,394
Net loss	$ (50,077)	$ (62,003)	$ 11,926

Product revenue

During the year ended December 31, 2023, product revenue was $6.8 million, compared to $11.3 million for the year ended December 31, 2022, a decrease of $4.5 million, which was driven by lower consumables sales of $3.3 million primarily due to a decrease in sales of T2SARS-CoV-2 tests, product backorder due to manufacturing, supply chain, and raw material matters, lower T2Dx Instrument and related sales of $1.0 million, and lower revenue under our service agreements of $0.2 million.

Contribution revenue

Contribution revenue, all from the BARDA contract, was $0.4 million for the year ended December 31, 2023, compared to $11.0 million for the year ended December 31, 2022, a decrease of $10.6 million, which was driven by decreased contract activity and the timing and option amounts available in 2023 compared to 2022.

Cost of product revenue

During the year ended December 31, 2023, cost of product revenue was $15.4 million, compared to $21.0 million for the year ended December 31, 2022, a decrease of $5.6 million. The decrease was driven by $2.0 million of decreased costs related to lower consumable sales, $1.5 million of lower shipping and other costs, $1.5 million of lower service and repair costs, $0.9 million of costs related to lower instrument sales, and $0.1 million of lower royalty costs, partially offset by $0.4 million of increased costs due to the effect of a change in build plan and manufacturing inefficiencies.

Research and development expenses

Research and development expenses were $14.2 million for the year ended December 31, 2023, compared to $25.7 million for the year ended December 31, 2022, a decrease of $11.6 million. Lab and facility expenses decreased by $3.5 million primarily due to the timing of expenses associated with BARDA Option 3 compared to Option 2A, lower employee headcount, and lower material purchases; payroll related and stock-based compensation expenses decreased by $2.7 million due to lower employee headcount; clinical-related expenses decreased by $1.9 million due to the conclusion of several clinical trials; consulting expenses decreased by $1.8 million due to the completion of the T2Biothreat clinical trial; research and development project related expenses decreased by $1.6 million; and other costs decreased by $0.1 million.

Selling, general and administrative expenses

Selling, general and administrative expenses were $24.8 million for the year ended December 31, 2023, compared to $30.6 million for the year ended December 31, 2022, a decrease of $5.8 million. The decrease was driven by lower payroll related and stock-based compensation expenses of $4.6 million primarily due to lower employee headcount; lower other expenses of $1.2 million primarily due to the $1.0 million estimated liability recorded for our Billerica, Massachusetts lease for the year ended December 31, 2022; lower marketing expenses of $0.6 million; a decrease in travel expenses of $0.3 million; and a $0.2 million decrease in other expenses primarily due to less IT support services and less facilities costs, partially offset by an increase in consulting expenses of $0.6 million and an increase in legal expenses of $0.5 million.

Impairment of property and equipment

Impairment of property and equipment was $2.5 million for the year ended December 31, 2023, which was comprised of $2.3 million of impairment charges related to reagent manufacturing assets and $0.2 million of impairment charges related to T2-owned non-lease instruments. Impairment of property and equipment was $0.2 million for the year ended December 31, 2022.

Interest expense to related party

Interest expense to related party was $5.3 million for the year ended December 31, 2023, compared to $6.1 million for the year ended December 31, 2022. Interest expense to related party decreased by $0.8 million primarily due to the cancellation of $10.0 million of the CRG Term Loan's principal in exchange for common stock and Series B Convertible Preferred Stock in July 2023.

Change in fair value of derivative related to Term Loan with related party

The change in fair value of the derivative instrument associated with the CRG Term Loan Agreement (See Note 6 of the notes to our consolidated financial statements) was $0.5 million of expense for the year ended December 31, 2023 and $1.1 million of expense for the year ended December 31, 2022.

Change in fair value of warrant liabilities

The change in fair value of warrant liabilities consisted of $5.9 million of income primarily associated with the Common Stock Warrants and Pre-Funded Warrants (see Note 8 of the notes to our consolidated financial statements) for the year ended December 31, 2023. The change in fair value of warrant liabilities consisted of $0.3 million of income for the year ended December 31, 2022.

Other, net

Other, net was an expense of $0.5 million for the year ended December 31, 2023, primarily consisting of issuance costs allocated to the Common Stock Warrants of $0.7 million, partially offset by dividend income of $0.2 million and other income of $0.1 million. Other, net was immaterial for the year ended December 31, 2022.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of December 31, 2023 and 2022, we had an accumulated deficit of $584.3 million and $534.2 million, respectively. We have incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We may seek to continue to fund our operations through public equity or private equity or debt financings, as well as other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on our business, results of operations and financial condition.

Historically, the Company has primarily funded its operations through public equity and private debt financings. The Company believes its cash position is insufficient to fund future operations without financings by the first half of 2024. Financings may include public or private equity or debt financings. These financings may not be successful, however, or on terms favorable to the Company or its stockholders which would have a negative impact on the Company's business, results of operations, financial condition and the Company's ability to develop and commercialize its products and ultimately operate as a going-concern.

Equity Distribution Agreement

On March 31, 2021, the Company entered into an Equity Distribution Agreement ("Equity Distribution Agreement") with Canaccord Genuity LLC, as agent ("Canaccord"), pursuant to which the Company may offer and sell shares of common stock, for aggregate gross sale proceeds of up to $75.0 million from time to time from the effective date of the respective registration statement through Canaccord. In July 2023, the Company filed an amendment to the prospectus supplement relating to the offer and sale of shares under the Equity Distribution Agreement to increase the maximum amount of shares that the Company may sell pursuant to its Equity Distribution Agreement with Canaccord by $65 million. At the time of the amendment, the Company had sold shares of its common stock for gross proceeds of $71.3 million. Under the Equity Distribution Agreement, the Company sold 3,303,122 shares of common stock during the year ended December 31, 2023 for net proceeds of $41.8 million. Under the Equity Distribution Agreement, the Company sold 43,068 shares of common stock during the year ended December 31, 2022 for net proceeds of $29.2 million. Subsequent to December 31, 2023, the Company sold 628,470 shares of common stock for proceeds of $2.2 million under the Equity Distribution Agreement.

We pay Canaccord for its services of acting as agent 3% of the gross proceeds from the sale of the shares pursuant to the Equity Distribution Agreement. Legal and accounting fees are reclassified to share capital upon issuance of shares under the Equity Distribution Agreement.

Plan of operations and future funding requirements

As of December 31, 2023 and 2022 we had unrestricted cash and cash equivalents of approximately $15.7 million and $10.3 million, respectively. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, costs related to our products, clinical trials, laboratory and related supplies, supplies and materials used in manufacturing, legal and other regulatory expenses and general overhead costs.

Until such time as we can generate substantial product revenue, we expect to finance our cash needs, beyond what is currently available or on hand, through a combination of equity offerings, debt financings and revenue from existing and potential research and development and other collaboration agreements. If we raise additional funds in the future, we may need to relinquish valuable rights to our technologies, future revenue streams or grant licenses on terms that may not be favorable to us.

Going Concern

We believe that our cash, cash equivalents, and restricted cash of $16.2 million on December 31, 2023 will not be sufficient to fund our current operating plan at least a year from issuance of these financial statements unless additional funds are raised in the first half of 2024. Certain elements of our operating plan cannot be considered probable.

The Company's Term Loan Agreement (See Note 6 of the notes to our consolidated financial statements) has a minimum liquidity covenant, which initially required the Company to maintain a minimum cash balance of $5.0 million. In May 2023, CRG reduced the minimum liquidity covenant under the Term Loan Agreement from $5.0 million to $500,000 until December 31, 2023. In July 2023, the Company also converted $10.0 million of the outstanding debt with CRG to equity. In October 2023, the Term Loan Agreement was amended to extend both the interest-only period and the maturity date by one year from December 30, 2024 to December 31, 2025, and permanently reduce the minimum liquidity covenant from $5.0 million to $500,000. There can be no assurances that the Company will continue to be in compliance with the cash covenant in future periods without additional funding.

On March 30, 2023, the Company received notice from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 555(a)(2) (the "Minimum Bid Price Rule"). On May 23, 2023, Nasdaq notified the Company that its securities were subject to delisting due to non-compliance with the Minimum Bid Price Rule and to maintain a minimum value of listed securities (the "MVLS Rule") of at least $35 million. The Company requested a hearing with Nasdaq and, on July 6, 2023, appealed to the Nasdaq Hearings Panel for an extension to the time period in which to regain compliance with the MVLS Rule and the Minimum Bid Price Rule. On July 26, 2023, we filed a definitive proxy statement to effect a reverse stock split of our common stock in connection with our annual meeting that occurred in September 2023 as required by the Nasdaq Hearings Panel. On August 9, 2023, the Company received written notice from Nasdaq informing the Company that it had regained compliance with the MVLS Rule. On September 15, 2023, at the Company's annual meeting of stockholders, the Company's stockholders approved an amendment to the Company's restated certificate of incorporation to effect a reverse stock split of the Company's common stock. On October 12, 2023, the Company announced that its board of directors had approved the reverse stock split at the ratio of 1 post-split share for every 100 pre-split shares, which was effective as of October 12, 2023.

On October 31, 2023, the Company received written notice from Nasdaq informing the Company that it has regained compliance with the Minimum Bid Price Rule. The Company will be subject to a Mandatory Panel Monitor for a period of one year. If, within that one-year monitoring period, the Company fails to comply with the Minimum Bid Price Rule, the Company will not be permitted additional time to regain compliance with the Minimum Bid Price Rule. However, the Company will have an opportunity to request a new hearing with the Nasdaq Hearings Panel prior to the Company's securities being delisted from Nasdaq.

On November 20, 2023, the Company received written notice from Nasdaq informing the Company that it no longer satisfied the MVLS Rule. In accordance with the terms of the Mandatory Panel Monitor, the Company was not granted a grace period but rather issued a delist determination, which will be stayed if the Company exercises its right to appeal by requesting a hearing and paying a non-refundable $20,000 fee. The Company has paid the $20,000 applicable fee and requested a new hearing, which will stay any further action by Nasdaq at least pending the issuance of its decision and the expiration of any extension that may be granted to the Company as a result of the hearing. On February 15, 2024, the Company appealed to the Nasdaq Hearings Panel for an extension to the time period in which to regain compliance with the MVLS Rule. On March 11, 2024, the Company received notice from the Nasdaq Hearings Panel that it had granted the Company's request for continued listing on Nasdaq, subject to the Company demonstrating compliance with Nasdaq's MVLS Rule on or before May 20, 2024.

These conditions raise substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that the financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt include raising additional funding and maintaining reduced operating expenses in order to continue as a going concern for a period of 12 months from the date these audited consolidated financial statements are issued. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources or maintain reduced expenditures, while reasonably possible, is less than probable. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of these financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

Cash flows

The following is a summary of cash flows for each of the periods set forth below:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (48,136)	$ (50,629)
Investing activities	(192)	9,659
Financing activities	52,688	29,054
Net change in cash, cash equivalents and restricted cash	$ 4,360	$ (11,916)

Net cash used in operating activities

Net cash used in operating activities was $48.1 million for the year ended December 31, 2023, and consisted primarily of a net loss of $50.1 million adjusted for non-cash items including a change in fair value of warrant liabilities of $5.9 million, stock-based compensation expense of $4.4 million, an impairment of property and equipment of $2.5 million, non-cash interest expense to related party of $1.7 million, non-cash lease expense of $1.3 million, depreciation and amortization expense of $0.9 million, issuance costs related to Common Stock Warrants of $0.7 million, a change in fair value of the derivative related to Term Loan with related party of $0.5 million, and a net change in operating assets and liabilities of $4.1 million. The net change in operating assets and liabilities was primarily driven by a decrease in accrued expenses of $2.5 million primarily due to a $1.0 million reduction to accrued legal fees due to expensing of the $1.0 million rent deposit for the Billerica lease and a reduction of $0.8 million accrued clinical trial and development expenses, a decrease in operating lease liabilities of $1.4 million, an increase in inventory of $0.7 million due to timing of purchases and shipments, and an increase in prepaid expenses and other assets of $0.5 million due to timing of deposits for goods and services, partially offset by a decrease in accounts receivable of $0.7 million due to payment from BARDA and the timing and volume of instrument and consumable sales, an increase in accounts payable of $0.2 million due to timing of invoices and payments, and an increase in deferred revenue of $0.1 million.

Net cash used in operating activities was $50.6 million for the year ended December 31, 2022, and consisted primarily of a net loss of $62.0 million, an adjustment for non-cash items including stock-based compensation expense of $6.4 million, non-cash interest expense to related party of $2.1 million, non-cash lease expense of $1.2 million, a change in fair value of the derivative related to Term Loan with related party of $1.0 million, depreciation and amortization expense of $1.0 million, impairment of property and equipment of $0.1 million, loss on issuance of Series A redeemable convertible preferred stock and derivative warrant liability of $0.1 million, a change in fair value of derivative warrant liability which is a reduction of expense of $0.3 million and a net change in operating assets and liabilities of $0.5 million. The net change in operating assets and liabilities was primarily driven by a decrease in accounts receivable of $2.9 million due to BARDA payments and the timing and volume of instrument and consumable sales, a decrease in prepaid expenses and other assets of $0.5 million due to timing of deposits for goods and services and an increase in accrued expenses of $0.3 million due to the $1.0 million estimated liability recorded for the Billerica, Massachusetts lease and the additional clinical activity for our T2Resistance 510(k) Study, partially offset by decreased bonus. These changes were partially offset by a decrease in operating lease liabilities of $1.4 million, a decrease in accounts payable of $1.6 million primarily due to timing of invoices and payments, a decrease in inventory of $0.9 million due to securing raw materials and bulk materials purchases for favorable pricing and a decrease in deferred revenue of $0.3 million due to timing of our ratably recognized service agreements.

Net cash used in investing activities

Net cash used in investing activities was $0.2 million for the year ended December 31, 2023, and consisted of $0.2 million of costs to acquire property and equipment.

Net cash provided by investing activities was $9.7 million for the year ended December 31, 2022, and consisted of $10.0 million of proceeds from the sale of marketable securities, offset by $0.3 million of costs to acquire property and equipment.

Net cash provided by financing activities

Net cash provided by financing activities was $52.7 million for the year ended December 31, 2023, and consisted primarily of proceeds from sales of our common stock under the Equity Distribution Agreement, net of issuance costs, of $41.8 million and proceeds from our February public offering, net of issuance costs, of $10.9 million, offset by payment of debt issuance costs of $0.1 million.

Net cash provided by financing activities was $29.1 million for the year ended December 31, 2022, and consisted primarily of net proceeds from issuance of common stock in public offerings of $29.1 million, proceeds of $0.3 million from the issuance of Series A redeemable convertible preferred stock and derivative warrant liability, net proceeds of $0.1 million from issuance of common stock and stock option exercises, redemption of Series A redeemable convertible preferred stock of $0.3 million and payment of employee restricted stock tax withholdings of $0.2 million.

Borrowing Arrangements

Term Loan Agreement

In December 2016, we entered into the Term Loan Agreement with CRG. We initially borrowed $40.0 million under the Term Loan Agreement and had the ability to borrow an additional $10.0 million upon receiving specified clearance for the marketing of T2Bacteria by April 30, 2018 (the “Approval Milestone”). We agreed to pay (1) a financing fee based on the amount of principal drawn and (2) a final payment fee based on the principal outstanding upon repayment. The debt discount related to the financing fee and the fees paid to CRG are being amortized over the loan term as interest expense. The final payment fee is accrued as interest expense and is classified consistent with the classification of the Term Loan.

The Term Loan's principal is prepayable at any time partially or in full without a prepayment penalty. Borrowings are collateralized by a lien on substantially all of our assets, including intellectual property. The Term Loan Agreement provides for affirmative and negative covenants, including a requirement to maintain a minimum cash balance of $5.0 million. The Term Loan Agreement includes a subjective acceleration clause whereby an event of default, including a material adverse change in the business, operations, or conditions (financial or otherwise), could result, at CRG's discretion, in the acceleration of the obligations under the Term Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.0% per annum may apply, at CRG's discretion, on all outstanding obligations during the occurrence and continuance of an event of default.

The Term Loan originally had a six-year term, with three years of interest-only payments accruing at a fixed rate of 12.5%, of which 4.0% could be paid in-kind by increasing the principal balance. After achievement of the Approval Milestone, such rates would be reduced and a fourth year of interest-only payments would be granted, after which quarterly payments of principal and interest would be owed through the December 30, 2022 maturity date. Upon achievement of certain performance metrics, the loan would be converted to interest-only until its maturity, at which time all unpaid principal and interest would be due and payable.

In connection with the Term Loan Agreement, we issued warrants to CRG to purchase a total of 105 shares of our common stock, exercisable any time prior to December 30, 2026.

Amendments

The Term Loan Agreement has been amended nine times. As a result of those amendments, certain terms of the Term Loan have been revised as follows:

- In 2018, upon our achievement of the Approval Milestone, interest on borrowings began accruing at 11.50% per year, 8% of which is payable in cash quarterly and 3.5% of which is deferred and added to principal until maturity.
- In 2019:
  - The final payment fee was increased from 8% to 10% of the principal outstanding upon repayment.
  - We issued additional warrants to CRG to purchase 113 shares of our common stock, exercisable any time prior to September 9, 2029 at an exercise price of $7,750.00 per share, with provisions for termination upon a change of control or a sale of all or substantially all of our assets (these warrants, along with the warrants to purchase 105 shares of common stock previously issued to CRG, are collectively referred to as the "CRG Warrants").
  - We reduced the exercise price for the warrants previously issued to CRG to $7,750.00.
- In 2022, the principal maturity date was extended to December 30, 2024, and the Term Loan's interest-only payment period was extended until that maturity date.
- In 2023:
  - We entered into a waiver and consent with CRG that reduced the minimum liquidity covenant to $500,000 until December 31, 2023.
  - CRG waived certain specified events of default associated with our issuance of shares of Series A Redeemable Convertible Preferred Stock in August 2022 and the subsequent redemption (See Note 7 of the notes to our consolidated financial statements).
  - In July 2023, CRG canceled $10.0 million of the Term Loan's principal in exchange for 483,457 shares of common stock and 93,297 shares of Series B Convertible Preferred Stock.
  - In October 2023, the interest-only period and maturity of the Term Loan were extended to December 31, 2025 and the $500,000 liquidity covenant was made permanent.

The warrants to purchase 218 shares of our common stock remain outstanding on December 31, 2023. There were no covenant violations during the year ended December 31, 2023.

Amendments made in February 2022, November 2022, October 2023, and the partial principal cancellation in July 2023 were accounted for as troubled debt restructurings. For all restructurings, at the time of the restructuring the future undiscounted cash outflows required under the amended agreement exceeded the carrying value of the debt and no gain was recognized as a result of the restructurings. The effects of each restructuring were accounted for prospectively.

Classification

The Term Loan Agreement with CRG was classified as a non-current liability on December 31, 2022. In May 2023, we received a modification and waiver reducing the Term Loan's minimum cash covenant from $5.0 million to $500,000 until December 31, 2023. In addition, in October 2023, the interest-only period and maturity of the Term Loan were extended to December 31, 2025, and the $500,000 liquidity covenant was made permanent. Because management believes it is probable that we will not be able to comply with the covenant through December 31, 2024 unless additional funds are raised, we concluded that the Term Loan and related liabilities should be classified as current on December 31, 2023.

We have a single compound derivative instrument related to our Term Loan Agreement that requires us to pay additional interest of 4% per annum upon an event of default or if any obligation other than the unpaid principal amount of the Term Loan is not paid when due. Fair value is determined quarterly. The fair value of the derivative on December 31, 2023 is $1.6 million and is classified as a current liability on the balance sheet on December 31, 2023 to match the classification of the related Term Loan Agreement. The fair value of the derivative on December 31, 2022 is $1.1 million and is classified as a non-current liability on the balance sheet on December 31, 2022 to match the classification of the related Term Loan Agreement.

Contingent Liabilities and Commitments, Including Tax Matters

We have net deferred tax assets of $87.2 million as of December 31, 2023, which have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. The deferred tax assets are primarily composed of federal and state net operating loss ("NOL") tax carryforwards and research and development tax credit carryforwards. As of December 31, 2023, we had federal NOL carryforwards of $273.7 million available to reduce future taxable income, if any. Out of the total NOL carryforwards of $273.7 million, $10.4 million begin to expire in 2026 and $263.3 million carryforward indefinitely. As of December 31, 2023, we had state NOL carryforwards of $245.4 million, of which $168.7 million expire at various dates through 2043 and $76.7 million is carried forward indefinitely. As of December 31, 2023, we had federal tax credit carryforwards of $28.0 thousand and state tax credit carryforwards of $0.4 million which expire at various dates through 2043 and 2038, respectively.

In 2023, we completed a study which identified an additional ownership change in 2023. If we experience a Section 382 ownership change in connection with or as a result of future changes in our stock ownership, some of which changes are outside of our control, the tax benefits related to the NOL and tax credit carryforwards may be limited or lost.

We entered into a 10-year lease agreement (the "Lease") on September 8, 2021, with Farley White Concord Road, LLC (the "Landlord"), to lease 70,125 square feet of office, laboratory and manufacturing space at 290 Concord Road, Billerica, Massachusetts. On January 17, 2023, the Landlord terminated the Lease and alleged that we failed to perform its obligations under the Lease in a timely manner and breached covenants of good faith and fair dealing. The Landlord filed a complaint in the Massachusetts Superior Court and unilaterally deducted the $1,000,000 security deposit for alleged damages. In addition, the Landlord is seeking damages for unpaid rent, brokerage fees, transaction costs, attorney's fees and court costs. We recorded an estimated liability of $1.0 million related to this lease on December 31, 2022. The Company filed a response to the landlord's complaint and a counterclaim alleging that the landlord breached its obligations under the contract and unlawfully drew on the security deposit, in addition to breaching its covenants of good faith and fair dealing, making fraudulent misrepresentations, and engaging in deceptive and unfair trade practices. The Company intends to vigorously defend itself and pursue all legal remedies available under applicable laws. The Company believes it will continue to meet its current manufacturing needs with its operations at its Lexington and Wilmington, Massachusetts facilities.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Critical Accounting Policies and Significant Judgments

This management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

The accounting policies we believe are critical in the preparation of our consolidated financial statements relate to revenue recognition, inventory valuation, and impairments of long-lived assets.

Revenue recognition

Certain contracts with customers include promises to transfer multiple products and services to a customer. Determining whether products and services are considered distinct performance obligations that should be accounted for separately versus together may require significant judgment. Once the performance obligations are determined, the Company determines the transaction price, which includes estimating the amount of variable consideration, based on the most likely amount, to be included in the transaction price, if any. The Company then allocates the transaction price to each performance obligation in the contract based on a relative standalone selling price method. The corresponding revenue is recognized as the related performance obligations are satisfied.

Judgment is required to determine the standalone selling price for each distinct performance obligation. The Company determines standalone selling price based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as a range of selling prices, market conditions and the expected costs and margin related to the performance obligations.

Inventory valuation

Inventories are stated at the lower of cost or net realizable value. The Company determines the approximate cost of its inventories, which includes amounts related to materials, direct labor, and manufacturing overhead, on a first-in, first-out basis. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period and records a charge to expense for cost basis in excess of net realizable value in the period in which the impairment is first identified, and writes down any excess and obsolete inventories as appropriate. These reserves require judgment. The net realizable value reserve is primarily based on expected future selling price while the excess and obsolete reserve is primarily based on future expected sales.

Impairment of long-lived assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Impairment is evaluated by comparing the carrying value of the long-lived assets with the estimated future net undiscounted cash flows expected to result from the use of the assets, including cash flows from disposition. Should the sum of the expected future net cash flows be less than the carrying value, the Company would recognize an impairment loss at that date. An impairment loss would be measured by comparing the amount by which the carrying value exceeds the fair value, or the estimated discounted future cash flows, of the long-lived assets.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide this information.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
T2 Biosystems, Inc.
Lexington, Massachusetts

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of T2 Biosystems, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, Series A redeemable convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated 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 the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations, has an accumulated deficit, and has experienced cash outflows from operating activities over the past year, will require additional capital to fund its current operating plan and, accordingly, has stated that substantial doubt exists about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Recoverability of Certain Capitalized Inventory

The Company's consolidated inventories balance was $4.8 million at December 31, 2023. As described in Note 2 to the consolidated financial statements, the Company performs an assessment of the recoverability of capitalized inventory during each reporting period and records a charge to expense for cost basis in excess of net realizable value in the period in which the impairment is first identified, and writes down any excess and obsolete inventories as appropriate. These reserves require judgment. The net realizable value is primarily based on expected future selling price while the excess and obsolete reserve is primarily based on future expected sales.

We identified the recoverability of certain capitalized inventory as a critical audit matter. Assessing the recoverability of capitalized inventory requires significant judgment due to the subjectivity of assumptions related to future selling prices to determine net realizable value and future estimated sales utilized to determine excess and obsolete inventories. Auditing these elements required especially challenging and subjective auditor judgment due to the nature and extent of audit effort required to address these matters.

The primary procedures we performed to address this critical audit matter included:

- Evaluating the reasonableness of the assumption related to future selling prices through comparison of the assumption to historical selling prices, and actual selling prices subsequent to year end.
- Evaluating the reasonableness of the assumption related to future estimated sales through comparison of excess and obsolete inventories determined by the Company to our independent expectation of the estimate based on historical sales and sales subsequent to year end.

Accounting for Warrants

As described in Notes 2 and 8 to the consolidated financial statements, in February 2023 the Company sold shares of common stock, Pre-Funded Warrants to purchase common stock and Common Stock Warrants to an underwriter pursuant to an underwriting agreement (the "February 2023 Offering"). The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives requiring bifurcation in accordance with ASC Topic 815, Derivatives and Hedging. The Company determined that the Common Stock Warrants issued in February 2023 are precluded from equity classification and are derivative instruments. The Company concluded that the Pre-Funded Warrants issued in February 2023 met the requirements for equity classification. The total proceeds of $12.0 million from the February 2023 offering were allocated between the common stock, Pre-Funded Warrants and Common Stock Warrants.

We identified the accounting for the issuance of the Pre-Funded Warrants and Common Stock Warrants as a critical audit matter. Evaluating whether the Pre-Funded Warrants and Common Stock Warrants are derivatives or contain features that qualify as embedded derivatives requires significant judgment due to the application of complex technical accounting guidance. Auditing these elements involved especially challenging and complex auditor judgment due to the nature and extent the effort required to address these matters, including the extent of specialized skills and knowledge needed.

The primary procedures we performed to address this critical audit matter included:

- Inspecting the agreements related to the Pre-Funded and Common Stock Warrants to identify relevant terms and conditions that affect whether they are derivatives or contain features that qualify as embedded derivatives.
- Evaluating whether the Pre-Funded and Common Stock Warrants are derivatives or contain features that qualify as embedded derivatives.
- Utilizing personnel with specialized knowledge and skill in the relevant technical accounting guidance to evaluate the appropriateness of the Company's application of the relevant technical accounting guidance in determining whether the Pre-Funded and Common Stock Warrants are derivatives or contain features that qualify as embedded derivatives.

/s/ BDO USA, P.C.
We have served as the Company's auditor since 2018.
Boston, Massachusetts
April 1, 2024

T2 Biosystems, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 15,689	$ 10,329
Accounts receivable, net	1,420	2,163
Inventories	4,819	4,285
Prepaid expenses and other current assets	3,261	2,582
Total current assets	25,189	19,359
Property and equipment, net	1,658	4,533
Operating lease right-of-use assets	7,395	8,741
Restricted cash	551	1,551
Other assets	4	143
Total assets	$ 34,797	$ 34,327
Liabilities and stockholders' deficit		
Current liabilities:		
Notes payable to related party	$ 41,284	$ —
Accounts payable	1,527	1,296
Accrued expenses and other current liabilities	4,905	7,269
Accrued final payment fee on Term Loan with related party	4,807	—
Operating lease liability	1,616	1,352
Derivative liability related to Term Loan with related party	1,554	—
Warrant liabilities	235	39
Deferred revenue	224	172
Total current liabilities	56,152	10,128
Notes payable to related party	—	49,651
Operating lease liabilities, net of current portion	6,598	8,214
Deferred revenue, net of current portion	83	52
Derivative liability related to Term Loan with related party	—	1,088
Accrued final payment fee on Term Loan with related party	—	4,849
Total liabilities	62,833	73,982
Commitments and contingencies (see Note 14)		
Stockholders' deficit		
Preferred stock, $0.001 par value; 10,000,000 shares authorized: Series B Convertible Preferred Stock, 93,297 shares designated on December 31, 2023, 93,297 and 0 shares issued and outstanding to related party on December 31, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 4,058,381 and 77,165 shares issued and outstanding on December 31, 2023 and December 31, 2022, respectively	4	—
Additional paid-in capital	556,256	494,564
Accumulated deficit	(584,296)	(534,219)
Total stockholders' deficit	(28,036)	(39,655)
Total liabilities and stockholders' deficit	$ 34,797	$ 34,327

See accompanying notes to consolidated financial statements.

T2 Biosystems, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Year Ended December 31,	
	2023	2022
Revenue:		
Product revenue	$ 6,770	$ 11,259
Contribution revenue	423	11,046
Total revenue	7,193	22,305
Costs and expenses:		
Cost of product revenue	15,363	21,010
Research and development	14,153	25,715
Selling, general and administrative	24,830	30,625
Impairment of property and equipment	2,511	151
Total costs and expenses	56,857	77,501
Loss from operations	(49,664)	(55,196)
Other income (expense):		
Interest expense to related party	(5,343)	(6,084)
Change in fair value of derivative related to Term Loan with related party	(466)	(1,088)
Change in fair value of warrant liabilities	5,891	326
Other, net	(495)	39
Total other income (expense)	(413)	(6,807)
Net loss	$ (50,077)	$ (62,003)
Deemed dividend on Series A Redeemable Convertible Preferred Stock	$ —	$ (330)
Net loss attributable to common stockholders	$ (50,077)	$ (62,333)
Net loss per share — basic and diluted	$ (19.19)	$ (1,222.14)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	2,609,984	51,003
Other comprehensive loss:		
Net loss	$ (50,077)	$ (62,003)
Net unrealized gain on marketable securities arising during the period	—	2
Net realized gain on marketable securities included in net loss	—	2
Total other comprehensive income, net of taxes	—	4
Comprehensive loss	$ (50,077)	$ (61,999)

See accompanying notes to consolidated financial statements.

T2 Biosystems, Inc.
Consolidated Statements of Series A Redeemable Convertible Preferred Stock and Stockholders' Deficit
(In thousands, except share data)

	Temporary Equity		Permanent Equity							
	Series A Redeemable Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance on December 31, 2021	—	$ —	—	$ —	33,280	$ —	$ 459,317	$ (472,216)	$ (4)	$ (12,903)
Stock-based compensation expense	—	—	—	—	—	—	6,493	—	—	6,493
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	—	—	—	—	923	—	165	—	—	165
Shares surrendered for income taxes	—	—	—	—	(107)	—	(243)	—	—	(243)
Issuance of common stock from secondary offering, net	—	—	—	—	43,069	—	29,162	—	—	29,162
Issuance of Series A Redeemable Convertible Preferred Stock	3,000	—	—	—	—	—	—	—	—	—
Deemed dividend for Series A Redeemable Convertible Preferred Stock	—	330	—	—	—	—	(330)	—	—	(330)
Redemption of Series A Redeemable Convertible Preferred Stock	(3,000)	(330)	—	—	—	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	4	4
Net loss	—	—	—	—	—	—	—	(62,003)	—	(62,003)
Balance on December 31, 2022	—	$ —	—	$ —	77,165	$ —	$ 494,564	$ (534,219)	$ —	$ (39,655)
Stock-based compensation expense	—	—	—	—	—	—	4,351	—	—	4,351
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	—	—	—	—	5,749	—	19	—	—	19
Issuance of common stock from secondary offering, net	—	—	—	—	3,303,122	4	41,809	—	—	41,813
Issuance of common stock and Pre-Funded Warrant from public offering, net	—	—	—	—	90,173	—	4,031	—	—	4,031
Issuance of common stock upon Common Stock Warrant cashless exercises	—	—	—	—	77,770	—	1,480	—	—	1,480
Issuance of common stock upon Pre-Funded Warrant exercises	—	—	—	—	20,924	—	2	—	—	2
Issuance of common stock to CRG	—	—	—	—	483,457	—	3,413	—	—	3,413
Issuance of Series B Convertible Preferred Stock to CRG	—	—	93,297	—	—	—	6,587	—	—	6,587
Issuance of Series A Redeemable Preferred Stock to CRG	1,000	—	—	—	—	—	—	—	—	—
Redemption of Series A Redeemable Preferred Stock issued to CRG	(1,000)	—	—	—	—	—	—	—	—	—
Common stock retired in connection with cash paid for fractional shares for reverse stock split	—	—	—	—	(41)	—	—	—	—	—
Reverse stock split rounding adjustment	—	—	—	—	62	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(50,077)	—	(50,077)
Balance on December 31, 2023	—	$ —	93,297	$ —	4,058,381	$ 4	$ 556,256	$ (584,296)	$ —	$ (28,036)

See accompanying notes to consolidated financial statements.

T2 Biosystems, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities		
Net loss	$ (50,077)	$ (62,003)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	859	1,047
Non-cash lease expense	1,346	1,224
Stock-based compensation expense	4,351	6,493
Change in fair value of derivative related to Term Loan with related party	466	1,088
Loss on sales of marketable securities	—	2
Change in fair value of warrant liabilities	(5,891)	(326)
Issuance costs related to Common Stock Warrants	682	—
Loss on issuance of Series A Redeemable Convertible Preferred Stock and derivative warrant liability	—	65
Loss on disposal of property and equipment	3	—
Non-cash interest expense to related party	1,656	2,133
Impairment of property and equipment	2,511	151
Changes in operating assets and liabilities:		
Accounts receivable	743	2,971
Prepaid expenses and other assets	(550)	471
Inventories	(744)	(949)
Accounts payable	231	(1,566)
Accrued expenses and other liabilities	(2,453)	261
Deferred revenue	83	(322)
Operating lease liabilities	(1,352)	(1,369)
Net cash used in operating activities	(48,136)	(50,629)
Cash flows from investing activities		
Proceeds from sales of marketable securities	—	9,998
Purchases and manufacture of property and equipment	(192)	(339)
Net cash (used in) provided by investing activities	(192)	9,659
Cash flows from financing activities		
Payment of employee restricted stock tax withholdings	—	(243)
Proceeds from issuance of shares from employee stock purchase plan and stock option exercises	19	165
Proceeds from public offering, net of issuance costs	10,918	—
Proceeds from secondary offering, net of issuance costs	41,813	29,162
Proceeds from issuance of Series A Redeemable Convertible Preferred Stock and derivative warrant liability	—	300
Redemption of Series A redeemable convertible preferred stock	—	(330)
Payment of debt issuance costs to related party	(62)	—
Net cash provided by financing activities	52,688	29,054
Net change in cash, cash equivalents and restricted cash	4,360	(11,916)
Cash, cash equivalents and restricted cash at beginning of period	11,880	23,796
Cash, cash equivalents and restricted cash at end of period	$ 16,240	$ 11,880

See accompanying notes to consolidated financial statements.

T2 Biosystems, Inc.
Consolidated Statements of Cash Flows (Continued)
(In thousands)

	Year Ended December 31,	
	2023	2022
Reconciliation of cash, cash equivalents and restricted cash at end of period		
Cash and cash equivalents	$ 15,689	$ 10,329
Restricted cash	551	1,551
Total cash, cash equivalents and restricted cash	$ 16,240	$ 11,880

	Year Ended December 31,	
	2023	2022
Supplemental disclosures of cash flow information		
Cash paid for interest to related party	$ 3,860	$ 3,917
Supplemental disclosures of noncash activities		
Transfer of T2 owned instruments and components from inventory	$ 210	$ 573
Cashless exercise of Common Stock Warrants	$ (1,480)	$ —
Cancellation of Term Loan in exchange for common stock and Series B Convertible Preferred Stock to related party	$ 10,000	$ —
Deemed dividend on Series A Redeemable Convertible Preferred Stock	—	330
Right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 199
Purchases of property and equipment included in accounts payable and accrued expenses	$ 131	$ 117

See accompanying notes to consolidated financial statements.

1. Nature of Business

T2 Biosystems, Inc. and its subsidiary (the "Company," "we," or "T2") have operations based in Lexington, Massachusetts. T2 Biosystems, Inc. was incorporated on April 27, 2006 as a Delaware corporation. The Company is an in vitro diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. The Company has developed a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. The Company's technology enables rapid detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, plasma, serum, saliva, sputum, cerebral spinal fluid and urine, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter ("CFU/mL"). We are currently targeting a range of critically underserved healthcare conditions, focusing initially on those for which a rapid diagnosis will serve an important dual role – saving lives and reducing costs. The Company's current development efforts primarily target sepsis, bioterrorism and Lyme disease, which are areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics.

Liquidity and Going Concern

On December 31, 2023, the Company had cash, cash equivalents, and restricted cash of $16.2 million, an accumulated deficit of $584.3 million, stockholders' deficit of $28.0 million, and has experienced cash outflows from operating activities since its inception. The future success of the Company is dependent on its ability to successfully commercialize its products, obtain regulatory clearance for and successfully launch its future product candidates, obtain additional capital and ultimately attain profitable operations. Historically, the Company has funded its operations primarily through its August 2014 initial public offering, its December 2015 public offering, its September 2016 private investment in public equity ("PIPE") financing, its September 2017 public offering, its June 2018 public offering, its July 2019 establishment of an equity distribution agreement and equity purchase agreement, its March 2021 establishment of an Equity Distribution Agreement (Note 9), its February 2023 public offering (Note 8), private placements of redeemable convertible preferred stock and through debt financing arrangements.

Historically, the Company has primarily funded its operations through public equity and private debt financings. The Company believes its cash position is insufficient to fund future operations without financings by the first half of 2024, which may include public or private equity or debt financings. These financings may not be successful, however, or on terms favorable to the Company or its stockholders which would have a negative impact on the Company's business, results of operations, financial condition and the Company's ability to develop and commercialize its products and ultimately operate as a going-concern.

The Company is subject to a number of risks similar to other early commercial stage life science companies, including, but not limited to commercially launching the Company's products, development and market acceptance of the Company's product candidates, development by its competitors of new technological innovations, protection of proprietary technology, and raising additional capital.

In September 2023, the Company's milestone-based product development contract with the Biomedical Advanced Research and Development Authority ("BARDA") (Note 16) expired, which may impact the Company's ability to continue to fund the development of its next-generation products.

The Company's T2Dx Instrument and T2Candida, T2Bacteria, and the T2Biothreat Panels are authorized for use in the United States by the FDA.

Pursuant to the requirements of Accounting Standards Codification 205-40, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASC 205-40"), management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued.

The Company believes that its cash, cash equivalents, and restricted cash of $16.2 million on December 31, 2023 will not be sufficient to fund its current operating plan for at least one year from issuance of these financial statements, as certain elements of its operating plan cannot be considered probable. Absent any reductions in current operating expenses, the Company believes it will require additional financing during the first half of 2024, which may include public or private equity or debt financings. Under ASC 205-40, the future receipt of potential funding from co-development partners and other resources cannot be considered probable at this time because none of the plans are entirely within the Company's control.

The Company's Term Loan Agreement (the "Term Loan Agreement") with certain CRG entities (collectively, "CRG") (Note 6) has a minimum liquidity covenant, which initially required the Company to maintain a minimum cash balance of $5.0 million. In May 2023, CRG reduced the minimum liquidity covenant under the Term Loan Agreement from $5.0 million to $500,000 until December 31, 2023. In July 2023, the Company also converted $10.0 million of the outstanding debt with CRG to equity. In October 2023, the Term Loan Agreement was amended to extend both the interest-only period and the maturity date by one year from December 30, 2024 to December 31, 2025, and permanently reduce the minimum liquidity covenant from $5.0 million to $500,000. There can be no assurances that the Company will continue to be in compliance with the cash covenant in future periods without additional funding.

On March 30, 2023, the Company received notice from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 555(a)(2) (the "Minimum Bid Price Rule"). On May 23, 2023, Nasdaq notified the Company that its securities were subject to delisting due to non-compliance with the Minimum Bid Price Rule and to maintain a minimum value of listed securities (the "MVLS Rule") of at least $35 million. The Company requested a hearing with Nasdaq and, on July 6, 2023, appealed to the Nasdaq Hearings Panel for an extension to the time period in which to regain compliance with the MVLS Rule and the Minimum Bid Price Rule. On July 26, 2023, we filed a definitive proxy statement to effect a reverse stock split of our common stock in connection with our annual meeting that occurred in September 2023 as required by the Nasdaq Hearings Panel. On August 9, 2023, the Company received written notice from Nasdaq informing the Company that it had regained compliance with the MVLS Rule. On September 15, 2023, at the Company's annual meeting of stockholders, the Company's stockholders approved an amendment to the Company's restated certificate of incorporation to effect a reverse stock split of the Company's common stock. On October 12, 2023, the Company announced that its board of directors had approved the reverse stock split at the ratio of 1 post-split share for every 100 pre-split shares, which was effective as of October 12, 2023.

On October 31, 2023, the Company received written notice from Nasdaq informing the Company that it has regained compliance with the Minimum Bid Price Rule. The Company will be subject to a Mandatory Panel Monitor for a period of one year. If, within that one-year monitoring period, the Company fails to comply with the Minimum Bid Price Rule, the Company will not be permitted additional time to regain compliance with the Minimum Bid Price Rule. However, the Company will have an opportunity to request a new hearing with the Nasdaq Listing Qualifications Hearing Panel prior to the Company's securities being delisted from Nasdaq.

On November 20, 2023, the Company received written notice from Nasdaq informing the Company that it no longer satisfied the MVLS Rule. In accordance with the terms of the Mandatory Panel Monitor, the Company was not granted a grace period but rather issued a delist determination, which will be stayed if the Company exercises its right to appeal by requesting a hearing and paying a non-refundable $20,000 fee. The Company has paid the $20,000 applicable fee and requested a new hearing, which will stay any further action by Nasdaq at least pending the issuance of its decision and the expiration of any extension that may be granted to the Company as a result of the hearing. The Company's common stock will remain listed and eligible to trade on Nasdaq pending the outcome of the hearing. On February 15, 2024, the Company appealed to the Nasdaq Hearings Panel for an extension to the time period in which to regain compliance with the MVLS Rule. On March 11, 2024, the Company received notice from the Nasdaq Hearings Panel that it had granted the Company's request for continued listing on Nasdaq, subject to the Company demonstrating compliance with Nasdaq's MVLS Rule on or before May 20, 2024.

These conditions raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date that the financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt include raising additional funding, delaying certain research projects and capital expenditures, and eliminating certain future operating expenses in order to fund operations at reduced levels for the Company to continue as a going concern for a period of 12 months from the date these audited consolidated financial statements are issued. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources or maintain reduced expenditures, while reasonably possible, is less than probable. Accordingly, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least 12 months from the date of issuance of these financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The Company’s financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”). The Company’s consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, T2 Biosystems Securities Corporation. All intercompany balances and transactions have been eliminated.

On October 12, 2023, the Company effected a 1-for-100 reverse stock split. One share of common stock was issued for every 100 shares of issued and outstanding common stock, and fractional shares were settled in cash. All references to share and per share amounts (excluding authorized shares) in the consolidated financial statements and accompanying notes have been retroactively restated to account for the reverse split.

Prior to this, on October 12, 2022, the Company effected a 1-for-50 reverse stock split. One share of common stock was issued for every 50 shares of issued and outstanding common stock, and fractional shares were settled in cash.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation, including the reclassification of expenses related to the impairment of property and equipment and the consolidation of other income and expense items on the Consolidated Statement of Operations and Comprehensive Loss. Such reclassifications had no impact on the Company's reported total revenues, expenses, net loss, current assets, total assets, current liabilities, total liabilities, stockholders' equity (deficit) or cash flows. No reclassifications of prior period balances were material to the consolidated financial statements.

Prior Year Impairment of Property and Equipment Reclassification

For the purposes of comparability to the current period, in order to conform with current period presentation, the Company has reclassified expenses related to the impairment of property and equipment for the year ended December 31, 2022 out of cost of product revenue and research and development expense and into impairment of property and equipment on the Consolidated Statements of Operations and Comprehensive Loss, as summarized in the following table:

	Year Ended December 31, 2022	
	As Reported	As Reclassified
Costs and expenses:		
Cost of product revenue	21,101	21,010
Research and development	25,775	25,715
Selling, general and administrative	30,625	30,625
Impairment of property and equipment	—	151
Total costs and expenses	77,501	77,501

Use of Estimates

The preparation of the Company’s consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company utilizes certain estimates in the determination of the accounts receivable allowance, the excess and obsolete inventory, the net realizable value of inventory, the fair value of its stock options, as well as restricted stock units that have market conditions, deferred tax valuation allowances, revenue recognition, expenses relating to research and development contracts, accrued expenses, the fair value of a derivative instrument liability, the fair value of a warrant liability, the fair value of warrants and classification of the value of instrument raw material and work-in-process inventory between inventory and property and equipment. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results could differ from such estimates.

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, which is the business of developing and, upon regulatory clearance, launching commercially its diagnostic products aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier.

Geographic Information

The Company sells its products worldwide and attributes revenue from external customers to individual countries on the basis of the location of the customer. Total international sales were approximately $2.7 million, or 38% of total revenue in 2023, and $3.9 million, or 18% of total revenue, in 2022. International sales to Italy were approximately $1.3 million, or 19% of total revenue, and $1.3 million, or 6% of total revenue, for the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023 and 2022, the Company had outstanding receivables of $0.3 million and $0.4 million, respectively, from customers located outside of the U.S.

Off-Balance Sheet Risk and Concentrations of Risk

The Company has no significant off-balance sheet risks, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Cash and cash equivalents are financial instruments that potentially subject the Company to concentrations of credit risk. On December 31, 2023 and 2022, substantially all of the Company's cash and cash equivalents were deposited in accounts at two financial institutions. The Company maintains its cash deposits, which at times may exceed the federally insured limits, with a large financial institution and, accordingly, the Company believes such funds are subject to minimal credit risk. Cash deposits aggregating $550 thousand and collateralizing office leases were held at Silicon Valley Bank, which was taken over by the Federal Deposit Insurance Corporation ("FDIC") in March 2023. The Company's full exposure was ultimately covered by the FDIC and no loss was incurred.

The following table shows entities and customers that represent greater than 10% of revenue for the period presented:

	Year Ended December 31,	
	2023	2022
Entity A	—%	50%
Customer A	19%	—%
Customer B	10%	—%

The following table shows entities and customers that represent greater than 10% of the accounts receivable balance for the period presented:

	December 31, 2023	December 31, 2022
Entity A	—%	32%
Customer B	13%	—%
Customer C	16%	—%

Entity A is a U.S. government entity (BARDA). Customer A is an international distributor. Customer B is a U.S. healthcare system comprised of multiple hospitals. Customer C is a clinical laboratory company.

The Company relies on single-source suppliers for some components and materials used in its products and product candidates. The Company has entered into supply agreements with most of its suppliers to help ensure component availability and flexible purchasing terms with respect to the purchase of such components. While the Company believes replacement suppliers exist for all components and materials obtained from single sources, establishing additional or replacement suppliers for any of these components or materials, if required, may not be accomplished quickly. Even if the Company is able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. If third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and the Company is unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of products, the supply of products to customers and the development of any future products would be delayed, limited or prevented, which could have an adverse impact on the business.

Cash Equivalents

Cash equivalents include all highly liquid investments with original maturities of 90 days or less. Cash equivalents consist of money market funds and money market accounts as of December 31, 2023 and money market accounts as of December 31, 2022.

Marketable Securities

The Company's marketable securities typically consist of certificates of deposit and U.S. treasury securities, which are classified as available-for-sale and included in current and non-current assets. Available-for-sale debt securities are carried at fair value with unrealized gains and losses reported as a component of stockholders' deficit in accumulated other comprehensive income. Realized gains and losses, if any, are determined based on a specific identification basis and are included in other, net in the consolidated statements of operations.

Available-for-sale securities are reviewed for possible impairment at least quarterly, or more frequently if circumstances arise that may indicate impairment. When the fair value of the securities declines below the amortized cost basis, impairment is indicated and it must be determined whether it is other than temporary. Impairment is considered to be other than temporary if the Company: (i) intends to sell the security, (ii) will more likely than not be forced to sell the security before recovering its cost, or (iii) does not expect to recover the security's amortized cost basis. If the decline in fair value is considered other than temporary, the cost basis of the security is adjusted to its fair market value and the realized loss is reported in earnings. Subsequent increases or decreases in fair value are reported as a component of stockholders' deficit in accumulated other comprehensive income. There were no other-than-temporary unrealized losses as of December 31, 2023 and 2022.

The Company had no marketable securities on December 31, 2023 and 2022.

Accounts Receivable

The Company's accounts receivable consists of amounts due from product sales to commercial customers. At each reporting period, management reviews historical loss information, characteristics of the Company's customers, its credit practices and the economic conditions, along with all outstanding balances to determine if the facts and circumstances indicate the need for a credit loss allowance. Receivables are written off against these allowances in the period they are determined to be uncollectible. The Company does not require collateral. The Company's allowance for doubtful accounts was $0.1 million for one customer on both December 31, 2023 and December 31, 2022, respectively. Bad debt expense is classified as a selling, general and administrative expense.

The opening and closing balances of the Company's accounts receivable, net were $2.2 million and $1.4 million for the year ended December 31, 2023, respectively, and $5.1 million and $2.2 million for the year ended December 31, 2022, respectively.

Inventories

Inventories are stated at the lower of cost or net realizable value. The Company determines the approximate cost of its inventories, which includes amounts related to materials, direct labor, and manufacturing overhead, on a first-in, first-out basis. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period and records a charge to expense for cost basis in excess of net realizable value in the period in which the impairment is first identified, and writes down any excess and obsolete inventories as appropriate. These reserves require judgment. The net realizable value reserve is primarily based on expected future selling price while the excess and obsolete reserve is primarily based on future expected sales. Shipping and handling costs incurred for inventory purchases are capitalized and recorded upon sale in cost of product revenues in the consolidated statements of operations and comprehensive loss or are included in the value of T2-owned instruments and components, a component of property and equipment, net, and depreciated.

The Company capitalizes inventories in preparation for sales of products when the related product candidates are considered to have a high likelihood of regulatory clearance and the related costs are expected to be recoverable through sales of the inventories. In addition, the Company capitalizes inventories related to the manufacture of instruments that have a high likelihood of regulatory clearance and will be retained as the Company's assets, upon determination that the instrument has alternative future uses. In determining whether or not to capitalize such inventories, the Company evaluates, among other factors, information regarding the product candidate's status of regulatory submissions and communications with regulatory authorities, the outlook for commercial sales and alternative future uses of the product candidate. Costs associated with development products prior to satisfying the inventory capitalization criteria are charged to research and development expense as incurred.

The components of inventory consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Raw materials	$ 1,881	$ 2,004
Work-in-process	1,441	1,176
Finished goods	1,497	1,105
Total inventories	$ 4,819	$ 4,285

Fair Value Measurements

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820"), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The hierarchy defines three levels of valuation inputs:

Level 1 — Quoted unadjusted prices for identical instruments in active markets.

Level 2 — Quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-derived valuations in which all observable inputs and significant value drivers are observable in active markets.

Level 3 — Model derived valuations in which one or more significant inputs or significant value drivers are unobservable, including assumptions developed by the Company.

The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability (Note 3).

For certain financial instruments, including accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and debt, the carrying amounts approximate their fair values as of December 31, 2023 and 2022 because of their short-term nature. The carrying value of the Term Loan Agreement approximates the fair value, which the Company measured using Level 3 inputs. On December 31, 2023, the fair value of the derivative liability was determined using Level 3 inputs using a valuation model that includes assumptions from the Company (Note 3).

Property and Equipment, Net

Property and equipment are recorded at cost and depreciated over their estimated useful lives using the straight-line method. Depreciation of T2-owned instruments commences when they are placed in service as a reagent rental with a customer. Equipment that has not been placed in service is considered construction in progress and is not depreciated until placed in service. Repairs and maintenance costs are expensed as incurred, whereas major improvements are capitalized as additions to property and equipment.

Derivative Instruments

The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives requiring bifurcation in accordance with ASC Topic 815, *Derivatives and Hedging*. Derivative instruments are measured at fair value at issuance and at each reporting date in accordance with ASC 820 with changes in fair value recognized in the period of change in the consolidated statements of operations and comprehensive loss.

The Company determined that both the warrant issued in conjunction with the Series A Redeemable Convertible Preferred Stock in August of 2022 and the Common Stock Warrants issued in February 2023 are derivative instruments. The warrant liabilities are classified on the consolidated balance sheets as current because settlement of the warrant liability could be required by the holder within 12 months of the balance sheet date. Changes in fair value are recognized in change in fair value of warrant liabilities in the period of change in the consolidated statements of operations and comprehensive loss. See Notes 3 and 8.

The Company has identified a derivative liability related to its Term Loan Agreement with CRG that is classified as a current liability on the balance sheet on December 31, 2023 and a non-current liability on December 31, 2022, to match the classification of the related Term Loan Agreement. Changes in fair value are recognized in change in fair value of derivative related to Term Loan in the period of change in the consolidated statements of operations and comprehensive loss. See Note 6.

The Company does not designate its derivative instruments as hedging instruments.

Classification of Series A Redeemable Convertible Preferred Stock

The Company applied the guidance in ASC 480-10-S99-3A, *SEC Staff Announcement: Classification and Measurement of Redeemable Securities* and classified the Series A Redeemable Convertible Preferred Stock as temporary equity in the mezzanine section of the balance sheet on December 31, 2022. The Series A Redeemable Convertible Preferred Stock was recorded outside of stockholders' deficit because under the terms thereof, in the event of stockholder approval of the reverse stock split or a delisting event, which were events considered not solely within the Company's control, the Series A Redeemable Convertible Preferred Stock would become redeemable at the option of the holders.

Leases

Lessee

Pursuant to ASC Topic 842, *Leases* ("ASC 842"), at the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and long-term lease liabilities. The Company has elected not to recognize on the balance sheet leases with terms of one year or less. The exercise of lease renewal options is at the Company's discretion and the renewal to extend the lease terms are not included in the Company's right-of-use assets and lease liabilities as they are not reasonably certain of exercise. The Company will evaluate the renewal options and when they are reasonably certain of exercise, the Company will include the renewal period in its lease term. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. However, certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued lease payments. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rates, which are the rates incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

In accordance with the guidance in ASC 842, components of a lease should be split into three categories: lease components (e.g., land, building, etc.), non-lease components (e.g., common area maintenance, consumables, etc.), and non-components (e.g., property taxes, insurance, etc.). Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

The Company made the policy election to not separate lease and non-lease components. Each lease component and the related non-lease components are accounted for together as a single component.

Lessor

The Company derives revenue from leasing its T2-owned instruments through reagent rental agreements (see the Revenue Recognition section below). Customers typically have the right to cancel every twelve months, resulting in a lease term of generally one year. These lease agreements impose no requirement on the customer to purchase the instrument, and the instrument is not transferred to the customer at the end of the lease term. The short-term nature of the lease agreements does not result in lease payments accumulating to an amount that equals the value of the instrument nor is the lease term reflective of the economic life of the instrument. Instrument leases are generally classified as operating leases as they do not meet any of the sales-type lease criteria per ASC 842 and are recognized ratably over the duration of the lease. In accordance with these contracts, customers only make payments when consumables are ordered and delivered thus making these payments variable by nature. The Company estimates the expected volume of consumables to be purchased by each customer over the lease term to measure and recognize rental and consumables revenue.

Generally, lease arrangements include both lease and non-lease components. The lease component relates to the customer's right-to-use the T2-owned instrument over the lease term. The non-lease components relate to (1) consumables and (2) maintenance services. Because the timing and pattern of transfer for the operating lease component, the T2-owned instrument, and maintenance components of a reagent rental agreement are recognized over the same time period and in the same pattern, the Company elected the practical expedient to aggregate non-lease components with the associated lease component and account for the combined component as an operating lease for all instrument leases. In the evaluation of whether the lease component (T2-owned instrument) or the non-lease component associated with the lease component (maintenance) is the predominant component, the Company determined that the lease component is predominant as we believe the customer would ascribe more value to the use of the T2-owned instrument than that of the maintenance services. The T2-owned instrument lease and maintenance service performance obligations are classified as a single category of instrument rental revenue within product revenue in the consolidated statements of operations and comprehensive loss (see disaggregated revenue table below in Revenue Recognition section). The consumables non-lease component does not meet the requirements to elect the practical expedient because of its point-in-time pattern of transfer (versus over time for the combined lease component) and therefore must apply ASC 606, Revenue from Contracts with Customers, as described below in the Revenue Recognition section.

The Company considers the economic life of its T2-owned instruments to be five years. The Company believes five years is representative of the period during which the instrument is expected to be economically usable by one or more users, with normal service, for the purpose for which it is intended. The residual value is estimated to be the value at the end of the lease term based on the anticipated fair market value of the units. The Company mitigates residual value risk of its leased instrument by performing regular management and maintenance, as necessary.

Revenue Recognition

The Company generates revenue from the sale of instruments, consumable diagnostic tests, related services, reagent rental agreements and government contributions. For arrangements in the scope of ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company determines revenue recognition through the following steps:

- Identification of a contract with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations
- Recognition of revenue as a performance obligation is satisfied

The amount of revenue recognized reflects the consideration the Company expects to be entitled to receive in exchange for these goods and services.

Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations the Company must deliver and which of these performance obligations are distinct. The Company recognizes as revenues the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied. Generally, the Company's performance obligations are transferred to customers either at a point in time, typically upon shipment, or over time, as services are performed. Contracts typically have net 30 payment terms in the U.S. and net 60 payment terms internationally.

Most of the Company's contracts with distributors in geographic regions outside the United States contain only a single performance obligation, whereas most of the Company's contracts with direct sales customers in the United States contain multiple performance obligations. For these contracts, the Company accounts for individual performance obligations separately if they are distinct. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. Excluded from the transaction price are sales tax and other similar taxes which are presented on a net basis.

Product revenue is generated by the sale of instruments and consumable diagnostic tests predominantly through the Company's direct sales force in the United States and distributors in geographic regions outside the United States. The Company generally does not offer product returns or exchange rights (other than those relating to defective goods under warranty) or price protection allowances to its customers, including its distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors' receipt of payment from their end-user customers.

The Company either sells instruments to customers and international distributors, or retains title and places the instrument at the customer site pursuant to a reagent rental agreement. When an instrument is purchased by a customer or international distributor, the Company recognizes revenue when the related performance obligation is satisfied (i.e., when the control of an instrument has passed to the customer; typically, at shipping point).

When the instrument is placed under a reagent rental agreement, the Company's customers generally agree to fixed term agreements, which can be extended, and incremental charges on each consumable diagnostic test purchased. Revenue from the sale of consumable diagnostic tests (under a reagent rental agreement) is generally recognized upon shipment. The transaction price from consumables purchases is allocated between the lease and non-lease components when related performance obligations are satisfied, as a component of lease and product revenue, and is included as Instrument Rentals in the below table. Revenue associated with reagent rental consumables purchases is currently classified as variable consideration and constrained until a purchase order is received and related performance obligations have been satisfied.

Revenue from the sale of consumable diagnostic tests (under instrument purchase agreements) is recognized when control has passed to the customer, typically at shipping point.

Shipping and handling costs billed to customers in connection with a product sale are recorded as a component of the transaction price and allocated to product revenue in the consolidated statements of operations and comprehensive loss as they are incurred by the Company in fulfilling its performance obligations.

Direct sales of instruments include warranty, maintenance and technical support services typically for one year following the installation of the purchased instrument ("Maintenance Services"). Maintenance Services are separate performance obligations as they are service based warranties and are recognized on a straight-line basis over the service delivery period. After the completion of the initial Maintenance Services period, customers have the option to renew or extend the Maintenance Services typically for additional one year periods in exchange for additional consideration. The extended Maintenance Services are also service based warranties that represent separate purchasing decisions. The Company recognizes revenue allocated to the extended Maintenance Services performance obligation on a straight-line basis over the service delivery period.

Fees paid to member-owned group purchasing organizations ("GPOs") are deducted from related product revenues.

The Company warrants that consumable diagnostic tests will be free from defects, when handled according to product specifications, for the stated life of the product. To fulfill valid warranty claims, the Company provides replacement product free of charge. Warranty expense is recognized based on the estimated defect rates of the consumable diagnostic tests.

Contribution Revenue

The government contract with BARDA was considered a government grant and not considered a contract with a customer and thus not subject to ASC 606. Revenue under the government BARDA contract was earned under a cost-sharing arrangement in which the Company was reimbursed for direct costs incurred plus allowable indirect costs. The government contract revenue was recognized as the related reimbursable expenses were incurred. The cost reimbursement that was reported as revenue was presented gross of the related reimbursable expenses in the Company's consolidated statements of operations and comprehensive loss; the related reimbursable expenses were expensed as incurred as research and development expense. The Company accounted for these contracts as a government grant by analogy to International Accounting Standards 20 ("IAS 20"), Accounting for Government Grants and Disclosure of Government Assistance.

The BARDA contract expired in September 2023.

Disaggregation of Revenue

The Company disaggregates revenue from contracts with customers by type of products and services, as it best depicts how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors. The following table disaggregates total revenue by major source (in thousands):

	Year Ended December 31,	
	2023	2022
Product revenue		
Instruments	1,328	2,302
Consumables	4,842	8,185
Instrument rentals	124	78
Service	476	694
Total product revenue	6,770	11,259
Contribution revenue	423	11,046
Total revenue	$ 7,193	$ 22,305

Remaining Performance Obligations

Under ASC 606, the Company is required to disclose the aggregate amount of the transaction price that is allocated to unsatisfied or partially satisfied performance obligations as of December 31, 2023. However, the guidance provides certain practical expedients that limit this requirement, and therefore, the Company has elected to not disclose the value of unsatisfied performance obligations for contracts with an original expected length of one year or less. The nature of the excluded unsatisfied performance obligations pursuant to the practical expedient include consumable shipments, service contracts, warranties and installation services that will be performed within one year. The amount of the transaction price that is allocated to unsatisfied or partially satisfied performance obligations, that has not yet been recognized as revenue and that does not meet the elected practical expedient is $0.2 million as of December 31, 2023. The Company expects to recognize 46% of this amount as revenue within one year and the remainder within three years.

Judgments

Certain contracts with customers include promises to transfer multiple products and services to a customer. Determining whether products and services are considered distinct performance obligations that should be accounted for separately versus together may require significant judgment. Once the performance obligations are determined, the Company determines the transaction price, which includes estimating the amount of variable consideration, based on the most likely amount, to be included in the transaction price, if any. The Company then allocates the transaction price to each performance obligation in the contract based on a relative standalone selling price method. The corresponding revenue is recognized as the related performance obligations are satisfied as discussed in the revenue categories above.

Judgment is required to determine the standalone selling price for each distinct performance obligation. The Company determines standalone selling price based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as a range of selling prices, market conditions and the expected costs and margin related to the performance obligations.

Contract Assets and Liabilities

The Company's contract assets represent revenue recognized for performance obligations in advance of invoicing at the contract level based on the transaction price allocated to the respective performance obligations. The opening and closing balances of the Company's contract assets were $0.1 million and $0.1 million for the year ended December 31, 2023, respectively, and $0.0 million and $0.1 million for the year ended December 31, 2022, respectively.

The Company’s contract liabilities consist of upfront payments for maintenance services on instrument sales. Contract liabilities are classified in deferred revenue as current or non-current based on the timing of when revenue is expected to be recognized. The opening and closing balances of the Company's contract liabilities were $0.2 million and $0.3 million for the year ended December 31, 2023, respectively, and $0.5 million and $0.2 million for the year ended December 31, 2022, respectively. Revenue recognized during the year ended December 31, 2023 relating to contract liabilities on December 31, 2022 was $0.2 million and related to straight-line revenue recognition associated with maintenance agreements.

Costs to Obtain and Fulfill a Contract

The Company capitalizes commission expenses paid to sales personnel that are recoverable and incremental to obtaining capital purchase agreements within the United States. These costs are classified as prepaid expenses and other current assets and other assets, based on their current or non-current nature, respectively. The Company capitalizes only those costs that are determined to be incremental and would not have occurred absent the customer contract. These capitalized costs are amortized as selling, general and administrative costs on a straight-line basis over the expected period of benefit. These costs are reviewed periodically for impairment.

A practical expedient exists whereby costs may continue to be expensed as incurred if the performance period of the contract is equal to or less than one year. Generally, this guidance is applied on a contract-by-contract basis. However, the guidance permits an entity to apply its provisions on a portfolio basis as a practical expedient if the results using the portfolio approach would not differ materially from applying ASC 606 on a contract-by-contract basis. The Company elected to use the portfolio approach and considered consumables to be a separate portfolio. The related commission is expensed as incurred.

On December 31, 2023, capitalized costs to obtain contracts of less than $0.1 million were included in prepaid and other current assets. On December 31, 2022, capitalized costs to obtain contracts of less than $0.1 million were included in prepaid and other current assets. The Company amortized costs of less than $0.1 million during the year ended December 31, 2023 and less than $0.1 million during the year ended December 31, 2022.

Cost of Product Revenue

Cost of product revenue includes the cost of materials, direct labor and manufacturing overhead costs used in the manufacture of consumable diagnostic tests sold to customers, related warranty and license and royalty fees. Cost of product revenue also includes depreciation on T2-owned revenue generating T2Dx instruments that have been placed with customers under reagent rental agreements; costs of materials, direct labor and manufacturing overhead costs on the T2Dx instruments sold to customers; and other costs such as customer support costs, royalties and license fees, warranty and repair and maintenance expense on the T2Dx instruments that have been placed with customers under reagent rental agreements.

Research and Development Costs

Costs incurred in the research and development of the Company’s product candidates are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including activities associated with delivering products or services associated with contribution revenue, clinical trials to evaluate the clinical utility of product candidates, and costs associated with the enhancements of developed products. These costs include salaries and benefits, stock compensation, research related facility and overhead costs, laboratory supplies, equipment, depreciation on T2Dx instruments used for research and development activities and contract services.

Impairment of Long-lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Impairment is evaluated by comparing the carrying value of the long-lived assets with the estimated future net undiscounted cash flows expected to result from the use of the assets, including cash flows from disposition. Should the sum of the expected future net cash flows be less than the carrying value, the Company would recognize an impairment loss at that date. An impairment loss would be measured by comparing the amount by which the carrying value exceeds the fair value, or the estimated discounted future cash flows, of the long-lived assets.

The Company recorded impairment expense of $2.5 million and $0.2 million during the years ended December 31, 2023 and 2022, respectively.

Advertising Costs

Advertising costs are expensed as incurred and are reported within selling, general and administrative expenses on the Company's consolidated statements of operations and comprehensive loss. Advertising expense for the years ended December 31, 2023 and 2022 was less than $0.1 million and $0.1 million, respectively.

Contingencies

An estimated loss from a contingency is recorded if it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements and the amount of the loss can be reasonably estimated. Gain contingencies are not recorded until realization is assured beyond a reasonable doubt. Legal costs related to loss contingencies are expensed as incurred.

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. Comprehensive loss consists of net loss and other comprehensive loss, which includes certain changes in equity that are excluded from net loss.

Stock-Based Compensation

The Company issues stock-based awards to employees, generally in the form of stock options, restricted stock units and restricted stock awards. The Company accounts for stock-based awards in accordance with ASC Topic 718, *Compensation-Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based payments to employees, including grants of employee stock options, restricted stock units, and modifications to existing stock options, to be recognized in the consolidated statements of operations and comprehensive loss based on their grant date fair values. The Company’s policy is to use authorized and unissued shares in connection with the issuance of shares for exercises under option agreements. The Company recognized the compensation cost of stock-based awards to employees on a straight-line basis over the vesting period.

The Company estimates the fair value of the stock-based awards to employees using the Black-Scholes-Merton option pricing model, which requires the input of highly subjective assumptions, including (a) the expected volatility of the stock, (b) the expected term of the award, (c) the risk-free interest rate and (d) expected dividends. The Company estimates expected volatility based on the historical volatility of the stock using the daily closing prices during the equivalent period of the calculated expected term of its stock-based awards. The Company has estimated the expected life of the employee stock options using the "simplified" method, whereby the expected life equals the average of the vesting term, and the original contractual term of the option. The Company uses the simplified method due to the plain-vanilla nature of its share-based awards and because sufficient historical exercise data was not available to provide a reasonable basis for the expected term. The risk-free interest rates for periods within the expected life of the option are based on the U.S. Treasury yield curve in effect during the period in which the options were granted. The Company has not paid, and does not anticipate paying, cash dividends on shares of common stock; therefore, the expected dividend yield is assumed to be zero.

The Company elected an accounting policy to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from the estimates. Historical data is used to estimate pre-vesting option forfeitures and stock-based compensation expense is only recorded for those awards that are expected to vest. To the extent that actual forfeitures differ from the estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest. If the actual forfeiture rate is materially different from the estimate, stock-based compensation expense could be different from what we have recorded in the current period.

These assumptions used to determine stock compensation expense represent the Company's best estimates, but the estimates involve inherent uncertainties and the application of judgment. As a result, if factors change and the Company uses significantly different assumptions or estimates, stock-based compensation expense could be materially different. Refer to Note 10 for further details on the Company's stock-based compensation plan.

Income Taxes

The Company provides for income taxes using the liability method. The Company provides deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the Company's financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax assets to the amount that will more likely than not be realized.

The Company applies ASC 740 *Income Taxes* ("ASC 740") in accounting for uncertainty in income taxes. The Company does not have any material uncertain tax positions for which reserves would be required. The Company will recognize interest and penalties related to uncertain tax positions, if any, in income tax expense.

Net Loss Per Share

As discussed in Note 7, the Company issued 93,297 shares of Series B Convertible Preferred Stock on July 3, 2023. The Company has reviewed the terms of the Series B Convertible Preferred Stock and noted that such stock has no preferential rights and that the liquidation preference for the Series B Convertible Preferred Stock would be on parity with that of the Company's common shares. Because the Series B Convertible Preferred Stock has the same level of subordination and, in substance, the same characteristics as the Company's common shares, the Company included the Series B Convertible Preferred Stock, on an if-converted basis of 932,970 shares, in the basic and diluted net loss per share attributable to common stockholders calculation.

The Company has also issued certain securities that are participating securities. Therefore, the Company must apply the two-class method to determine basic and diluted earnings per share. The two-class method is an earnings allocation method under which net loss per share is calculated for each class of common stock and participating security considering both dividends declared, if any, and participation rights in undistributed earnings as if all such earnings had been distributed for the period. Because the Company incurred a net loss for the years ended December 31, 2023 and 2022, and the holders of the participating securities do not have the contractual obligation to share in the losses of the Company on a basis that is objectively determinable, none of the net loss attributable to common stockholders was allocated to the participating securities when computing earnings per share for 2023 or 2022. As the Company's participating securities do not have an obligation to share in the losses of the Company, to the extent that the Company remains in a net loss position, the entire net loss will be allocated to common stockholders.

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, in-substance common stock, and potential common shares exercisable for little to no consideration, and does not consider other common stock equivalents.

Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding, in-substance common stock, and potential common shares exercisable for little to no consideration used to compute basic earnings per share for the dilutive effect of other common stock equivalents that were outstanding during the period, determined using either the if-converted method or the treasury-stock method.

Foreign Currency Transactions

The Company's reporting currency is the U.S. dollar. The Company sells products outside of the United States and transacts foreign currencies. If transactions are recorded in a currency other than the Company's functional currency, remeasurement into the functional currency is required and may result in transaction gains or losses. Transaction losses were less than $0.1 million for both of the years ended December 31, 2023 and 2022. Amounts are recorded in other, net on the Company's consolidated statements of operations.

Recent Accounting Standards

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that its adoption of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations at the respective effective dates.

Accounting Standards Adopted

On September 29, 2022, the FASB issued ASU 2022-04, *Liabilities-Supplier Finance Programs (Subtopic 405-50) Disclosure of Supplier Finance Program Obligations* ("ASU 2022-04"). This ASU requires that a buyer in a supplier finance program disclose additional information about the program to allow financial statement users to better understand the effect of the programs on an entity's working capital, liquidity, and cash flows. This update is effective for the Company for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, except for the amendment on roll forward information, which is effective for fiscal years beginning after December 15, 2023. Early adoption is permitted. The Company adopted this standard as of January 1, 2023. The adoption did not have a material impact on the Company's financial statements.

Accounting Standards Issued, To Be Adopted

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). This ASU was issued to improve the disclosures about a public entity's reportable segments and address requests from investors for more detailed information about a reportable segment's expenses. This update will be effective for the Company for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently assessing the impact of this update on its disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"). This ASU was issued to enhance the transparency and decision usefulness of income tax disclosures. This update will be effective for the Company for fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently assessing the impact of this update on its disclosures.

3. Fair Value Measurements

The Company measures the following financial assets at fair value on a recurring basis. There were no transfers between levels of the fair value hierarchy during any of the periods presented. The following tables set forth the Company's financial assets and liabilities carried at fair value categorized using the lowest level of input applicable to each financial instrument as of December 31, 2023 and 2022 (in thousands):

	Balance at December 31, 2023	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 8,500	8,500	$ —	$ —
	$ 8,500	$ 8,500	$ —	$ —
Liabilities:				
Warrant liabilities	$ 235	$ —	$ 235	$ —
Derivative liability related to Term Loan with related party	1,554	—	—	1,554
	$ 1,789	$ —	$ 235	$ 1,554

	Balance at December 31, 2022	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities:				
Warrant liabilities	$ 39	$ —	$ 39	$ —
Derivative liability related to Term Loan with related party	1,088	—	—	1,088
	$ 1,127	$ —	$ 39	$ 1,088

The Company's cash equivalents are comprised of money market funds and money market accounts as of December 31, 2023 and money market accounts as of December 31, 2022. The Company also maintains money market accounts classified as restricted cash, which are Level 1 assets, for $0.6 million and $1.6 million on December 31, 2023 and 2022, respectively (Note 4).

The Company estimated the fair value of the warrant issued in conjunction with the Series A Redeemable Convertible Preferred Stock in August of 2022 (the "Series A Warrant") (Note 8) using the Black-Scholes Model, which uses multiple inputs including the Company's stock price, the exercise price of the warrant, volatility of the Company's stock price, the risk-free interest rate and the expected term of the warrant.

The estimated fair value of the Series A Warrant on December 31, 2023 was determined using the following assumptions:

Risk-free interest rate	3.91%
Expected dividend yield	0.00%
Expected volatility	147.00%
Expected term	4.13

The Company estimated the fair value of the Common Stock Warrant issued in February of 2023 (the "Common Stock Warrant") (Note 8) using both the Black-Scholes Model and Monte Carlo simulation methods to model different potential settlement outcomes. These models use multiple inputs including the Company's stock price, the exercise price of the warrant, volatility of the Company's stock price, the risk-free interest rate and the expected term of the warrant. Such inputs may vary depending on the model applied and the underlying scenario assumptions. Key inputs included the warrant exercise price of $108.00 per share, a risk-free interest rate of 3.91%, expected volatility ranging from 147% to 235%, an expected dividend yield of 0.00%, a stock price of $7.59 (adjusted to reflect volume weighting) and an expected term ranging from zero years to 4.13 years, depending on the simulation.

The following table provides a roll-forward of the fair value of the Common Stock Warrants (in thousands):

Balance on December 31, 2022	$ —
Issuance of Common Stock Warrant	7,568
Settlement due to cashless exercise	(1,480)
Change in fair value	(5,855)
Balance on December 31, 2023	$ 233

The Company has a single compound derivative instrument related to its Term Loan Agreement (Note 6) that requires the Company to pay additional interest of 4% per annum upon an event of default or if any obligation other than the unpaid principal amount of the Term Loan is not paid when due. Fair value is determined quarterly. The fair value of the derivative on December 31, 2023 is $1.6 million and is classified as a current liability on the balance sheet on December 31, 2023 consistent with the classification of the related Term Loan Agreement. The fair value of the derivative on December 31, 2022 was $1.1 million and was classified as a non-current liability on the balance sheet on December 31, 2022 consistent with the classification of the related Term Loan Agreement.

The estimated fair value of the derivative on December 31, 2023 was determined using a probability-weighted discounted cash flow model that includes contingent interest payments under the following scenarios:

	Probability
4% contingent interest beginning in Q2 2024	50%

Changes in assumptions regarding the probability of the 4% contingent interest feature being triggered and the timing of such a triggering event could significantly affect the estimated fair value of this derivative liability.

The following table provides a roll-forward of the fair value of the derivative liability (in thousands):

Balance on December 31, 2021	$ —
Change in fair value of derivative related to Term Loan with related party	1,088
Balance on December 31, 2022	$ 1,088
Change in fair value of derivative related to Term Loan with related party	466
Balance on December 31, 2023	$ 1,554

The Company is required to disclose the fair value and the level within the fair value hierarchy for financial instruments that are not measured at fair value on a recurring basis. For certain financial instruments, including accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses, the carrying amounts approximate their fair values as of December 31, 2023 and 2022 because of their short-term nature. Cash and cash equivalents were classified as Level 1 and all other financial instruments were classified as Level 2 within the fair value hierarchy. The Company used Level 3 inputs to measure the fair value of its Term Loan Agreement. Based on these measurements, the Company concluded that the carrying value of the Term Loan Agreement approximates its fair value on December 31, 2023.

4. Restricted Cash

The Company is required to maintain security deposits for its office lease agreements. On December 31, 2023 and 2022, the Company had lease security deposits, invested in money market accounts, aggregating $0.6 million and $1.6 million, respectively. In January 2023 one of these deposits of $1.0 million was claimed by a landlord as compensation for a lease dispute (Note 14). The remaining collateral deposits aggregating $550 thousand were held at Silicon Valley Bank, which was taken over by the FDIC in March 2023. The Company's full exposure was ultimately covered by the FDIC and no loss was incurred.

5. Supplemental Balance Sheet Information

Property and Equipment

Property and equipment consists of the following (dollar amounts in thousands)

	Estimated Useful Life (Years)	December 31, 2023	December 31, 2022
Office and computer equipment	3	$ 710	$ 757
Software	3	778	783
Laboratory equipment	5	5,104	5,570
Furniture	5-7	198	197
Manufacturing equipment	5	1,109	1,454
Manufacturing tooling and molds	0.5-5	371	494
T2-owned instruments and components	5	3,549	4,052
Leased T2-owned instruments	5	1,059	1,014
Leasehold improvements	Lesser of useful life or remaining lease term	3,608	3,784
Construction in progress	n/a	23	685
		16,509	18,790
Less accumulated depreciation and amortization		(14,851)	(14,257)
Property and equipment, net		$ 1,658	$ 4,533

Construction in progress is primarily comprised of equipment that has not been placed in service. T2-owned instruments and components is primarily comprised of instruments that will be used for internal research and development, clinical studies and reagent rental agreement with customers. Depreciation expense, a component of cost of product revenue, from instruments under the T2-owned reagent rental pool was $0.2 million and $0.1 million for the years ended December 31, 2023 and 2022, respectively.

Total depreciation expense for T2-owned instruments used for internal research and development and clinical studies is recorded as a component of research and development expense. Depreciation and amortization expense of $0.9 million and $1.0 million was charged to operations for the years ended December 31, 2023 and 2022, respectively.

In the third quarter of 2023, we determined a triggering event occurred that required us to evaluate our long-lived assets for impairment. The triggering event was the reassessment of the Company's sales demand forecast. We evaluated our long-lived assets by our two asset groups, which are T2-owned assets that are placed at customer sites as rental instruments and all other assets which support the Company's product research and manufacturing. As a result of the evaluation, the Company recorded impairment charges for T2-owned non-lease instruments and reagent manufacturing assets. T2-owned non-lease instruments were evaluated based on average historical sale prices for refurbished instruments. Reagent manufacturing assets were evaluated based on estimated cash flows from projected reagent test sales using historical margins and commission rates. The Company recorded a total loss on impairment of property and equipment of $2.5 million for the year ended December 31, 2023.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Accrued payroll and compensation	$ 2,705	$ 2,930
Accrued clinical trial and development expenses	285	1,097
Accrued professional services	554	1,626
Accrued interest	839	1,009
Other accrued expenses	522	607
Total accrued expenses and other current liabilities	$ 4,905	$ 7,269

Accrued professional services on December 31, 2022 includes a $1.0 million estimated liability related to the Billerica, Massachusetts lease (Note 14).

6. Notes Payable

Term Loan Agreement

In December 2016, the Company entered into the Term Loan Agreement with CRG. The Company initially borrowed $40.0 million under the Term Loan Agreement and had the ability to borrow an additional $10.0 million upon receiving specified clearance for the marketing of T2Bacteria by April 30, 2018 (the "Approval Milestone"). The Company agreed to pay (1) a financing fee based on the amount of principal drawn and (2) a final payment fee based on the principal outstanding upon repayment. The debt discount related to the financing fee and the fees paid to CRG are being amortized over the loan term as interest expense. Interest expense for the debt discount was $0.1 million for both of the years ended December 31, 2023 and 2022. The final payment fee is accrued as interest expense and is classified consistent with the classification of the Term Loan. The effective interest rate of the Term Loan was 10.2% as of December 31, 2023.

The Term Loan's principal is prepayable at any time partially or in full without a prepayment penalty. Borrowings are collateralized by a lien on substantially all Company assets, including intellectual property. The Term Loan Agreement provides for affirmative and negative covenants, including a requirement to maintain a minimum cash balance of $5.0 million. The Term Loan Agreement includes a subjective acceleration clause whereby an event of default, including a material adverse change in the business, operations, or conditions (financial or otherwise), could result, at CRG's discretion, in the acceleration of the obligations under the Term Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.0% per annum may apply, at CRG's discretion, on all outstanding obligations during the occurrence and continuance of an event of default.

The Term Loan originally had a six-year term, with three years of interest-only payments accruing at a fixed rate of 12.5%, of which 4.0% could be paid in-kind by increasing the principal balance. After achievement of the Approval Milestone, such rates would be reduced and a fourth year of interest-only payments would be granted, after which quarterly payments of principal and interest would be owed through the December 30, 2022 maturity date. Upon achievement of certain performance metrics, the loan would be converted to interest-only until its maturity, at which time all unpaid principal and interest would be due and payable.

In connection with the Term Loan Agreement, the Company issued warrants to CRG to purchase a total of 105 shares of the Company's common stock, exercisable any time prior to December 30, 2026.

Amendments

The Term Loan Agreement has been amended nine times. As a result of those amendments, certain terms of the Term Loan have been revised as follows:

- In 2018, upon the Company's achievement of the Approval Milestone, interest on borrowings began accruing at 11.50% per year, 8% of which is payable in cash quarterly and 3.5% of which is deferred and added to principal until maturity.
- In 2019:
    - The final payment fee was increased from 8% to 10% of the principal outstanding upon repayment.
    - The Company issued additional warrants to CRG to purchase 113 shares of its common stock, exercisable any time prior to September 9, 2029 at an exercise price of $7,750.00 per share, with provisions for termination upon a change of control or a sale of all or substantially all of the assets of the Company (these warrants, along with the warrants to purchase 105 shares of common stock previously issued to CRG, are collectively referred to as the "CRG Warrants").
    - The Company reduced the exercise price for the warrants previously issued to CRG to $7,750.00.
- In 2022, the principal maturity date was extended to December 30, 2024, and the Term Loan's interest-only payment period was extended until that maturity date.
- In 2023:
    - The Company and CRG entered into a waiver and consent that reduced the minimum liquidity covenant to $500,000 until December 31, 2023.
    - CRG waived certain specified events of default associated with the Company's issuance of shares of Series A Redeemable Convertible Preferred Stock in August 2022 and the subsequent redemption (Note 7).
    - In July 2023, CRG canceled $10.0 million of the Term Loan's principal in exchange for 483,457 shares of common stock and 93,297 shares of Series B Convertible Preferred Stock.
    - In October 2023, the interest-only period and maturity of the Term Loan were extended to December 31, 2025 and the $500,000 liquidity covenant was made permanent.

The warrants to purchase 218 shares of the Company's common stock remain outstanding on December 31, 2023. There were no covenant violations during the year ended December 31, 2023.

Amendments made in February 2022, November 2022, October 2023, and the partial principal cancellation in July 2023 were accounted for as troubled debt restructurings. For all restructurings, at the time of the restructuring the future undiscounted cash outflows required under the amended agreement exceeded the carrying value of the debt and no gain was recognized as a result of the restructurings. The effects of each restructuring were accounted for prospectively.

Related Party

Upon the close of the July 2023 transaction in which CRG canceled $10.0 million of the Term Loan's principal in exchange for 483,457 shares of common stock and 93,297 shares of Series B Convertible Preferred Stock, CRG became a holder of more than ten percent of our common stock outstanding, and therefore determined to be a principal owner and related party. As of December 31, 2023, CRG held no shares of common stock and 93,297 shares of Series B Convertible Preferred Stock, which was convertible into more than ten percent of our common stock outstanding as of December 31, 2023. Subsequent to December 31, 2023, in February 2024, CRG converted 82,422 shares of its Series B Preferred Stock into 824,220 shares of common stock, which represented more than ten percent of our common stock outstanding.

Classification

The Term Loan Agreement with CRG was classified as a non-current liability on December 31, 2022. In May 2023, the Company received a modification and waiver reducing the Term Loan's minimum cash covenant from $5.0 million to $500,000 until December 31, 2023. In addition, in October 2023, the interest-only period and maturity of the Term Loan were extended to December 31, 2025, and the $500,000 liquidity covenant was made permanent. Because management believes it is probable that the Company will not be able to comply with the covenant unless additional funds are raised, the Company concluded that the Term Loan and related liabilities should be classified as current on December 31, 2023.

Future Payments

Future principal payments on the notes payable are as follows (in thousands):

Year ended December 31,	
2024	—
2025	44,457
2026	—
2027	—
2028	—
Total including PIK interest, before unamortized discount and issuance costs	44,457
Less: unaccrued paid-in-kind interest	(3,037)
Less: unamortized discount and deferred issuance costs	(136)
Total notes payable to related party	$ 41,284

7. Preferred Stock

Series A Redeemable Preferred Stock

On July 5, 2023, the Company issued Series A Redeemable Preferred Stock (the "Series A Preferred Stock") to help effect a Reverse Stock Split Proposal. Subject to the terms and conditions of a Securities Purchase Agreement, the Company agreed to issue and sell to CRG 1,000 shares of newly designated Series A Preferred Stock, par value $0.001 per share, for a total purchase price of $100.00. A "Reverse Stock Split Proposal" means any proposal approved by the Company's Board of Directors and submitted to the Company's stockholders to adopt an amendment(s) to the Company's Amended and Restated Certificate of Incorporation to combine the outstanding shares of common stock into a smaller number of shares of common stock at a ratio to be specified.

Voting Rights

Shares of the Series A Preferred Stock had the right to vote only on any Reverse Stock Split Proposal and as may have been required by law. The Series A Preferred Stock represented an aggregate of 400,000,000 votes, and CRG agreed to vote in the same proportion as shares of common stock of the Company were voted on any Reverse Stock Split Proposal.

Redemption

The Series A Preferred Stock were redeemable (i) at any time if such redemption was ordered by the Board of Directors in its sole discretion, automatically and effective on such time and date specified by the Board of Directors in its sole discretion, or (ii) automatically immediately following the approval by the stockholders of the Company of a Reverse Stock Split Proposal at a redemption price of $100.00. On September 15, 2023, the Company's stockholders voted to approve an amendment to the Company's Amended and Restated Certificate of Incorporation to effect a reverse stock split of the Company's common stock, par value $0.001 per share, at a reverse split ratio ranging from any whole number between and including 1-for-50 and 1-for-150, with the exact ratio to be determined at the discretion of the Board of Directors of the Company. As a result of that stockholder vote, the Series A Preferred Stock was redeemed on September 15, 2023, for $100. Upon its redemption, the Company's Series A Preferred Stock ceased to be outstanding.

Series B Convertible Preferred Stock

On July 3, 2023, in conjunction with an agreement it reached with CRG to cancel $10.0 million of its Term Loan principal, the Company issued to CRG (i) an aggregate of 483,457 shares of common stock at a purchase price of $7.06 per share for a total purchase price of $3.4 million, and (ii) an aggregate of 93,297 shares of newly designated Series B Convertible Preferred Stock (the "Series B Preferred Stock"), par value $0.001 per share, at a purchase price of $70.60 per share (the "Stated Value") for a total purchase price of $6.6 million.

Dividends

Holders of Series B Preferred Stock are entitled to receive dividends on such shares (other than common stock dividends) equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of the common stock. No other dividends shall be paid on shares of Series B Preferred Stock. All declared but unpaid dividends on shares of Series B Preferred Stock will increase the Stated Value of such shares, but when such dividends are actually paid any such increase in the Stated Value will be rescinded.

Voting Rights

Except as may be required by law, the Series B Preferred Stock has no voting rights. However, as long as any shares of Series B Preferred Stock are outstanding, the Company shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series B Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock, (ii) increase or decrease (other than by conversion) the number of authorized shares of Series B Preferred Stock, or (iii) enter into any agreement with respect to any of the foregoing.

Liquidation Preference

The Series B Preferred Stock ranks (i) senior to any class or series of capital stock of the Corporation hereafter created specifically ranking by its terms junior to any Series B Preferred Stock (collectively, the "Junior Securities"); (ii) on parity with the common stock; (iii) on parity with any class or series of capital stock of the Company hereafter created specifically ranking by its terms on parity with the Series B Preferred Stock (together with the common stock, the "Parity Securities"); and (iv) junior to any class or series of capital stock of the Company hereafter created specifically ranking by its terms senior to any Series B Preferred Stock ("Senior Securities"), in each case, as to distributions of assets upon liquidation, dissolution or winding up of the Company, whether voluntarily or involuntarily (a "Liquidation"). No Junior Securities, Parity Securities or Senior Securities existed on December 31, 2023.

In a Liquidation, the Series B Preferred Stockholder will, subject to the prior and superior rights of the holders of any Senior Securities, be entitled to receive, in preference to any distributions of any of the assets or surplus funds of the Company to the holders of the Junior Securities and pari passu with any distribution to the holders of Parity Securities, an equivalent amount of any distributions as would be paid on the common stock underlying the Series B Preferred Stock, determined on an as-converted basis (without regard to any limitations on conversion), plus an additional amount equal to any dividends declared but unpaid on such shares, before any payments shall be made or any assets distributed to holders of any class of Junior Securities.

Conversion Rights

Each share of Series B Preferred Stock is convertible, at any time and from time to time from and after the Reverse Split Amendment has been filed with the Secretary of State of the State of Delaware, at the option of the holder thereof, into a number of shares of common stock equal to the product of the Conversion Ratio (which is the $70.60 Stated Value of such shares divided by the $7.06 Conversion Price, subject to adjustment) and the number of shares of Series B Preferred Stock to be converted. The Reverse Split Amendment was filed on October 12, 2023. The conversion feature is subject to certain beneficial ownership limitations. The Conversion Price also is subject to adjustment for stock dividends and stock splits.

8. Warrants

Series A Warrant

On August 15, 2022, the Company issued an aggregate of 3,000 shares of Series A Redeemable Convertible Preferred Stock with a par value of $0.001 per share and the Series A Warrant to purchase up to an aggregate of 428 shares of common stock of the Company at an exercise price of $750.00 per share (such number of shares and exercise price are adjusted for the reverse stock split described in Note 2) for an aggregate subscription amount equal to $0.3 million, before deducting estimated offering expenses payable by the Company. In the fourth quarter of 2022, the Series A Redeemable Convertible Preferred Stock was redeemed. The Series A Warrant became exercisable on February 15, 2023 and expires on February 15, 2028. The Series A Warrant contains certain anti-dilution provisions to protect the holder.

On February 17, 2023, the Company issued and sold shares of common stock, pre-funded warrants to purchase common stock and warrants to purchase common stock to an underwriter pursuant to an underwriting agreement (see discussion below). The terms of that offering triggered an adjustment to the exercise price of the Series A Warrant to $54.00 effective as of February 17, 2023.

The Company is required to measure the Series A Warrant at fair value at inception and in subsequent reporting periods with changes in fair value recognized in change in fair value of warrant liabilities in the period of change in the consolidated statements of operations and comprehensive loss. The fair value of the liability related to the Series A Warrant at inception was $0.4 million. The Series A Warrant was not exercised as of December 31, 2023 and remains outstanding. The change in fair value during the year ended December 31, 2023 was immaterial.

Pre-Funded Warrants and Common Stock Warrants

On February 17, 2023, the Company sold 90,185 shares of $0.001 par value common stock, 20,925 Pre-Funded Warrants and 222,222 Common Stock Warrants through an offering underwritten by Craig-Hallum Capital Group LLC. Each of the shares and Pre-Funded Warrants were sold in combination with an accompanying Common Stock Warrant to purchase two shares of the Company’s common stock. The combined purchase price for each share and accompanying Common Stock Warrant is $108.00, and for each Pre-Funded Warrant and accompanying Common Stock Warrant is $107.90, which was equal to the combined purchase price for each share and accompanying Common Stock Warrant sold in the offering, minus the Pre-Funded Warrant’s exercise price per share of $0.10.

The total proceeds of $12.0 million from the February 17, 2023 offering were allocated between the common stock, Pre-Funded Warrants and Common Stock Warrants. Because the Common Stock Warrants are liability-classified, an amount of proceeds equal to the fair value of the liability were first allocated to the Common Stock Warrants. The remaining proceeds were allocated on a relative fair value basis to the common stock and the Pre-Funded Warrants and recognized in additional paid-in capital. Total issuance costs related to the offering of $1.1 million were allocated in a similar manner as the total proceeds. As a result, approximately $0.7 million of issuance costs were expensed at the issuance date and recognized as other, net in the consolidated statements of operations and comprehensive loss. The remaining issuance costs were recognized within additional paid-in-capital as a reduction to the proceeds received for the common stock and Pre-Funded Warrants.

The Pre-Funded Warrants had (i) an exercise price per share of common stock equal to $0.10 or (ii) a cashless exercise option, with the number of shares received determined according to the formula set forth in the Pre-Funded Warrant. The Pre-Funded Warrants were exercisable upon issuance and did not expire. The exercise price and the number of shares of common stock issuable upon exercise of the Pre-Funded Warrants was subject to adjustment in the event of certain stock dividends and distributions, splits, combinations, reclassifications or similar events affecting the common stock. Holders of Pre-Funded Warrants participated in any distributions to common stockholders as if the holders had exercised the Pre-Funded Warrants.

The Company determined that the Pre-Funded Warrants were indexed to the Company’s own stock and met the requirements for equity classification. Proceeds allocated to such warrants totaled $0.8 million. No Pre-Funded Warrants remain outstanding on December 31, 2023.

The Common Stock Warrants have (i) an exercise price per share of common stock equal to $108.00 per share, (ii) a cashless exercise option if, at the time of exercise, there is no effective registration statement registering or the prospectus is not available for the issuance of the warrant shares to the holder, with the number of shares received determined according to the formula set forth in the Common Stock Warrant or (iii) an alternate cashless exercise option, which became exercisable on March 15, 2023, equal to the product of (x) the aggregate number of shares of common stock that would be issuable upon a cash exercise and (y) 0.5. The Common Stock Warrants are exercisable upon issuance and expire on February 17, 2028. The exercise price and the number of shares of common stock issuable upon exercise of the Common Stock Warrants is subject to adjustment in the event of certain stock dividends and distributions, splits, combinations, reclassifications or similar events affecting the common stock. Holders of the Common Stock Warrants will participate in any distributions to common stockholders as if the holders had exercised the Common Stock Warrants. The Common Stock Warrants are redeemable upon the occurrence of a Fundamental Transaction (as defined in the Common Stock Purchase Warrant Agreement).

The Company determined that the Common Stock Warrants are not indexed to the Company's own stock and therefore are precluded from equity classification. In addition, the Common Stock Warrant liability meets the definition of a derivative instrument. The Common Stock Warrants will be measured at fair value at inception and in subsequent reporting periods with changes in fair value recognized in income as change in fair value of warrant liabilities in the period of change in the consolidated statements of operations and comprehensive loss. The fair value of the Common Stock Warrant liability at inception was $7.6 million. During the year ended December 31, 2023, 155,557 Common Stock Warrants were exercised pursuant to the cashless exercise option resulting in the issuance of 77,776 shares of common stock. On December 31, 2023, 66,665 Common Stock Warrants remain outstanding. The change in fair value after issuance consisted of a reduction of expense of $5.9 million during the year ended December 31, 2023.

The Company has also issued certain warrants in conjunction with its Term Loan Agreement. See Note 6.

9. Stockholders' Deficit

Preferred Stock

We have authorized the issuance of up to 10,000,000 shares of $0.001 par value preferred stock. The Board of Directors will determine the preferred stock's rights, preferences, privileges, restrictions, voting rights, dividend rights, conversion rights, redemption privileges, and liquidation preferences.

Common Stock

We have authorized the issuance of 400,000,000 shares of $0.001 par value common stock.

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all classes of stock outstanding. As of December 31, 2023, a total of 1,573 shares, 3,691 shares, and 67,311 shares of common stock were reserved for issuance upon (i) the exercise of outstanding stock options, (ii) the issuance of stock awards, and (iii) the exercise of warrants, respectively, under the Company's 2014 Incentive Award Plan, Inducement Award Plan and 2014 Employee Stock Purchase Plan.

Equity Distribution Agreement

On March 31, 2021, the Company entered into an Equity Distribution Agreement ("Equity Distribution Agreement") with Canaccord Genuity LLC ("Canaccord"), through which the Company may sell up to $75.0 million of gross proceeds of common stock. In July 2023, the Company filed an amendment to the prospectus supplement relating to the offer and sale of shares under the Equity Distribution Agreement to increase the maximum amount of shares that the Company may sell pursuant to its Equity Distribution Agreement with Canaccord by $65 million. At the time of the amendment, the Company had sold shares of its common stock for gross proceeds of $71.3 million.

Canaccord, as agent, sells shares at the Company's request through "at the market" offerings, subject to shelf limitations, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, or by any other method permitted by law, including negotiated transactions. Canaccord receives a fee of 3% of gross proceeds of common stock sold under the Equity Distribution Agreement for its services. Legal and accounting fees from sales under the Equity Distribution Agreement are charged to share capital. Under the Equity Distribution Agreement, the Company sold 3,303,122 shares of common stock during the year ended December 31, 2023 for net proceeds of $41.8 million. Under the Equity Distribution Agreement, the Company sold 43,068 shares of common stock during the year ended December 31, 2022 for net proceeds of $29.2 million. Subsequent to December 31, 2023, the Company sold 628,470 shares of common stock for proceeds of $2.2 million under the Equity Distribution Agreement.

10. Stock-Based Compensation

Stock Incentive Plans

2006 Stock Incentive Plan

The Company's Amended and Restated 2006 Employee, Director and Consultant Stock Plan (the "2006 Plan") was established for granting stock incentive awards to directors, officers, employees and consultants of the Company. Upon closing of the Company's IPO in August 2014, the Company ceased granting stock incentive awards under the 2006 Plan. The 2006 Plan provided for the grant of incentive and non-qualified stock options and restricted stock grants as determined by the Company's Board of Directors. Under the 2006 Plan, stock options were generally granted with exercise prices equal to or greater than the fair value of the common stock as determined by the Board of Directors, expired no later than 10 years from the date of grant, and vest over various periods not exceeding 4 years.

2014 Stock Incentive Plan

The Company's 2014 Incentive Award Plan (the "2014 Plan," and together with the 2006 Plan, the "Stock Incentive Plans"), which was amended and restated in October 2023, provides for the issuance of shares of common stock in the form of stock options, awards of restricted stock, awards of restricted stock units, performance awards, dividend equivalent awards, stock payment awards and stock appreciation rights to directors, officers, employees and consultants of the Company. Since the establishment of the 2014 Plan, the Company has primarily granted stock options and restricted stock units. Generally, stock options are granted with exercise prices equal to or greater than the fair value of the common stock on the date of grant, expire no later than 10 years from the date of grant, and vest over various periods not exceeding 4 years.

The number of shares reserved for future issuance under the 2014 Plan is the sum of (1) 823,529 (2) any shares that were granted under the 2006 Plan which are forfeited, lapse unexercised or are settled in cash subsequent to the effective date of the 2014 Plan and (3) an annual increase on the first day of each calendar year, beginning January 1, 2015 and ending on and including January 1, 2026, equal to the lesser of (A) 4% of the shares outstanding (on an as-converted basis) on the final day of the immediately preceding calendar year and (B) such smaller number of shares determined by the Company's Board of Directors; provided, however, no more than 35 million shares may be issued upon the exercise of incentive stock options. As of December 31, 2023, there were 825,533 shares available for future grant under the 2014 Plan.

Inducement Award Plan

The Company's Inducement Award Plan (the "Inducement Plan"), which was adopted in March 2018 without stockholder approval pursuant to Rule 5635(c)(4) of The Nasdaq Stock Market LLC listing rules ("Rule 5635(c)(4)") and most recently amended and restated in December 2021, provides for the grant of equity awards to new employees, including options, restricted stock awards, restricted stock units, performance awards, dividend equivalent awards, stock payment awards and stock appreciation rights. In accordance with Rule 5635(c)(4), awards under the Inducement Plan may only be made to a newly hired employee who has not previously been a member of the Company's Board of Directors, or an employee who is being rehired following a bona fide period of non-employment by us as a material inducement to the employee's entering into employment with us. The aggregate number of shares of common stock which may be issued or transferred pursuant to awards under the Inducement Plan is 6,925 shares. Any awards that forfeit, expire, lapse, or are settled for cash without the delivery of shares to the holder are available for the grant of an award under the Inducement Plan. Any shares repurchased by or surrendered to the Company that are returned shall be available for the grant of an award under the Inducement Plan. The payment of dividend equivalents in cash in conjunction with any outstanding award shall not be counted against the shares available for issuance under the Inducement Plan. As of December 31, 2023, there were 5,038 shares available for future grant under the Inducement Plan.

Stock Options

The aggregate fair value of stock options granted during the year ended December 31, 2023 was immaterial. During the year ended December 31, 2022, the Company granted options with an aggregate fair value of $0.6 million, which are being amortized into compensation expense over the vesting period of the options as the services are being provided.

The following is a summary of option activity under the Stock Incentive Plans and Inducement Plan (in thousands, except term, share and per share amounts):

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding on December 31, 2022	1,674	$ 13,855.94	5.93	$ —
Granted	461	29.90		
Exercised	—	—		
Forfeited	(325)	1,321.39		
Cancelled	(237)	14,006.16		
Outstanding on December 31, 2023	1,573	$ 12,371.09	6.08	$ —
Exercisable on December 31, 2023	1,200	$ 15,816.25	5.20	$ —
Vested or expected to vest on December 31, 2023	1,489	$ 13,018.64	5.91	$ —

There were no options exercised in the years ended December 31, 2023 and 2022. The weighted-average fair values of options granted in the years ended December 31, 2023 and 2022 were $25.64 and $1,757.55 per share, respectively, and were calculated using the following estimated assumptions:

	Year Ended December 31,	
	2023	2022
Weighted-average risk-free interest rate	3.99%	2.27%
Expected dividend yield	—%	—%
Expected volatility	120%	106%
Expected terms	6.0 years	5.2 years

The total fair values of stock options that vested during the years ended December 31, 2023 and 2022 were $1.0 million and $1.7 million, respectively.

As of December 31, 2023, there was $0.3 million of total unrecognized compensation cost related to non-vested stock options granted under the Stock Incentive Plans. Total unrecognized compensation cost will be adjusted for future changes in the estimated forfeiture rate. The Company expects to recognize that cost over a remaining weighted-average period of 1.4 years as of December 31, 2023.

Restricted Stock Units

During the year ended December 31, 2023, the Company awarded restricted stock units to certain employees and directors at no cost to them. The restricted stock units, excluding any restricted stock units with market conditions, vest through the passage of time, assuming continued service. Restricted stock units are not included in issued and outstanding common stock until the underlying shares are vested and released. The fair value of the restricted stock units, at the time of the grant, is expensed on a straight line basis. The granted restricted stock units had an aggregate fair value of $0.3 million, which are being amortized into compensation expense over the vesting period of the restricted stock units as the services are being provided.

The following is a summary of restricted stock unit activity under the 2014 Plan:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Nonvested on December 31, 2022	2,006	$ 4,473.87
Granted	4,199	59.43
Vested	(902)	4,556.78
Forfeited	(1,612)	418.69
Nonvested on December 31, 2023	3,691	$ 1,202.65

As of December 31, 2023, there was $2.4 million of total unrecognized compensation cost related to nonvested restricted stock units granted under the 2014 Plan. Total unrecognized compensation cost will be adjusted for future changes in the estimated forfeiture rate. The Company expects to recognize that cost over a remaining weighted-average period of 0.7 years as of December 31, 2023.

Employee Stock Purchase Plan

Under the 2014 Employee Stock Purchase Plan (the “2014 ESPP”) participants may purchase the Company’s common stock during semi-annual offering periods at 85% of the lower of (i) the market value per share of common stock on the first day of the offering period or (ii) the market value per share of the common stock on the purchase date. Each participant can purchase up to a maximum of $25,000 per calendar year in fair market value as calculated in accordance with applicable tax rules. The first offering period began on August 7, 2014. Stock-based compensation expense from the 2014 ESPP for the years ended December 31, 2023 and 2022 was approximately $0.1 million and $0.1 million, respectively. During the year ended December 31, 2023, 4,847 shares were purchased through the 2014 ESPP.

The fair value of the purchase rights granted under this plan was estimated on the date of grant and uses the following weighted-average assumptions, which were derived in a manner similar to those discussed in Note 2 relative to stock options:

	Year Ended December 31,	
	2023	2022
Weighted-average risk-free interest rate	5.25%	0.82%
Expected dividend yield	—%	—%
Expected volatility	123%	106%
Expected terms	0.5 years	0.5 years

The 2014 ESPP, which was amended and restated effective October 2023, provides for the issuance of up to 400,000 shares of the Company's common stock to eligible employees. On December 31, 2023, there were 394,477 shares available for issuance under the 2014 ESPP.

Stock-Based Compensation Expense

The following table summarizes the stock-based compensation expense resulting from awards granted under Stock Incentive Plans, the Inducement Plan, and the 2014 ESPP, that was recorded in the Company's results of operations for the periods presented (in thousands):

	Year Ended December 31,	
	2023	2022
Cost of product revenue	$ 132	$ 367
Research and development	583	1,017
Selling, general and administrative	3,674	5,079
Total stock-based compensation expense	$ 4,389	$ 6,463

For the years ended December 31, 2023 and 2022, stock-based compensation expense capitalized as part of inventory or T2-owned instruments and components was immaterial.

11. Net Loss Per Share

The Company applies the two-class method for computing earnings per share because its Series A Warrants, Pre-Funded Warrants and Common Stock Warrants are participating securities. Because the Company incurred a net loss for the years ended December 31, 2023 and 2022, and the holders of the participating securities do not have the contractual obligation to share in the losses of the Company, none of the net loss attributable to common stockholders was allocated to the participating securities when computing earnings per share. The basic and diluted net loss per share calculation includes the Series B Convertible Preferred Shares, on an if-converted basis, given that these instruments have essentially the same economic rights and privileges as the currently outstanding common stock.

The Pre-Funded Warrants allowed the holders to acquire a specified number of common shares at a nominal exercise price of $0.10 per share and were classified as equity. Since the shares underlying the Pre-Funded Warrants were exercisable for little or no consideration, the underlying shares were considered outstanding at the issuance of the Pre-Funded Warrants for purposes of calculating the weighted-average number of shares of common stock outstanding in basic and diluted earnings per share for common stock. On December 31, 2023, none of the Pre-Funded Warrants were outstanding.

For the year ended December 31, 2022, the net loss attributable to common stockholders was increased by $0.3 million to reflect the deemed dividend paid to holders of the Series A Redeemable Convertible Preferred Stock to accrete the carrying amount of that preferred stock to its redemption value.

The following shares were excluded from the calculation of diluted net loss per share applicable to common stockholders, prior to the application of the treasury stock or if-converted methods, because their effect would have been anti-dilutive for the periods presented:

	Year Ended December 31,	
	2023	2022
Options to purchase common shares	1,573	1,796
Restricted stock units	3,691	2,019
Term Loan Warrants	218	218
Series A Warrant	428	428
Common Stock Warrants	66,665	—
Total	72,575	4,461

The Series A Redeemable Convertible Preferred Stock was redeemed on October 26, 2022.

Note that all net loss per share computations for all periods presented reflect the changes in the number of shares resulting from the 1-for-100 reverse stock split that was approved by shareholders on September 15, 2023 and became effective as of October 12, 2023.

12. Income Taxes

The reconciliation of the U.S. federal statutory rate to the Company's effective tax rate is as follows:

	December 31,	
	2023	2022
Tax at statutory rates	21.0%	21.0%
State income taxes	3.0	4.6
Stock-based compensation	(2.9)	(2.4)
Permanent differences	2.1	0.1
Research and development credits	0.6	1.7
Difference and changes in tax rates	(2.2)	(0.2)
Other	(2.7)	0.3
Limitations on credits and net operating losses	(20.1)	(20.1)
Change in valuation allowance	1.2	(4.9)
Effective tax rate	0.0%	0.0%

The significant components of the Company's deferred tax asset consist of the following on December 31, 2023 and 2022 (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 72,149	$ 72,360
Tax credits	361	1,012
Other temporary differences	3,801	3,745
Start-up expenditures	1,595	2,068
Capitalized research and development expenses	7,248	5,793
Stock option expenses	2,230	3,025
Lease liability	1,973	2,494
Total deferred tax assets	89,357	90,497
Deferred tax asset valuation allowance	(87,236)	(87,843)
Net deferred tax assets	2,121	2,654
Deferred tax liabilities:		
Right of use asset	(1,776)	(2,279)
Prepaid expenses	(345)	(375)
Net deferred taxes	$ —	$ —
Net deferred tax asset	—	—
Net deferred tax liability	—	—

In 2023 and 2022, the Company did not record a benefit for income taxes related to its operating losses incurred. ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Based upon the level of historical U.S. losses and future projections over the period in which the net deferred tax assets are deductible, at this time, management believes it is more likely than not that the Company will not realize the benefits of these deductible differences, and as a result the Company continues to maintain a valuation allowance for the full amount of the 2023 deferred tax assets. The valuation allowance decreased by $0.6 million and increased by $3.0 million for the years ended December 31, 2023 and 2022, respectively. The decrease in the 2023 valuation allowance is primarily attributable to increases in Section 382 and 383 limitations as a result of an ownership change that occurred in November of 2023, partially offset by an increase in capitalized R&D expenses and the current period taxable loss. The increase in the 2022 valuation allowance is primarily attributable to the additional net operating losses, capitalized R&D expenses, and tax credits generated in 2022 that required additional valuation allowance, partially offset by the prior year increase in Section 382 and 383 limitations on the Company's tax attributes as a result of an ownership change that occurred in August of 2022.

As of December 31, 2023, the Company had federal and state net operating losses of $273.7 million and $245.4 million, respectively, which are available to offset future taxable income, if any, of which $10.4 million of federal and $168.7 million of state carryforwards will expire in varying amounts through 2037 and 2043, respectively. Additionally, $263.3 million of federal net operating loss carryforwards and $76.7 million of state net operating loss carryforwards will carryforward indefinitely, subject to annual taxable income limitations in the year of utilization. The Company also had federal and state research and development tax credits of $28.0 thousand and $0.4 million, respectively. The federal credits will expire at various dates through 2043 if not utilized, and the state credits of approximately $9.7 thousand will expire at various dates through 2038 if not utilized.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Sections 382 and 383 of the Internal Revenue Code of 1986, as amended ("the Code"), as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an “ownership change” as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders. The Company completed an assessment on December 31, 2023 and December 31, 2022 regarding whether there may have been a Section 382 ownership change. The study concluded that there were limitations on the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income. The Company has not included NOL carryforwards in its financial statements that will expire before they are utilized due to the limitation imposed by Section 382.

The Company has no balance of gross unrecognized tax benefits as of December 31, 2023. Interest and penalty charges, if any, related to uncertain tax positions would be classified as income tax expenses in the accompanying consolidated statements of operations. On December 31, 2023 and 2022, the Company had no accrued interest or penalties related to uncertain tax positions.

The Company files income tax returns in the U.S. federal tax jurisdiction and various state jurisdictions. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available. The Company does not have any international operations as of December 31, 2023. The statute of limitations for assessment by federal and state tax jurisdictions in which the Company has business operations is open for tax years ending after December 31, 2020 and December 31, 2019, respectively. The tax years open to examination vary by jurisdiction.

13. Leases

Operating Leases

The Company leases certain office space, laboratory space, and equipment. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. The Company does not recognize right-of-use assets or lease liabilities for leases determined to have a term of 12 months or less. For new and amended leases, the Company has elected to account for the lease and non-lease components as a combined lease component.

In August 2010, the Company entered into an operating lease for office and laboratory space at its headquarters in Lexington, Massachusetts. The lease commenced in January 2011, with the Company providing a security deposit of $400,000. In accordance with the operating lease agreement, the Company reduced its security deposit to $160,000 in January 2018, which is recorded as restricted cash in the consolidated balance sheets. In March 2017, the Company entered into an amendment to extend the term to December 2021. In October 2020, the Company entered into an amendment to extend the term to December 31, 2028. In accordance with the October 2020 amendment, the Company increased its security deposit to $420,438, which is classified as restricted cash on December 31, 2023 and 2022.

In May 2013, the Company entered into an operating lease for additional office, laboratory and manufacturing space in Wilmington, Massachusetts. In August 2018, the Company entered into an amendment to extend the term to December 2020. In October 2020, the Company entered into an amendment to extend the term to December 31, 2022. In September 2022, the Company entered into an amendment to extend the term to December 31, 2024.

In November 2014, the Company entered into a lease for additional laboratory space in Lexington, Massachusetts. The lease term commenced in April 2015 and extended for six years. The rent expense, inclusive of the escalating rent payments, is recognized on a straight-line basis over the lease term. As an incentive to enter into the lease, the landlord paid approximately $1.4 million of the $2.2 million space build-out costs. The unamortized balance of the lease incentive as of January 1, 2019 was reclassified as a reduction to the initial recognition of the right-of-use asset related to this lease. In connection with this lease agreement, the Company paid a security deposit of $281,000, which was recorded as a component of both prepaid expenses and other current assets and other assets in the consolidated balance sheets on December 31, 2019. In October 2020, the Company entered into an amendment to extend the term of the lease to October 31, 2025. In accordance with this amendment, the Company paid a replacement security deposit of $130,977, which is classified as restricted cash on December 31, 2023 and 2022 and received the initial $281,000 security deposit in return.

In September 2021, the Company entered into a lease for office, research, laboratory and manufacturing space in Billerica, Massachusetts. The lease has a term of 126 months from the commencement date. The Company opened a money market account for $1.0 million, which represents collateral as a security deposit for this lease and is classified as restricted cash on December 31, 2022. Occupancy of the building had been delayed due to disagreement between the Company and the landlord as to the parties' obligations under the lease agreement. Included within accrued expenses and other current liabilities on the balance sheet on December 31, 2022 is a $1.0 million estimated liability pertaining to this lease. In January 2023, the Company was notified that the landlord terminated the lease because of the Company's alleged failure to perform its obligations under the Lease in a timely manner and the Company's alleged breach of the covenant of good faith and fair dealing and exercised its right to draw upon the $1.0 million security deposit. In addition, the landlord is seeking damages for unpaid rent, brokerage fees, transaction costs, attorney's fees and court costs. The Company filed a response to the landlord's complaint and a counterclaim alleging that the landlord breached its obligations under the contract and unlawfully drew on the security deposit, in addition to breaching its covenants of good faith and fair dealing, making fraudulent misrepresentations, and engaging in deceptive and unfair trade practices. The matter is in dispute (Note 14). The Company intends to pursue legal remedies available under applicable laws. The Company believes it will continue to meet its current manufacturing needs with its operations at its Lexington and Wilmington, Massachusetts facilities.

Operating leases are amortized over the lease term and included in costs and expenses in the consolidated statement of operations and comprehensive loss. Variable lease costs are recognized in costs and expenses in the consolidated statement of operations and comprehensive loss as incurred. Variable lease costs may include costs such as common area maintenance, utilities, real estate taxes or other costs. Expenses related to short-term leases were not material for periods presented.

The following table summarizes the effect of operating lease costs in the Company's consolidated statement of operations and comprehensive loss (in thousands):

	Year Ended December 31,	
Lease cost	**2023**	**2022**
Operating lease cost	2,398	2,402
Variable lease cost	957	915
Total lease cost	$ 3,355	$ 3,317

The following table summarizes supplemental information for the Company's operating leases:

	Year Ended December 31,	
Other information	**2023**	**2022**
Weighted-average remaining lease term - operating leases (in years)	4.6	5.5
Weighted-average discount rate - operating leases	12.0%	12.0%

The minimum lease payments for the next five years and thereafter is expected to be as follows (in thousands):

Maturity of lease liabilities	December 31, 2023 Operating Leases
2024	$ 2,487
2025	2,331
2026	1,893
2027	1,950
2028	2,008
Thereafter	—
Total lease payments	$ 10,669
Less: effect of discounting	(2,455)
Present value of lease liabilities	$ 8,214

14. Commitments and Contingencies

Guarantees

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while each such officer or director is, or was, serving at the Company's request in such capacity. The term of the indemnification is the officer's or director's lifetime. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' liability insurance coverage that limits its exposure and enables the Company to recover a portion of any future amounts paid.

The Company leases office, laboratory and manufacturing space under noncancelable operating leases. The Company has standard indemnification arrangements under the leases that require it to indemnify the landlords against all costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from any breach, violation or nonperformance of any covenant or condition of the Company's leases.

In the ordinary course of business, the Company enters into indemnification agreements with certain suppliers and business partners where the Company has certain indemnification obligations limited to the costs, expenses, fines, suits, claims, demands, liabilities and actions directly resulting from the Company's gross negligence or willful misconduct, and in certain instances, breaches, violations or nonperformance of covenants or conditions under the agreements.

As of December 31, 2023 and 2022, the Company had not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Contingencies

In September 2021, the Company entered into a lease for office, research, laboratory and manufacturing space in Billerica, Massachusetts. The lease had a term of 126 months from the commencement date. The Company opened a money market account for $1.0 million, which represents collateral as a security deposit for this lease and is classified as restricted cash on December 31, 2022. Occupancy of the building had been delayed due to disagreement between the Company and the landlord as to the parties' obligations under the lease agreement. Included within accrued expenses and other current liabilities on the balance sheet on December 31, 2022 is a $1.0 million estimated liability pertaining to this lease. In January 2023, the Company was notified that the landlord terminated the lease because of the Company's alleged failure to perform its obligations under the Lease in a timely manner and the Company's alleged breach of the covenant of good faith and fair dealing and exercised its right to draw upon the $1.0 million security deposit. In addition, the landlord is seeking damages for unpaid rent, brokerage fees, transaction costs, attorney's fees and court costs. The Company filed a response to the landlord's complaint and a counterclaim alleging that the landlord breached its obligations under the contract and unlawfully drew on the security deposit, in addition to breaching its covenants of good faith and fair dealing, making fraudulent misrepresentations, and engaging in deceptive and unfair trade practices. The Company intends to pursue legal remedies available under applicable laws. The Company believes it will continue to meet its current manufacturing needs with its operations at its Lexington and Wilmington, Massachusetts facilities.

Leases

Refer to Note 13, Leases, for discussion of the commitments associated with the Company's leases.

License Agreement

In 2006, the Company entered into a license agreement with a third party, pursuant to which the third party granted the Company an exclusive, worldwide, sublicensable license under certain patent rights to make, use, import and commercialize products and processes for diagnostic, industrial and research and development purposes. The Company agreed to pay an annual license fee ranging from $5,000 to $25,000 for the royalty-bearing license to certain patents. The Company also issued a total of 16 shares of common stock pursuant to the agreement in 2006 and 2007, which were recorded at fair value at the date of issuance. The Company is required to pay royalties on net sales of products and processes that are covered by patent rights licensed under the agreement at a percentage ranging between 0.5% - 3.5%, subject to reductions and offsets in certain circumstances, as well as a royalty on net sales of products that the Company sublicenses at 10% of specified gross revenue. Royalties that became due under this agreement for the years ended December 31, 2023 and 2022 were $0.1 million and $0.1 million, respectively.

Letter Agreements

On March 30, 2023, the Company entered into agreements with Mr. Sprague, Mr. Giffin, and Mr. Gibbs that provide for the payment of retention bonuses, subject to the respective executive's continued employment through such payment dates, of $80,000 each, to be paid in two installments of $40,000. The first installment, of $40,000 each, was paid in July 2023, and the second installment, of $40,000 each, was paid in November 2023.

15. 401(k) Savings Plan

In March, 2008, the Company established a retirement savings plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers substantially all employees of the Company who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. Company contributions to the 401(k) Plan may be made at the discretion of the Board of Directors. Company contributions to the 401(k) Plan were $115,000 and $244,000 for the years ended December 31, 2023 and 2022, respectively.

16. U.S. Government Contract

In September 2019, BARDA awarded the Company a milestone-based product development contract, with an initial value of $6.0 million, and a potential value of up to $69.0 million, which was amended with Option 3 to $62.0 million due to a change in scope, if BARDA exercises all contract options (the "U.S. Government Contract"). BARDA operates within the Office of the Assistant Secretary for Preparedness and Response ("ASPR") at the U.S. Department of Health and Human Services' ("HHS"). If BARDA exercises and the Company completes all options, the Company's management believes it will enable a significant expansion of the Company's current portfolio of diagnostics for sepsis-causing pathogen and antibiotic resistance genes. In September 2020, BARDA exercised the first contract option valued at $10.5 million. In September 2021, BARDA exercised an option valued at approximately $6.4 million.

In April 2021, BARDA agreed to accelerate product development by modifying the contract to advance future deliverables into the currently funded Option 1 of the BARDA contract for the T2Biothreat Panel and the T2Resistance Panel. The modification did not change the overall total potential value of the BARDA contract.

On March 31, 2022, the Company announced that BARDA had exercised Option 2B under the existing multiple-year cost-share contract between BARDA and the Company and provided an additional $4.4 million in funding to the Company.

The option exercise occurred simultaneously on March 31, 2022 with a modification to the BARDA contract to make immaterial changes to, among other things, the statement of work.

In September 2022, BARDA exercised Option 3 and agreed to provide an additional $3.7 million in funding for the multiple-year cost-share contract. The additional funding under Option 3 was used to advance the U.S. clinical trials for the T2Biothreat Panel and T2Resistance Panel, and to file submissions to the FDA for U.S. regulatory clearance.

The Company recorded contribution revenue of $0.4 million and $11.0 million for the years ended December 31, 2023 and 2022, respectively, under the BARDA contract.

The Company had no outstanding accounts receivable on December 31, 2023 and unbilled accounts receivable of $0.7 million on December 31, 2022, respectively, under the BARDA contract.

The BARDA contract expired in September 2023.

17. Subsequent Events

On February 15, 2024, CRG converted 82,422 shares of its Series B Preferred Stock into 824,220 shares of common stock.

On February 15, 2024, the Company entered into a Securities Purchase Agreement with CRG and affiliated entities pursuant to which the Company will issue (i) shares of the Company's common stock and (ii) to the extent that the issuance of the shares common stock results in CRG beneficially owning greater than 49.99% of the Company's outstanding shares of common stock (or in the case of one of the affiliated entities, greater than 9.99% of the Company's outstanding shares of common stock, determined without regard to any convertible securities held by CRG or affiliated entities), shares of newly designated convertible preferred stock, par value $0.001 per share, at a price per share of the lower of (a) the closing price for the Company's common stock on Nasdaq on the date immediately prior to the closing of the transaction and (b) the average closing price over the five business days prior to the closing of the transaction, in exchange for CRG surrendering for cancellation $15.0 million of outstanding borrowing under the Term Loan Agreement. The closing of the transaction is conditioned on the approval of the Company's stockholders at a stockholder meeting to be held on April 11, 2024, and is expected to occur within 10 business days following the approval of the Company's stockholders.

On March 11, 2024, the Company received notice from the Nasdaq Hearings Panel that it had granted the Company's request for continued listing on the Nasdaq Stock Market, subject to the Company demonstrating compliance with Nasdaq's MVLS Rule on or before May 20, 2024.

Equity Distribution Agreement

Subsequent to December 31, 2023, the Company sold 628,470 shares of common stock for net proceeds of $2.2 million under the Equity Distribution Agreement.

Letter Agreements

On March 31, 2024, the Company entered into letter agreements with Mr. Sprague and Mr. Gibbs that provide for the payment of a retention bonus in the total aggregate amount of $80,000, to be paid in two installments of $40,000. The first installment, in the amount of $40,000, shall be paid within five business days following June 30, 2024, and the second installment, in the amount of $40,000, shall be paid within five business days following November 15, 2024. Each such installment payment is subject to the applicable executive's continued employment through such payment date.

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

Management of the Company, with the participation of the Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of December 31, 2023. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported on a timely basis and that such information is accumulated and communicated to management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate, to allow timely decisions regarding disclosure.

Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, the Company's disclosure controls and procedures were not effective due to material weaknesses in our internal control over financial reporting as described below.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel 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 and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles and that receipts and expenditures of the issuer are being made only in accordance with authorizations of management and directors; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the Company's consolidated financial statements.

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. 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control—Integrated Framework (2013). Based on our assessment, the Company identified material weaknesses in our internal control over financial reporting that resulted in certain material misstatements in preliminary financial statement accounts that were corrected prior to the issuance of interim and annual consolidated financial statements.

We identified a material weakness in our internal control over the timeliness of assumptions and accounting conclusions reached for unusual transactions. This includes (1) the valuation of the common stock warrants sold in the Company's February 2023 public offering, in which we determined that the assumptions and valuation methodologies used to initially value and classify the warrants were inconsistent with recent generally accepted accounting principles and the time required to refine the assumptions and methodologies and reach the appropriate conclusions prevented the Company from filing its 2023 first quarter Form 10-Q timely, (2) the classification of the Company's term loan and related liabilities as of June 30, 2023, where we did not initially assess the probability of the Company not complying with the covenant for the subsequent 12-month period, and therefore would be classified as current liabilities as of June 30, 2023, following a modification and waiver that temporarily reduced the minimum cash covenant, and (3) the EPS accounting treatment of the Series B Convertible Preferred Stock for the third quarter of 2023, where we initially concluded to disclose the EPS related to the Series B Preferred Stock separately but ultimately determined that such EPS should be grouped with common stock equivalents due to the nature and characteristics of the Series B Preferred Stock. The Company will establish enhanced evaluation considerations of unusual transactions including the timely use of third-party experts to prevent future occurrences.

We identified a material weakness in our internal control over the impact of changes in our sales demand forecast. In October 2023, the Company reassessed and reduced its 2024 sales forecast but did not subsequently reassess the effect on inventory valuation allowances as of September 30, 2023. After consideration of the effect of changes in the sales demand forecast, inventory valuation allowances were materially increased. In addition, the reassessment of the 2024 sales forecast caused the Company to reconsider its conclusions regarding the sufficiency of future cash flows to support the carrying values of property, plant, and equipment. After considering the cash flows attributed to reagent test sales as disclosed in the revenue attribution footnote of our financial statements, the Company concluded that our fixed asset groups' carrying values were materially impaired. Previous assessments only considered the lowest levels of cash flows from a customer contract and invoice perspective. The Company will establish enhanced evaluation procedures to consider the effect of changes in its sales demand forecast to prevent future occurrences.

We identified a material weakness in our internal control over our year-end reagent inventory count process. In the fourth quarter of 2023, due to staff constraints and turnover, the Company employed consultants to assist with the year-end reagent inventory count. The consultant noted count discrepancies between final inventories on hand and the inventory count sheets and made corrections to the count sheets. However, the corrections were made after the Company’s auditors had secured copies of the count sheets and these discrepancies invalidated the integrity of the count sheets and prompted a recount. The annual physical inventory is considered a key internal control and therefore we identified the need for a recount as a material weakness. The Company will implement enhanced count procedures to prevent future occurrences.

We identified a material weakness in our internal control over the review of the tax provision and 382 study prepared by third-party experts for the year ended December 31, 2023. Management did not initially identify an error in the 382 study that had a material impact on the calculation and disclosure of our net deferred tax assets and federal and state net operating losses for the year ended December 31, 2023, and therefore identified the matter as a material weakness in internal control. The Company will establish enhanced review procedures to prevent future occurrences.

The above material weaknesses created a possibility that a material misstatement to our consolidated financial statements would not be prevented or detected on a timely basis. Based on our assessment, the Company concluded that the above material weaknesses were unremediated as of December 31, 2023. As such, the Company concluded that our internal control over financial reporting was not effective as of December 31, 2023.

Changes in Internal Control over Financial Reporting

Except as noted above, there have been no changes to the Company’s internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f)) that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

Item 9B. OTHER INFORMATION

On March 31, 2024, the Company entered into letter agreements with Mr. Sprague and Mr. Gibbs that provide for the payment of a retention bonus in the total aggregate amount of $80,000, to be paid in two installments of $40,000. The first installment, in the amount of $40,000, shall be paid within five business days following June 30, 2024, and the second installment, in the amount of $40,000, shall be paid within five business days following November 15, 2024. Each such installment payment is subject to the applicable executive's continued employment through such payment date.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III.

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Board of Directors

Our Board of Directors currently consists of seven directors. Set forth below is certain information regarding our current directors as of the date hereof.

Name	Positions and Offices Held with T2 Biosystems	Director Since	Class and Year in Which Term Will Expire	Age
John Sperzel	Chief Executive Officer, President and Chairman of the Board	2020	Class II - 2025	60
Ninfa Saunders	Director	2020	Class II - 2025	72
John Cumming	Director	2014	Class III - 2026	78
David Elsbree	Director	2014	Class III - 2026	76
Seymour Liebman	Director	2016	Class I - 2024	74
Laura Adams	Director	2021	Class I - 2024	67
Robin Toft	Director	2020	Class I - 2024	63

Set forth below are the biographies of each director, as well as a discussion of the particular experience, qualifications, attributes, and skills that led our Board of Directors to conclude that each person nominated to serve or currently serving on our Board of Directors should serve as a director. In addition to the information presented below, we believe that each director meets the minimum qualifications established by the nominating and corporate governance committee of our Board of Directors.

John Sperzel has served as our President and Chief Executive Officer and a member of our Board of Directors since January 2020 and has served as Chairman of our Board of Directors since July 2021. From March 2014 to January 2020, Mr. Sperzel was the Chief Executive Officer, President and a member of the Board of Directors of Chembio Diagnostics, Inc., a point-of-care diagnostics company focused on infectious diseases. From September 2011 to December 2013, Mr. Sperzel was the Chief Executive Officer and President of International Technidyne Corporation, a developer of point-of-care cardiovascular diagnostic testing solutions. Mr. Sperzel received his Bachelor of Science degree in Business Administration/Management from Plymouth State College. Mr. Sperzel's extensive management experience as a senior executive and his diagnostic company experience contributed to our Board of Directors' conclusion that he should serve as a director of our company.

Laura Adams has served as a member of our Board of Directors since October 2021. Since 1998, Ms. Adams has been Principal at Laura Adams Consulting, a strategic advisory firm serving the healthcare industry. Ms. Adams has served as Special Adviser to the National Academy of Medicine, a non-governmental organization that provides national and international advice on issues relating to digital health, medicine, health policy, and biomedical science, since November 2019. From April 2019 to April 2021 she served as a Catalyst for X4 Health, a company working with health systems to partner with patients and families in new designs of care. From 2001 to 2019 she was the Founder and Chief Executive Officer of The Rhode Island Quality Institute, a center for collaborative innovation that advances health and care information. Ms. Adams received a Bachelor of Science from the University of Northern Colorado and a Masters of Science from the University of Northern Colorado Health Center. Ms. Adams' extensive knowledge of and experience with digital health and healthcare quality initiatives contributed to our Board of Directors' conclusion that she should serve as a director of our company.

Robin Toft has served as a member of our Board of Directors since June 2020. Ms. Toft has been employed by ZRG Partners (formerly Toft Group), an executive search firm that focuses on biotechnology, pharmaceutical, diagnostics, medical device, life science tools and healthcare high tech companies since July 2010 and currently serves as Advisor Global Life Sciences & Board Diversity. Prior to ZRG Partners, Ms. Toft was employed by Sanford Rose Associates – Toft Group from 2006 to 2010. Prior to that, Ms. Toft was employed by Roche Diagnostics, a diagnostics company that manufactures equipment and reagents for research and medical diagnostic applications from January 2003 to November 2005, as Senior Vice President of Commercial Operations. Ms. Toft holds a B.S. in Medical Technology (Clinical Laboratory Science) from Michigan State University. Ms. Toft's leadership and industry experience contributed to our Board of Directors' conclusion that she should serve as a director of our company.

Seymour Liebman has served as a member of our Board of Directors since September 2016. Mr. Liebman has been employed by Canon USA, Inc., a leading provider of consumer, business-to-business, and industrial imaging solutions to the United States and to the Latin American and the Caribbean markets, since 1974 and currently serves as the Executive Vice President, Chief Administrative Officer and General Counsel and Senior Managing Executive Officer of Canon Inc., Japan. Mr. Liebman received his J.D. from Touro Law School, his M.S. in mathematics from Rutgers University, his M.S. in accounting from Long Island University and his B.A. in mathematics from Hofstra University. Mr. Liebman's management and board experience contributed to our Board of Directors' conclusion that he should serve as a director of our company.

Ninfa Saunders has served as a member of our Board of Directors since June 2020. Ms. Saunders served as President and Chief Executive Officer of Navicent Health, the second largest hospital in Georgia from October 2012 to October 2020. Prior to joining Navicent Health, Ms. Saunders served as President and COO of Virtua Health, the largest health system in southern New Jersey, from 2003 to 2012. Dr. Saunders has a Doctorate in Healthcare Administration from the Medical University of South Carolina, a Master's of Business Administration from Emory University, a Master of Science in Nursing from Rutgers University and a Bachelor of Science in Nursing from Concordia College. Ms. Saunders' leadership and industry experience contributed to our Board of Directors' conclusion that she should serve as a director of our company.

John W. Cumming has served as a member of our Board of Directors since July 2014 and Lead Independent Director since June 2020. He also serves as a member of the Board of Directors of TransMed7, LLC. Mr. Cumming has served as Chief Executive Officer and Managing Director of Cumming & Associates LLC, a strategic advisory firm serving the healthcare industry since January 2014. From August 2000 until December 2013, Mr. Cumming served in a number of leadership roles at Hologic Inc., a diagnostics company, including as Chief Executive Officer from 2001 through 2009 and again from July 2013 through December 2013, as President from 2001 until 2003, as Chairman of the Board from 2002 until 2007 and again from 2008 through 2011, and as Global Strategic Advisor from 2011 through July 2013. Mr. Cumming attended the University of South Carolina. Mr. Cumming's extensive knowledge of and experience with diagnostic product companies and expertise as a strategic advisor focused on the healthcare industry contributed to our Board of Directors' conclusion that he should serve as a director of our company.

David Elsbree has served as a member of our Board of Directors since July 2014. From 1970 until 2004, Mr. Elsbree was employed by Deloitte & Touche, most recently as a senior partner. Mr. Elsbree served in a number of leadership roles in the firm's high technology practice, including partner-in-charge of the New England High Technology Practice. Mr. Elsbree served on the Board of Directors of Art Technology Group, Inc. from June 2004 until January 2011 and on the board of directors of Acme Packet, Inc. from November 2006 until March 2013. Mr. Elsbree received his B.A. from Northeastern University. Mr. Elsbree's extensive knowledge of and experience with technology companies and financial expertise contributed to our Board of Directors' conclusion that he should serve as a director of our company.

Information about our Executive Officers and Significant Employees

The following table identifies our executive officers and significant employees and sets forth their current position(s) at T2 Biosystems and their ages as of the date hereof.

Name	Age	Position
John Sperzel	60	President, Chief Executive Officer and Chairman of the Board of Directors
John Sprague	65	Chief Financial Officer
Michael Gibbs, Esq.	53	Senior Vice President and General Counsel
Brett Giffin	65	Chief Commercial Officer
Roger Smith, Ph.D.	59	Senior Vice President of Science Research and Development

Information concerning John Sperzel, our Chief Executive Officer, may be found above under "*Board of Directors.*"

John Sprague has served as our Chief Financial Officer since January 2018. Prior to joining our company, Mr. Sprague was Chief Financial Officer at Caliber Imaging & Diagnostics, Inc., a medical technologies company that designs, develops and markets innovative digital imaging solutions that show tissue at the cellular level using confocal microscopes designed specifically for imaging skin and other tissues for pathology and life sciences, from February 2017 to January 2018. From 2011 to 2017, Mr. Sprague held various positions at GE Healthcare, with his last assignment serving as Finance Manager of GE's North American Core Imaging business. Mr. Sprague is a certified public accountant and received his B.S. in accounting from Boston College.

Michael Gibbs, Esq. has served as our Senior Vice President and General Counsel since January 2016. Mr. Gibbs joined our company in December 2014 as Senior Corporate Counsel. From 2011 until he joined our company, Mr. Gibbs was General Counsel for Keystone Dental, Inc., a medical device company focused on dental implants and biomaterials. From 2003 to 2011, Mr. Gibbs was a corporate attorney with the law firm Bingham McCutchen LLP (now Morgan Lewis & Bockius). Prior to joining Bingham McCutchen LLP, he was an officer in the United States Marine Corps, departing with the rank of Major. Mr. Gibbs received his J.D. from Boston College Law School and his B.S. in Political Science from Syracuse University.

Brett Giffin has served as our Chief Commercial Officer since November 2021. Prior to joining the company, Mr. Giffin served as a Managing Director for Mancini Burfield Edgerton, a retained executive search and management consulting firm focused on life sciences from April 2019 until November 2021. From September 2017 to April 2019, Mr. Giffin was the Chief Executive Officer of Fibronostics, a healthcare technology company developing and commercializing algorithm-based diagnostic tests. From June 2015 to September 2017, Mr. Giffin was the Chief Executive Officer and President of 3SI Systems, LLC, a healthcare technology company offering a novel software and hardware IT based speech recognition workflow system. Mr. Giffin received a Bachelor of Arts degree in Political Science from Christopher Newport University and a Masters degree in Business Administration from the University of Phoenix.

Roger Smith, Ph.D. has served as the Senior Vice President of Science Research and Development since March 2022. Mr. Smith joined our company in January 2014 as Senior Manager of Assay Development. From 2011 until joining our company in 2014 he was Head of Microbiology at Semprus Biosciences, a company focused on the development of novel microbial resistant surfaces for medical devices. From 2007 to 2012 he was Head of Microbial Genetics at the Broad Institute focused on the production of microbial libraries that were used for novel drug discovery. Dr. Smith received his Ph.D. in microbiology from the University of Rochester and completed post-doctoral studies at Harvard Medical School. He has authored numerous scientific publications in the fields of microbiology and medical devices and holds several patents.

Family Relationships

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

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our officers and directors and persons who beneficially own more than 10% of any class of our equity securities registered pursuant to Section 12 of the Exchange Act (collectively, "Reporting Persons") to file reports of beneficial ownership and changes in beneficial ownership with the SEC. Based on a review of copies of Forms 3, 4 or 5 filed electronically with the SEC during the fiscal year ended December 31, 2023 and upon any written representations of the Reporting Persons received by us, the Company believes that during and with respect to the fiscal year ended December 31, 2023, there has been compliance with all Section 16(a) filing requirements applicable to such Reporting Persons, except that one Form 4 for Mr. Sperzel, Mr. Gibbs and Mr. Sprague, and two Form 4's for Mr. Giffin were inadvertently filed late.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics for our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, which is available on our website at www.t2biosystems.com in the Investor Relations section under "Corporate Governance." If we make any amendments to the code of business conduct and ethics or grant any waiver from a provision of the code of business conduct and ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website to the extent required by law or the listing standards of The Nasdaq Stock Market LLC ("Nasdaq"). The information on, or that can be accessed from, our website is not incorporated by reference into this Annual Report.

Procedures for the Recommendation of Director Nominees by Stockholders

There have been no changes to the procedures by which stockholders can recommend nominees to the Board of Directors since such procedures were previously disclosed in the Company's Proxy Statement for its 2023 Annual Meeting of Stockholders.

Audit Committee and Audit Committee Financial Expert

David Elsbree, Ninfa Saunders and Seymour Liebman, who joined the audit committee on January 2, 2024, currently serve on the audit committee, which is chaired by David Elsbree. Thierry Bernard served on the audit committee until January 2, 2024. Our Board of Directors has determined that each member of the audit committee is currently, and was during 2023, "independent" for audit committee purposes as that term is defined in the rules of the SEC and the applicable Nasdaq Rules. Our Board of Directors has designated David Elsbree as an "audit committee financial expert," as defined under the applicable rules of the SEC. The audit committee's responsibilities include:

- appointing, overseeing the independence of, and setting the compensation of our independent auditor;
- overseeing the work of the independent auditor, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and our independent auditor our annual and quarterly financial statements and related disclosures;
- coordinating the Board's oversight of our internal control over financial reporting, disclosure controls and procedures;

- discussing our risk management and risk assessment policies;
- establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls or auditing matters;
- reviewing the company's policies and procedures for reviewing and approving or ratifying any related person transactions;
- meeting independently with our internal auditing staff, if any, independent auditors and management; and
- preparing the audit committee report.

Item 11. EXECUTIVE COMPENSATION

This section discusses the material components of the executive compensation program offered to our named executive officers identified below. For 2023, our named executive officers and their positions as of December 31, 2023 were:

- John Sperzel, Chairman of the Board of Directors, President and Chief Executive Officer;
- John Sprague, Chief Financial Officer; and
- Michael Gibbs, Senior Vice President and General Counsel.

Overview

Our compensation programs are designed to:

- attract and retain individuals with superior ability and managerial experience;
- align executive officers' incentives with our corporate strategies, business objectives and the long-term interests of our stockholders; and
- increase the incentive to achieve key strategic performance measures by linking incentive award opportunities to the achievement of performance objectives and by providing a portion of total compensation for executive officers in the form of ownership in the company.

Our compensation committee is primarily responsible for establishing and approving, or recommending for approval by the Board of Directors, the compensation for all of our executive officers. The compensation committee oversees our compensation and benefit plans and policies, administers our equity incentive plans and reviews and approves, or recommends for approval by the Board of Directors, all compensation decisions relating to all of our executive officers, including our President and Chief Executive Officer. The compensation committee typically considers, and during 2023 did consider, recommendations from our President and Chief Executive Officer regarding the compensation of our executive officers other than for himself. Our compensation committee has the authority under its charter to engage the services of a consulting firm or other outside advisor to assist it in designing our compensation programs and in making compensation decisions and has engaged Arnosti Consulting to provide these services. The compensation committee reviewed compensation assessments provided by Arnosti Consulting comparing our executive compensation program to that of a group of peer companies within our industry and met with Arnosti Consulting to discuss compensation of our executive officers, including the President and Chief Executive Officer, and to receive input and advice. The compensation committee has considered the adviser independence factors required under SEC rules as they relate to Arnosti Consulting and does not believe Arnosti Consulting's work in 2023 raised a conflict of interest.

Executive Compensation Components

Our executive compensation program consists of base salary, cash incentive bonuses, long-term incentive compensation in the form of stock options and restricted stock units, and a broad-based benefits program. We have not adopted any formal guidelines for allocating total compensation between long-term and short-term compensation, cash compensation and non-cash compensation, or among different forms of non-cash compensation. The compensation committee considers a number of factors in setting compensation for its executive officers, including company performance, as well as the executive's performance, experience, responsibilities and the compensation of executive officers in similar positions at comparable companies.

Base Salary

Our named executive officers receive base salaries to compensate them for the satisfactory performance of duties to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Base salaries for our named executive officers have generally been set at levels deemed necessary to attract and retain individuals with superior talent. For 2023, Mr. Sperzel's annual base salary was $575,000 (unchanged from 2022). Mr. Sprague's

annual base salary was $385,000 (increased from $370,000) and Mr. Gibbs' base salary was $390,000 (increased from $375,000) in order to align to more market-competitive levels. Base salary increases were effective March 1, 2023.

Cash Incentive Compensation

Each of our named executive officers is eligible to participate in an annual cash incentive compensation program which provides participants with an opportunity to earn variable cash incentive compensation based on individual and company performance. For 2023, Mr. Sperzel's target bonus was 100% of his base salary, Mr. Sprague's target bonus was 60% of his base salary, and Mr. Gibbs' target bonus was 60% of his base salary.

Objectives for the 2023 annual cash incentive compensation program, established in January 2023 by our compensation committee, included the attainment of clinical, business development and financing milestones and certain publication, commercialization and operational goals. The determination of 2023 bonus amounts was based on a non-formulaic assessment of these goals, as well as our compensation committee's subjective evaluation of our company's overall performance and each named executive officer's individual performance and contribution to our company. The compensation committee did not assign specific weights to any elements of our bonus program in determining 2023 bonuses.

After considering these factors, the Board of Directors, based upon the recommendation of our compensation committee, approved bonuses for our named executive officers for 2023 as set forth in the "Non-Equity Incentive Plan Compensation" column of our 2023 Summary Compensation Table.

Equity-Based Compensation

We generally grant stock options and restricted stock unit awards to our employees, including our named executive officers, as the long-term incentive component of our compensation program. We typically grant stock options or restricted stock units to employees when they commence employment with us and may thereafter grant additional options and restricted stock unit awards in the discretion of our Board of Directors. Our stock options granted upon commencement of employment typically vest as to 25% of the shares subject to the option on the first anniversary of the date of grant and in substantially equal monthly installments over the ensuing 36 months, subject to the holder's continued employment with us. Additional stock options granted after the commencement of employment typically vest in substantially equal monthly installments over 48 months. Our restricted stock unit awards typically vest in substantially equal annual installments over 24 to 36 months, subject to the holder's continued employment with us. Each restricted stock unit entitles the holder to receive one share of our common stock or its cash value upon vesting or a later settlement date. From time to time, our Board of Directors may also construct alternate vesting schedules as it determines are appropriate to motivate particular employees.

Due to the limited number of shares available for grant under our equity plan, and in order to preserve shares for equity grants to other employees, there were no stock options or restricted stock unit awards granted to our named executive officers in 2023.

Retirement, Health, Welfare and Additional Benefits

Our named executive officers are eligible to participate in our employee benefit plans and programs, including medical and dental benefits, flexible spending accounts and short-and long-term disability and life insurance, to the same extent as our other full-time employees, subject to the terms and eligibility requirements of those plans. Our named executive officers are also eligible to participate in a tax-qualified 401(k) defined contribution plan to the same extent as all of our other full-time employees. We make company contributions for participants in the 401(k) plan equal to 50% of the participant's contribution, up to 2% of the participant's eligible compensation or $3,000 per year, whichever is less.

2023 Summary Compensation Table

Name and Principal Position	Year	Salary ($)(1)	Bonus ($)(2)	Stock Awards ($)(3)	Non-Equity Incentive Plan Compensation ($)(4)	All Other Compensation ($)(5)	Total ($)
John Sperzel,	2023	575,000	—	—	287,500	3,000	865,500
President, Chief Executive Officer and Chairman of the Board of Directors	2022	575,000	—	1,119,840	287,500	3,000	1,985,340
John Sprague,	2023	382,500	80,000	—	115,500	3,000	581,000
Chief Financial Officer	2022	368,333	—	279,960	111,000	3,000	762,293
Michael Gibbs,	2023	387,500	80,000	—	152,100	3,000	622,600
SVP and General Counsel	2022	371,833	—	279,960	112,500	3,000	767,293

(1) Amounts in this column represent base salaries earned for 2023 and 2022 and reflect mid-year changes.
(2) Represents $80,000 each of retention bonuses to Mr. Sprague and Mr. Gibbs. On March 30, 2023, the Company entered into agreements with Mr. Sprague and Mr. Gibbs that provide for the payment of retention bonuses, subject to the respective executive's continued employment through such payment dates, of $80,000 each, to be paid in two installments of $40,000. The first installment, of $40,000 each, was paid in July 2023, and the second installment, of $40,000 each, was paid in November 2023.
(3) Represents the aggregate grant date fair value of the restricted stock unit awards granted during the given year computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. For a description of the assumptions used in valuing these awards, see Note 10 to the audited consolidated financial statements included in this Annual Report on Form 10-K.
(4) Represents awards earned under our annual cash incentive compensation program. For additional information regarding these amounts, see the section titled "Executive Compensation Components—Cash Incentive Compensation" above.
(5) Represents Company matching contributions under our 401(k) plan of $3,000 each to Mr. Sperzel, Mr. Sprague, and Mr. Gibbs.

Outstanding Equity Awards at Fiscal Year-End Table—2023

	Option Awards					Stock Awards	
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)(1)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)(2)	Market Value of Shares of Units of Stock That Have Not Vested ($)(3)
John Sperzel							
	1/8/2020	587	13	5,750.00	1/8/2023		
	2/24/2021					67	420.43
	2/20/2022					320	2,008.00
John Sprague							
	1/30/2018	45	—	25,400.00	3/1/2028		
	2/21/2019	12	—	18,600.00	2/21/2029		
	9/10/2019	10	—	7,150.00	9/10/2029		
	2/24/2021					29	181.98
	2/20/2022					80	502.00
Michael Gibbs							
	12/1/2014	8	—	85,050.00	12/1/2024		
	1/20/2016	11	—	45,100.00	1/20/2026		
	2/9/2017	6	—	28,350.00	2/9/2027		
	3/1/2018	17	—	25,400.00	3/1/2028		
	2/21/2019	11	—	18,600.00	2/21/2029		
	9/10/2019	9	—	7,150.00	9/10/2029		
	3/24/2020	18	1	1,950.00	3/24/2030		
	2/24/2021					29	181.98
	2/20/2022					80	502.00

(1) All unvested options for Mr. Sperzel vest in substantially equal monthly installments over the 48 month vesting period from the vesting commencement date, subject to his continued employment with us through the applicable vesting date. The unvested options for Mr. Gibbs with a vesting commencement date of March 24, 2020 vest in substantially equal monthly installments over the 48 month period from the vesting commencement date; subject to Mr. Gibbs's continued employment with us through the applicable vesting date. The options are subject to potential accelerated vesting as described in the sections titled "Employment Letter Agreements with Our Named Executive Officers" and "Potential Payments upon a Change in Control" below.
(2) The unvested restricted stock units for Mr. Sperzel, Mr. Sprague and Mr. Gibbs with a vesting commencement date of February 20, 2022 vest in three substantially equal annual installments beginning on February 20, 2023, subject to the holder's continued employment with us through the applicable vesting date and potential accelerated vesting as described in the sections titled "Employment Letter Agreements with Our Named Executive Officers" and "Potential Payments upon a Change in Control" below. All unvested restricted stock units for Mr. Sperzel, Mr. Sprague and Mr. Gibbs with a vesting commencement date of February 24, 2021 vest in three substantially equal annual installments beginning on February 24, 2022, each subject to the holder's continued employment with us through the applicable vesting date and potential accelerated vesting as described in the sections titled "Employment Letter Agreements with Our Named Executive Officers" and "Potential Payments upon a Change in Control" below.
(3) Based on the closing price of our common stock on December 31, 2023 of $6.28.

Employment Arrangements with Our Named Executive Officers

We have entered into employment and/or severance letter agreements with each of the named executive officers. Certain key terms of these agreements are described below. We believe that these terms serve our retention objectives by permitting our named executive officers to maintain continued focus and dedication to their responsibilities in order to maximize stockholder value, including in the event of a transaction that could result in a change in control of the Company.

John Sperzel. We have entered into an employment agreement with Mr. Sperzel, which provides that if Mr. Sperzel's employment is terminated by us without cause or by Mr. Sperzel for good reason, in each case, other than on or within 12 months following the date of a change of control, subject to his signing and not revoking a general release of claims in our favor, he will be entitled to receive 12 months of base salary continuation, plus a pro-rata portion of his target annual cash bonus for the calendar year in which the termination occurs, payable at such time as such year's annual bonus would have been paid had his employment not terminated, and reimbursement for a portion (based on active employee cost sharing rates) of COBRA healthcare premiums for up to 12 months following termination. In the event that Mr. Sperzel's employment is terminated by us without cause or by Mr. Sperzel for good reason, in each, case on or within 12 months following the date of a change in control, subject to signing and not revoking a release of claims in our favor, he will be entitled to receive 18 months of base salary continuation, plus a pro-rata portion of his target annual cash bonus for the calendar year in which the termination occurs, payable at such time as such year's annual bonus would have been paid had his employment not terminated, reimbursement for a portion (based on active employee cost sharing rates) of COBRA healthcare premiums for up to 18 months following termination and full accelerated vesting of all equity or equity-based awards held by Mr. Sperzel.

Mr. Sperzel has also entered into a non-compete, non-disclosure and invention assignment agreement with us pursuant to which he has agreed to refrain from disclosing our confidential information indefinitely and from competing with us or soliciting our employees or consultants for 12 months following termination of his employment.

John Sprague. We have entered into a severance letter agreement with Mr. Sprague, which provides that if Mr. Sprague's employment is terminated by us without cause within the three months preceding or the 12 months following a change in control, or if Mr. Sprague resigns his employment for good reason within the 12 months following a change in control, and he timely executes a release of claims in our favor, he will be entitled to receive 12 months of base salary continuation, accelerated vesting of all outstanding unvested equity awards and reimbursement for a portion (based on active employee cost sharing rates) of healthcare premiums for up to 12 months. In 2022, we amended and restated the severance letter agreement with Mr. Sprague, which provides that if Mr. Sprague's employment is terminated by us without cause within the three months preceding or the 12 months following a change in control, or if Mr. Sprague resigns his employment for good reason within the 12 months following a change in control, and he timely executes a release of claims in our favor, he will be entitled to receive 12 months of base salary continuation, accelerated vesting of all outstanding unvested equity awards, a pro-rated bonus payment and reimbursement for a portion (based on active employee cost sharing rates) of healthcare premiums for up to 12 months. In addition, if his employment is terminated by us without cause not related to a change in control, or if Mr. Sprague resigns his employment for good reason not related to a change in control, and he timely executes a release of claims in our favor, he will be entitled to receive 9 months of base salary continuation and reimbursement for a portion (based on active employee cost sharing rates) of healthcare premiums for up to 9 months.

Mr. Sprague has also entered into a non-compete, non-disclosure and invention assignment agreement with us pursuant to which he has agreed to refrain from disclosing our confidential information indefinitely and from competing with us or soliciting our employees or consultants for 12 months following termination of his employment.

Michael Gibbs. We have entered into a change of control severance letter agreement with Mr. Gibbs, which provides that if Mr. Gibbs' employment is terminated by us without cause within the three months preceding or the 12 months following a change in control, or if Mr. Gibbs resigns his employment for good reason within the 12 months following a change in control, and he timely executes a release of claims in our favor, he will be entitled to receive 12 months of base salary continuation, accelerated vesting of all outstanding unvested equity awards, a pro-rated bonus payment and reimbursement for a portion (based on active employee cost sharing rates) of healthcare premiums for up to 12 months. In addition, if his employment is terminated by us without cause not related to a change in control, or if Mr. Gibbs resigns his employment for good reason not related to a change in control, and he timely executes and does not revoke a release of claims in our favor, he will be entitled to receive 9 months of base salary continuation and reimbursement for a portion (based on active employee cost sharing rates) of healthcare premiums for up to 9 months.

Mr. Gibbs has also entered into a non-compete, non-disclosure and invention assignment agreement with us pursuant to which he has agreed to refrain from disclosing our confidential information indefinitely and from competing with us or soliciting our employees or consultants for 12 months following termination of his employment.

Potential Payments Upon a Change in Control

As described above, under the terms of their individual agreements with the Company, Mr. Sperzel, Mr. Sprague and Mr. Gibbs may become entitled to payments or benefits in connection with certain terminations of employment that occur at specified times around a change in control.

In addition, the agreements governing Mr. Sperzel's, Mr. Sprague's and Mr. Gibbs' unvested stock options and restricted stock units provide for full accelerated vesting if their employment is terminated by us without cause within the three months preceding or the 12 months following a change of control or if they resign for good reason within 12 months following a change in control.

DIRECTOR COMPENSATION

The following table presents the total compensation for each person who served as a non-employee member of our Board of Directors during 2023. Mr. Sperzel did not receive compensation for his service as a director in 2023. Mr. Sperzel's compensation for his services as an employee is discussed above.

Director Compensation Table—2023

	Fees Earned or Paid in Cash ($)	Total ($)
John W. Cumming	96,000	96,000
David B. Elsbree	60,000	60,000
Seymour Liebman	40,000	40,000
Ninfa M. Saunders	50,000	50,000
Robin Toft	60,000	60,000
Laura Adams	40,000	40,000
Thierry Bernard	50,000	50,000

The table below shows the aggregated numbers of outstanding option awards (exercisable and unexercisable) and unvested stock awards held as of December 31, 2023 by each non-employee director.

	Option Awards Outstanding at 2023 Fiscal Year End	Unvested Stock Awards Outstanding at 2023 Fiscal Year End
John W. Cumming	23	—
David B. Elsbree	23	—
Seymour Liebman	17	—
Ninfa M. Saunders	—	—
Robin Toft	—	—
Laura Adams	—	7
Thierry Bernard	—	—

We maintain a non-employee director compensation program pursuant to which all non-employee directors were paid cash compensation as set forth below for 2023:

	Annual Retainer ($)
Board of Directors:	
All non-employee members	40,000
Additional retainer for Lead Independent Director	40,000
Audit Committee:	
Chairperson	20,000
Membership	10,000
Compensation Committee:	
Chairperson	15,000
Membership	6,000
Nominating and Corporate Governance Committee:	
Chairperson	10,000
Membership	5,000

Annual retainers are earned on a quarterly basis and paid in arrears following the end of each calendar quarter. Retainers are prorated for partial quarters of service. Each director also has the opportunity to elect to be paid the director's $40,000 annual retainer for board service in the form of restricted stock units that vest in a single installment on January 1 of the following year.

In addition to the annual retainer, the non-employee director compensation program typically provides for an annual equity grant of restricted stock units to continuing non-employee directors who have been serving for at least six months. Under the program, on the date of the annual meeting of stockholders, continuing non-employee directors will be granted an award of restricted stock units equal to (A) 2,600 in the case of the Chairman and Lead Independent Director, and (B) 2,300 for all other Non-Employee Directors (which number shall be subject to adjustment in accordance with the applicable equity incentive plan of the Company in the event of any stock splits, dividends, recapitalizations and the like). The restricted stock units subject to the annual grant will vest in a single installment on the earlier of (i) the first anniversary of the grant date and (ii) the date of the next annual meeting of stockholders, subject to the director's continued service on the Board of Directors. The non-employee director compensation program also provides for an initial non-employee director grant of restricted stock units covering a number of shares equal to one and a half times the number of restricted stock units subject to the last (or concurrent) annual grant for continuing directors. The grant is made on the date he or she first became a non-employee director. The initial grant vests in substantially equal installments on each of the first three anniversaries of the date of grant, subject to the director's continued service on the Board of Directors. Due to the limited number of shares available for grant under our equity plan, and in order to preserve shares for equity grants to employees, the members of the Board of Directors waived the annual equity grant in 2023.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

EQUITY COMPENSATION PLAN INFORMATION

The following table provides information on our equity compensation plans as of December 31, 2023.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, and Rights		Weighted Average Exercise Price of Outstanding Options, and Rights		Number of Securities Available for Future Issuance Under Equity Compensation Plans	
Equity compensation plans approved by security holders (1)	3,429	(2)	$ 26,567.26	(3)	1,220,010	(4)
Equity compensation plans not approved by security holders (5)	1,835	(6)	4,991.82	(7)	5,038	
Total	5,264		$ 12,371.09		1,225,048	

(1) Consists of the Amended and Restated 2006 Employee, Director and Consultant Stock Plan, or the 2006 Plan, the 2014 Incentive Award Plan, as amended and restated, or the 2014 Plan, and the 2014 Employee Stock Purchase Plan, or 2014 ESPP. We ceased issuing new awards under the 2006 Plan when the 2014 Plan became effective.

(2) Consists of 45 outstanding options to purchase shares of our common stock under the 2006 Plan, 493 outstanding options to purchase shares of our common stock under the 2014 Plan, and 2,891 outstanding restricted stock units under the 2014 Plan.

(3) Represents the weighted-average exercise price of options under the 2014 Plan and 2006 Plan as of December 31, 2023. Amounts shown do not take into account any restricted stock units awarded under the 2014 Plan, which do not have an exercise price.

(4) Pursuant to the terms of the 2014 Plan, the number of shares of common stock available for issuance under the 2014 Plan automatically increases on January 1 of each year, beginning January 1, 2015 and ending on and including January 1, 2026. The annual increase in the number of shares is equal to the lesser of: (A) 4% of our shares of common stock outstanding (on an as-converted basis) on the final day of the immediately preceding calendar year; and (B) such smaller number of shares of common stock determined by the Board of Directors; provided, however, no more than 35 million shares may be issued upon the exercise of incentive stock options. Pursuant to the terms of the 2014 ESPP, as amended and restated effective October 2023, the aggregate number of shares that may be issued pursuant to rights granted under the 2014 ESPP shall be 400,000 shares. As of December 31, 2023, a total of 394,477 shares of stock were available for issuance under the 2014 ESPP, 100,000 of which were subject to purchase with respect to the purchase period in effect as of December 31, 2023, which purchase period ends on May 15, 2024.

(5) Consists of the Inducement Award Plan. See Note 10 to the audited consolidated financial statements included in this Annual Report on Form 10-K for a description of the material features of the plan.

(6) Consists of outstanding options to purchase shares of our common stock under the Inducement Award Plan.

(7) Represents the weighted-average exercise price of options under the Inducement Award Plan.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding beneficial ownership of our common stock as of December 31, 2023, for: each person known to us to be the beneficial owner of more than five percent of our outstanding common stock; each of our named executive officers; each of our directors and nominees; and all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Except as noted by footnote, and subject to community property laws where applicable, we believe based on the information provided to us that the persons and entities named in the table below have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them. Except as noted by footnote, the address of each beneficial holder named below is 101 Hartwell Ave., Lexington, MA 02421.

The table lists applicable percentage ownership based on 4,058,381 shares of our common stock outstanding as of December 31, 2023. The number of shares beneficially owned includes shares of our common stock that each person has the right to acquire within 60 days of December 31, 2023, except as noted in the footnotes below, including upon the exercise of stock options and vesting of restricted stock units. These stock options and restricted stock units shall be deemed to be outstanding for the purpose of computing the percentage of outstanding shares of our common stock owned by such person but shall not be deemed to be outstanding for the purpose of computing the percentage of outstanding shares of our common stock owned by any other person.

	Shares Beneficially Owned Title or Class of Securities:			
	Common Stock		Series B Convertible Preferred Stock	
Name of Beneficial Owner	Shares	Percent	Shares	Percent
5% or Greater Stockholders				
CRG (1)	932,970	18.7%	93,297	100.0%
Named Executive Officers and Directors				
John Sperzel (2)	1,000	*		
Michael Gibbs (3)	215	*		
John Sprague (4)	208	*		
John W. Cumming (5)	75	*		
David B Elsbree (6)	101	*		
Seymour Liebman (7)	1,313	*		
Ninfa M. Saunders (8)	73	*		
Robin Toft (9)	57	*		
Laura Adams (10)	37	*		
All executive officers and directors as a group (10 persons) (11)	3,156	0.1%		

* Less than 1%.

(1) Based on a Schedule 13G filed on July 13, 2023, Nathan D. Hukill, CR Group L.P., a Delaware limited partnership ("CR Group"), CRG Partners III L.P., a Delaware limited partnership ("CRG Partners III"), CRG Partners III – Parallel Fund "A" L.P., a Delaware limited partnership ("CRG Parallel Fund A"), CRG Partners III – Parallel Fund "B" (Cayman) L.P., a limited partnership organized under the laws of the Cayman Islands ("CRG Parallel Fund B"), CRG Partners III (Cayman) Lev AIV I L.P., a limited partnership organized under the laws of the Cayman Islands ("CRG Lev AIV"), and CRG Partners III (Cayman) Unlev AIV I L.P., a limited partnership organized under the laws of the Cayman Islands ("CRG Unlev AIV"), share voting and dispositive power with respect to such shares. CRG Parallel Fund A, CRG Parallel Fund B, CRG Lev AIV, CRG Unlev AIV and CRG Partners III are collectively referred to as the "CRG Entities." CR Group serves as the investment manager for the CRG Entities. CR Group is indirectly controlled by Mr. Hukill. The address of CR Group, the CRG Entities and Mr. Hukill is 1000 Main St., Suite 2500, Houston, TX 77002. Common stock beneficially owned by CRG consists of 932,970 shares of common stock that CRG has the right to acquire within 60 days of December 31, 2023 upon the conversion of all 93,297 shares of its Series B Convertible Preferred Stock.

(2) Consists of (a) 173 shares of common stock, (b) options to purchase 600 shares of common stock which Mr. Sperzel has the right to acquire pursuant to outstanding stock options which are, or will be, immediately exercisable within 60 days of December 31, 2023 and (c) 227 restricted stock units vesting within 60 days of December 31, 2023.

(3) Consists of (a) 66 shares of common stock, (b) options to purchase 80 shares of common stock which Mr. Gibbs has the right to acquire pursuant to outstanding stock options which are, or will be, immediately exercisable within 60 days of December 31, 2023 and (c) 69 restricted stock units vesting within 60 days of December 31, 2023.

(4) Consists of (a) 72 shares of common stock, (b) options to purchase 67 shares of common stock which Mr. Sprague has the right to acquire pursuant to outstanding stock options which are, or will be, immediately exercisable within 60 days of December 31, 2023, and (c) 69 restricted stock units vesting within 60 days of December 31, 2023.

(5) Consists of (a) 52 shares of common stock and (b) options to purchase 23 shares of common stock, which Mr. Cumming has the right to acquire pursuant to outstanding stock options which are, or will be, immediately exercisable within 60 days of December 31, 2023.

(6) Consists of (a) 78 shares of common stock and (b) options to purchase 23 shares of common stock which Mr. Elsbree has the right to acquire pursuant to outstanding stock options which are, or will be, immediately exercisable within 60 days of December 31, 2023.

(7) Based on information set forth in a Schedule 13D filed with the SEC by Canon U.S.A., Inc. on September 21, 2016, this amount includes 1,211 shares held by Canon U.S.A., Inc. Mr. Seymour Liebman is the Executive Vice President, Chief Administrative Officer and General Counsel of Canon U.S.A., Inc. and the Senior Managing Executive Officer of Canon Inc., Japan and may be deemed to have beneficial ownership of the shares held by Canon U.S.A., Inc. Canon U.S.A., Inc. and Mr. Liebman each disclaim beneficial ownership of the shares held directly or indirectly by Canon U.S.A., Inc., except to the extent of its pecuniary interest therein, if any. In addition, this amount consists of (a) 85 shares of common stock and (b) options to purchase 17 shares of common stock which Mr. Liebman has the right to acquire pursuant to outstanding stock options which are, or will be, immediately exercisable within 60 days of December 31, 2023.

(8) Consists of 73 shares of common stock for Ms. Saunders.

(9) Consists of 57 shares of common stock for Ms. Toft.
(10) Consists of 37 shares of common stock for Ms. Adams.
(11) Consists of (a) 1,968 shares of common stock, (b) 810 shares of common stock which our directors and executive officers as a group have the right to acquire pursuant to outstanding stock options which are, or will be, immediately exercisable within 60 days of December 31, 2023 and (c) 378 restricted stock units vesting within 60 days of December 31, 2023.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Policies for Approval of Related Person Transactions

We have adopted a written policy that transactions with directors, officers and holders of 5% or more of our voting securities and their affiliates, or each, a related party, must be approved by our audit committee or another independent body of our Board of Directors. All related party transactions shall be disclosed in our applicable filings with the SEC as required under SEC rules.

Transactions with Related Persons

Based on a review of the transactions and arrangements between us and any related person or related person's affiliate, we describe below the transactions or arrangements since January 1, 2023 in which any related person or related person affiliate has a direct or indirect material interest and the amount involved exceeds $120,000.

Transactions with CRG Entities

On July 3, 2023, when we converted $10.0 million of outstanding debt under the Term Loan Agreement, the CRG Entities, including their beneficial owners, became a greater than 5% beneficial owner of our common stock. The CRG Entities are comprised of CRG Partners III L.P., CRG Partners III - Parallel Fund "A" L.P., CRG Partners III (Cayman) Unlev AIV I L.P., CRG Partners III (Cayman) Lev AIV I L.P. and CRG Partners III Parallel Fund "B" (Cayman) L.P. The beneficial owners of the CRG Entities are CR Group L.P., the investment manager, and Nathan D. Hukill, who indirectly controls CR Group L.P. As a result of acquiring a greater than 5% beneficial ownership of our common stock, certain transactions with the CRG Entities on or after July 3, 2023, are related party transactions required to be disclosed under SEC rules.

Consent to Term Loan Agreement and Series B Purchase Agreement

On July 3, 2023, we entered into a Consent to Term Loan Agreement (the "Consent"), by and among the Company, CRG Servicing LLC, as administrative agent and collateral agent, and the CRG Entities, under which the parties consented and agreed to the cancellation of $10.0 million of the term loan (approximately 20% of the total term loan debt) in exchange for (i) an aggregate of 483,457 shares of common stock, and (ii) an aggregate of 93,297 shares of newly designated Series B Convertible Preferred Stock, par value $0.001 per share ("Series B Preferred Stock"), which were issuable pursuant to a Securities Purchase Agreement. Each share of Series B Preferred Stock is convertible into 10 shares of our common stock at the holder's election, subject to beneficial ownership limitations. The closing of the exchange occurred on July 3, 2023. The CRG Entities sold their shares of common stock in advance of the 1-for-100 reverse stock split effected by the Company in October 2023.

Series A Purchase Agreement

On July 5, 2023, we entered into a Purchase Agreement (the "Series A Purchase Agreement") with the CRG Entities pursuant to which we agreed to issue and sell a total of 1,000 shares of the Company's newly designated Series A Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock"), to the CRG Entities for a purchase price of $100.00. The closing of the sale of the shares of Series A Preferred Stock was completed on July 5, 2023.

The shares of Series A Preferred Stock were not convertible into, or exchangeable for, shares of any other class or series of stock or other securities of the Company. The shares of Series A Preferred Stock were entitled to receive dividends on a pari passu basis with the outstanding shares of common stock. The shares of Series A Preferred Stock were also entitled to an aggregate of 400,000,000 votes, but only with respect to a vote relating to any proposal to effectuate a reverse stock split of our common stock. Pursuant to the Series A Purchase Agreement, the CRG Entities agreed only to vote those shares in the same proportion as shares of common stock of the Company were voted (excluding any shares of common stock that are not voted, whether due to abstentions, broker non-votes or otherwise) on such proposal.

The shares of Series A Preferred Stock were redeemable automatically at a total redemption price of $100 immediately following the approval by our stockholders of any proposal to effectuate a reverse stock split of our common stock. On September 15, 2023, our stockholders voted to approve an amendment to the Company's Amended and Restated Certificate of Incorporation to effect a reverse stock split of the Company's common stock, at a reverse stock split ratio ranging from any whole number between and including 1-for-50 and 1-for-150, with the exact ratio to be determined at the discretion of the Board of Directors. As a result of that stockholder vote, the Series A Preferred Stock was redeemed on September 15, 2023, for $100. Upon its redemption, the Company's Series A Preferred Stock ceased to be outstanding.

Stockholder Approval of Debt-to-Equity Conversions

On September 15, 2023, our stockholders approved the issuance of common stock to the CRG Entities upon the conversion of our Series B Convertible Preferred Stock by the CRG Entities. Stockholders were required to approve such conversion in accordance with Nasdaq Listing Rule 5635(b) as it would result in the CRG Entities beneficially owning securities representing more than 19.99% of our outstanding common stock.

Amendment to Term Loan Agreement

On October 18, 2023, we amended the Term Loan Agreement to extend the interest-only payment period from December 30, 2024 to December 31, 2025, extend the maturity date from December 30, 2024 to December 31, 2025, and permanently reduce the minimum liquidity covenant from $5 million to $500,000.

Conversion of Series B Preferred Stock and Securities Purchase Agreement

On February 15, 2024, the CRG Entities converted 82,422 shares of Series B Preferred Stock into 824,220 shares of common stock. Also, on February 15, 2024, we entered into a Securities Purchase Agreement with the CRG Entities and affiliated entities pursuant to which we will issue (i) shares of the common stock, and (ii) to the extent that the issuance of shares of common stock results in the CRG Entities beneficially owning greater than 49.99% of our outstanding shares of common stock (or, in the case of one of the affiliated entities, greater than 9.99% of our outstanding shares of common stock, determined without regard to any convertible securities held by the CRG Entities or affiliated entities), shares of newly designated convertible preferred stock, par value $0.001 per share, at a price per share equal to the lower of (a) the closing price of our common stock on Nasdaq on the date immediately prior to the closing of the transaction, and (b) the average closing price over the five business days prior to the closing of the transaction, in exchange for CRG Entities surrendering for cancellation $15.0 million of outstanding debt under the Term Loan Agreement. The closing of the transaction is conditioned on the approval of our stockholders at a stockholder meeting to be held on April 11, 2024, and is expected to occur within 10 business days following the approval of the transaction by our stockholders.

Indebtedness with CRG Entities

The largest aggregate amount of principal outstanding related to the Term Loan Agreement during the year ended December 31, 2023 was $53.5 million. The principal outstanding as of December 31, 2023 related to the Term Loan Agreement was $44.5 million. No principal was paid during the year ended December 31, 2023. The amount of interest paid related to the Term Loan Agreement during year ended December 31, 2023 was $3.9 million. Interest on the Term Loan accrues at 11.50% per year, 8% of which is payable in cash quarterly and 3.5% of which is deferred and added to principal until maturity.

Indemnification Agreements with Executive Officers and Directors. We have entered into an indemnification agreement with each of our directors and executive officers. These indemnification agreements and our certificate of incorporation and our bylaws indemnify each of our directors and officers to the fullest extent permitted by the DGCL. See the *"Limitation of Liability and Indemnification Agreements"* section for further details.

Limitation of Liability and Indemnification Agreements. We have adopted provisions in our certificate of incorporation and bylaws that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended.

Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our Board of Directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our Board of Directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and executive officers. These agreements provide that we will indemnify each of our directors, such executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us and/or in furtherance of our rights. Additionally, each of our directors may have certain rights to indemnification, advancement of expenses and/or insurance provided by their affiliates, which indemnification relates to and might apply to the same proceedings arising out of such director's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors are primary and any obligation of the affiliates of those directors to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or persons controlling the registrant under the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Independence of the Board of Directors

Board Leadership and Independence. Our Board of Directors has determined that all members of the Board of Directors, (including John W. Cumming, David B. Elsbree, Ninfa Saunders, Laura Adams, Seymour Liebman and Robin Toft), except John Sperzel, are independent, as determined in accordance with Nasdaq rules. The Board of Directors also determined that Thierry Bernard, who resigned from the Board of Directors on January 2, 2024, was independent. In making such independence determination, the Board of Directors considered the relationships that each such non-employee director has with us and all other facts and circumstances that the Board of Directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our Board of Directors considered the association of our directors with the holders of more than 5% of our common stock. There are no family relationships among any of our directors or executive officers.

Our Board of Directors is currently chaired by John Sperzel, our President and Chief Executive Officer. John Cumming currently serves as our lead director. The lead director's responsibilities include, but are not limited to: presiding over all meetings of the Board of Directors at which the chairperson is not present, including any executive sessions of the independent directors; approving Board meeting schedules and agendas; and acting as the liaison between the independent directors and the chief executive officer and chairperson of the Board. Our Corporate Governance Guidelines further provide flexibility for our Board of Directors to modify our leadership structure in the future as it deems appropriate. Our Board has determined that combining the roles of Chairman of the Board and Chief Executive Officer is in the best interests of our Company and its stockholders at this time because it promotes unified leadership by Mr. Sperzel and allows for a single, clear focus for management to execute the Company's strategy and business plans. For these reasons and because of the strong leadership of Mr. Sperzel, our Board has concluded that our current leadership structure is appropriate at this time. However, our Board of Directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth fees billed for professional audit services and other services rendered to us by BDO USA, P.C. ("BDO"), our independent registered public accounting firm, and its affiliates for the fiscal years ended December 31, 2023 and 2022.

	Fiscal 2023	Fiscal 2022
Audit Fees	$ 975,143	$ 793,692
Tax Fees	69,430	58,000
Total	$ 1,044,573	$ 851,692

Audit Fees. Audit fees consist of fees billed for professional services performed by BDO for the audit of our annual consolidated financial statements, the review of interim consolidated financial statements, and related services that are normally provided in connection with registration statements.

Tax Fees. Tax fees consist of fees for professional services, including tax consulting and compliance performed by BDO.

Audit Committee Pre-Approval of Audit and Non-Audit Services

The Audit Committee has adopted a policy (the "Pre-Approval Policy") that sets forth the procedures and conditions pursuant to which audit and non-audit services proposed to be performed by the independent auditor may be pre-approved. The Pre-Approval Policy generally provides that we will not engage BDO USA, P.C. to render any audit, audit-related, tax or permissible non-audit service unless the service is either (i) explicitly approved by the Audit Committee ("specific pre-approval") or (ii) entered into pursuant to the pre-approval policies and procedures described in the Pre-Approval Policy ("general pre-approval"). Unless a type of service to be provided by BDO USA, P.C. has received general pre-approval under the Pre-Approval Policy, it requires specific pre-approval by the Audit Committee or by a designated member of the Audit Committee to whom the committee has delegated the authority to grant pre-approvals. Any proposed services exceeding pre-approved cost levels or budgeted amounts will also require specific pre-approval. For both types of pre-approval, the Audit Committee will consider whether such services are consistent with the SEC's rules on auditor independence. The Audit Committee will also consider whether the independent auditor is best positioned to provide the most effective and efficient service, for reasons such as its familiarity with the Company's business, people, culture, accounting systems, risk profile and other factors, and whether the service might enhance the Company's ability to

manage or control risk or improve audit quality. All such factors will be considered as a whole, and no one factor should necessarily be determinative. The Audit Committee periodically reviews and generally pre-approves any services (and related fee levels or budgeted amounts) that may be provided by BDO USA, P.C. without first obtaining specific pre-approvals from the Audit Committee or the Chair of the Audit Committee. The Audit Committee may revise the list of general pre-approved services from time to time, based on subsequent determinations.

All BDO services and fees in the fiscal years ended December 31, 2023 and 2022 were pre-approved by the audit committee.

Item 15. EXHIBITS, FINANCIAL STATEMENTS AND SCHEDULES

a. *Documents filed as part of this Annual Report.*

1. The following financial statements of T2 Biosystems, Inc. and Report of Independent Registered Public Accounting Firm, are included in this report:

   Report of BDO USA P.C., Independent Registered Public Accounting Firm (BDO USA, P.C.; Boston, Massachusetts; PCAOB ID# 243)

   Consolidated Balance Sheets as of December 31, 2023 and 2022

   Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2023 and 2022

   Consolidated Statements of Series A Redeemable Convertible Preferred Stock and Stockholders' Deficit for the years ended December 31, 2023 and 2022

   Consolidated Statements of Cash Flows for the years ended December 31, 2023 and 2022

   Notes to Consolidated Financial Statements

2. List of financial statement schedules. All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

INDEX TO EXHIBITS

Exhibit Number		Description of Exhibit
3.1		Restated Certificate of Incorporation of the Company, as amended (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on August 12, 2014)
3.2		Certificate of Amendment of Restated Certificate of Incorporation of the Company dated July 23, 2021 (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on July 23, 2021)
3.3		Certificate of Amendment of Restated Certificate of Incorporation of the Company dated October 12, 2022 (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on October 12, 2022)
3.4		Certificate of Amendment of Restated Certificate of Incorporation of the Company dated October 12, 2023 (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on October 12, 2023)
3.5		Certificate of Designation of Preferences, Rights and Limitations of Series A Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K (File No. 001-36571) filed on July 6, 2023)
3.6		Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K (File No. 001-36571) filed on July 6, 2023)
3.7		Third Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.4 of the Company's Form 10-Q (File No. 001-36571) filed on August 16, 2022)
4.1		Form of Common Stock Certificate of the Company (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 28, 2014)
4.2		Fourth Amended and Restated Investors' Rights Agreement, dated as of March 22, 2013, as amended (incorporated by reference to Exhibit 4.2 of the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 28, 2014
4.3		Registration Rights Agreement dated as of July 29, 2019 by and between T2 Biosystems Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 4.1 of the Company's Form 8-K (File No. 001-36571) filed on July 30, 2019)
4.4	*	Description of Securities
4.5		Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of the Company's Form 10-Q (File No. 001-36571) filed on August 16, 2022)
4.6		Pre-Funded Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of the Company's Form 8-K (File No. 001-36571) filed on February 16, 2023)
4.7		Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 of the Company's Form 8-K (File No. 001-36571) filed on February 16, 2023)
10.1	#	Amended and Restated 2006 Employee, Director and Consultant Stock Plan, as amended, and form of option agreements thereunder (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-197193 filed on July 2, 2014)
10.2	#	Non-Employee Director Compensation Program, effective as of March 21, 2022 (incorporated by reference to Exhibit 10.2 to the Company's Form 10-K (File No. 001-36571) filed on March 23, 2022)
10.3	#	Form of Indemnification Agreement for Directors and Officers (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1/A (File No. 333-197193 filed on July 28, 2014)
10.4	†	Exclusive License Agreement, dated as of November 7, 2006, as amended on December 2, 2008 and February 21, 2011, by and between The General Hospital Corporation d/b/a Massachusetts General Hospital and the Company (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-197193) filed on July 2, 2014)
10.5		Commercial Lease, dated as of May 6, 2013, as amended on September 24, 2013, by and between the Company and Columbus Day Realty, Inc. (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-197193) filed on July 2, 2014)

10.6		Lease, dated as of August 6, 2010, by and between the Company and King 101 Hartwell LLC, as amended by the First Amendment to Lease on November 30, 2011 and the Second Amendment to Lease on July 11, 2014 (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1/A (File No. 333-197193) filed on July 16, 2014)
10.7		2014 Employee Stock Purchase Plan, as amended and restated (incorporated by reference to Exhibit 10.4 of the Company's Form 10-Q (File No. 001-36571) filed on November 15, 2023)
10.8	†	Supply Agreement by and between the Company and SMC Ltd., effective as of October 10, 2014 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K/A (File No. 001-36571) filed on January 21, 2015)
10.9		Third Amendment to Lease with King 101 Hartwell LLC on May 27, 2015 (incorporated by referenced to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on May 29, 2015)
10.10		Stock Purchase Agreement, dated September 21, 2016, by and among Canon U.S.A., Inc. and the Company (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on September 22, 2016)
10.11		Voting and Standstill Agreement, dated September 21, 2016, by and among Canon U.S.A., Inc. and the Company (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K (File No. 001-36571) filed on September 22, 2016)
10.12		Registration Rights Agreement, dated September 21, 2016, by and among Canon U.S.A., Inc. and the Company (incorporated by reference to Exhibit 10.3 of the Company's Form 8-K (File No. 001-36571) filed on September 22, 2016)
10.13	†	Term Loan Agreement, dated December 30, 2016, by and among the Company, CRG Servicing LLC, as administrative and collateral agent, and the lenders from time to time party thereto and the subsidiary guarantors from time to time party thereto (incorporated by reference to Exhibit 10.29 of the Company's Form 10-K (File No. 001-36571) filed on March 15, 2017)
10.14		Security Agreement, dated December 30, 2016, by and among the Company, the other grantors from time to time party thereto and CRG Servicing LLC, as administrative and collateral agent (incorporated by reference to Exhibit 10.30 of the Company's Form 10-K (File No. 001-36571) filed on March 15, 2017)
10.15		Warrant to Purchase Shares of Common Stock of T2 Biosystems, Inc., dated December 30, 2016, by and between the Company and CRG Partners III - Parallel Fund "A" L.P. (incorporated by reference to Exhibit 10.32 of the Company's Form 10-K (File No. 001-36571) filed on March 15, 2017)
10.16		Warrant to Purchase Shares of Common Stock of T2 Biosystems, Inc., dated December 30, 2016, by and between the Company and CRG Partners III L.P. (incorporated by reference to Exhibit 10.33 of the Company's Form 10-K (File No. 001-36571) filed on March 15, 2017)
10.17		Warrant to Purchase Shares of Common Stock of T2 Biosystems, Inc., dated December 30, 2016, by and between the Company and CRG Partners III Parallel Fund "B" (Cayman) L.P. (incorporated by reference to Exhibit 10.34 of the Company's Form 10-K (File No. 001-36571) filed on March 15, 2017)
10.18		Fourth Amendment to Lease, dated March 2, 2017, by and between the Company and King 101 Harwell LLC (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on March 3, 2017)
10.19		Amendment No. 1 to Term Loan Agreement, dated March 1, 2017, by and among the Company, CRG Servicing LLC, as administrative and collateral agent, and the lenders party thereto (incorporated by reference to Exhibit 10.3 of the Company's Form 10-Q (File No. 001-36571) filed on May 8, 2017)
10.20	†	Amendment to Supply Agreement, by and between the Company and SMC Ltd., dated August 29, 2017 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on August 29, 2017)
10.21		Second Amendment to Supply Agreement, by and between the Company and SMC Ltd., dated December 22, 2017 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on December 27, 2017)
10.22	#	Employment Offer Letter, dated as of January 30, 2018, by and between the Company and John M. Sprague (incorporated by reference to Exhibit 10.38 of the Company's Form 10-K (File No. 001-36571) filed on March 19, 2018)
10.23		Amendment No. 2 to Commercial Lease, dated as of September 21, 2015, by and between the Company and Columbus Day Realty, Inc. (incorporated by reference to Exhibit 10.40 of the Company's Form 10-K (File No. 001-36571) filed on March 19, 2018)
10.24		Amendment No. 3 to Commercial Lease, dated as of August 10, 2017, by and between the Company and Columbus Day Realty, Inc. (incorporated by reference to Exhibit 10.41 of the Company's Form 10-K (File No. 001-36571) filed on March 19, 2018)

10.25		Amendment No. 2 to Term Loan Agreement, dated December 18, 2017, by and among the Company, CRG Servicing LLC, as administrative and collateral agent, and the lenders party thereto (incorporated by reference to Exhibit 10.42 of the Company's Form 10-K (File No. 001-36571) filed on March 19, 2018)
10.26		Amendment No. 3 to Term Loan Agreement, dated March 16, 2018, by and among the Company, CRG Servicing LLC, as administrative and collateral agent, and the lenders party thereto (incorporated by reference to Exhibit 10.43 of the Company's Form 10-K (File No. 001-36571) filed on March 19, 2018)
10.27		Third Amendment to Supply Agreement, by and between the Company and SMC Ltd., dated May 16, 2018 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on May 17, 2018)
10.28		Amendment No. 4 to Commercial Lease, dated as of August 31, 2018, by and between the Company and Columbus Day Realty, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on September 7, 2018)
10.29		Fifth Amendment to Lease, dated December 6, 2018, by and between the Company and King 101 Harwell LLC (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on December 12, 2018)
10.30	#	Employment Offer Letter, dated as of October 29, 2014, by and between the Company and Michael Gibbs (incorporated by reference to Exhibit 10.45 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)
10.31		Amendment No. 4 to Term Loan Agreement, dated March 13, 2019, between the Company and CRG Servicing LLC (incorporated by reference to Exhibit 10.50 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)
10.32		Amendment to Warrant to Purchase Shares of Common Stock, dated March 13, 2019, between the Company and CRG Partners III L.P. (incorporated by reference to Exhibit 10.51 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)
10.33		Amendment to Warrant to Purchase Shares of Common Stock, dated March 13, 2019, between the Company and CRG Partners III – Parallel Fund "A" L.P. (incorporated by reference to Exhibit 10.52 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)
10.34		Amendment to Warrant to Purchase Shares of Common Stock, dated March 13, 2019, between the Company and CRG Partners III Parallel Fund "B" (CAYMAN) L.P. (incorporated by reference to Exhibit 10.53 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)
10.35		Replacement Warrant to Purchase Shares of Common Stock of T2 Biosystems, Inc., dated March 13, 2019, between the Company and CRG PARTNERS III (CAYMAN) LEV AIV L.P. (incorporated by reference to Exhibit 10.54 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)
10.36		Replacement Warrant to Purchase Shares of Common Stock of T2 Biosystems, Inc., dated March 13, 2019, between the Company and CRG PARTNERS III (CAYMAN) UNLEV AIV 1 L.P. (incorporated by reference to Exhibit 10.55 of the Company's Form 10-K (File No. 001-36571) filed on March 14, 2019)
10.37	†	Amendment No. 5 to Term Loan Agreement dated as of September 10, 2019 by and between T2 Biosystems, Inc., CRG Servicing LLC and the lenders listed on the signature pages thereto (incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q (File No. 001-36571) filed on November 18, 2019)
10.38	†	Supply Agreement, dated as of March 1, 2019, by and between the Company and GE Healthcare (incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q (File No. 001-36571) filed on May 10, 2019)
10.39	#	Employment Agreement, dated as of January 8, 2020, by and between the Company and John Sperzel (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on January 9, 2020)
10.40		Sixth Amendment to Lease by and between the Company and LS King Hartwell Innovation Campus LLC, dated as of October 19, 2020 (incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q (File No. 001-36571) filed on November 5, 2020)
10.41		First Amendment to Lease by and between the Company and LS King Hartwell Innovation Campus LLC, dated as of October 19, 2020 (incorporated by reference to Exhibit 10.3 of the Company's Form 10-Q (File No. 001-36571) filed on November 5, 2020)
10.42		Amendment No. 5 to Commercial Lease between Columbus Day Realty, Inc. and the Company, dated as of October 20, 2020 (incorporated by reference to Exhibit 10.4 of the Company's Form 10-Q (File No. 001-36571) filed on November 5, 2020)

10.43	†	Amendment No. 6 to Term Loan Agreement, dated January 25, 2021, between T2 Biosystems, Inc. and CRG Servicing LLC (incorporated by reference to Exhibit 10.63 of the Company's Form 10-K (File No. 001-36571) filed on March 31, 2021)
10.44		T2 Biosystems, Inc. 2014 Incentive Award Plan, as amended and restated (incorporated by reference to Exhibit 10.3 of the Company's Form 10-Q (File No. 001-36571) filed on November 15, 2023)
10.45	#	T2 Biosystems, Inc. Inducement Award Plan (as amended and restated, effective February 16, 2023) and form of option agreement, restricted stock agreement, and restricted stock unit agreement thereunder (incorporated by reference to Exhibit 10.51 of the Company's Form 10-K (File No. 001-36571) filed on March 31, 2023)
10.46	#	Employment Offer Letter, dated as of November 2, 2021, by and between the Company and Brett Giffin (incorporated by reference to Exhibit 10.52 of the Company's Form 10-K (File No. 001-36571) filed on March 31, 2023)
10.47	#	Change of Control Severance Agreement, dated March 21, 2022 by and between the Company and John Sprague (incorporated by reference to Exhibit 10.53 of the Company's Form 10-K (File No. 001-36571) filed on March 31, 2023)
10.48	#	Change of Control Severance Agreement, dated March 21, 2022 by and between the Company and Michael Gibbs (incorporated by reference to Exhibit 10.54 of the Company's Form 10-K (File No. 001-36571) filed on March 31, 2023)
10.49	#	Change of Control Severance Agreement, dated March 21, 2022 by and between the Company and Brett Giffin (incorporated by reference to Exhibit 10.55 of the Company's Form 10-K (File No. 001-36571) filed on March 31, 2023)
10.50		Amendment No. 7 to Term Loan Agreement, dated February 15, 2022, between T2 Biosystems, Inc. and CRG Servicing LLC (incorporated by reference to Exhibit 10.56 of the Company's Form 10-K (File No. 001-36571) filed on March 31, 2023)
10.51	†	Amendment No. 8 to Term Loan Agreement, dated November 10, 2022, between T2 Biosystems, Inc. and CRG Servicing LLC (incorporated by reference to Exhibit 10.5 of the Company's Form 10-Q (File No. 001-36571) filed on November 14, 2022)
10.52		Amendment No. 6 to Commercial Lease between Columbus Day Realty, Inc. and T2 Biosystems, Inc. dated September 26, 2022 (incorporated by reference to Exhibit 10.64 of the Company's Form 10-K (File No. 001-36571) filed on March 31, 2023)
10.53		Waiver, dated January 23, 2023 to that certain Term Loan Agreement, dated as of December 30, 2016, by and among the Company, CRG Servicing LLC, as administrative agent and collateral agent incorporated by reference to Exhibit 10.66 of the Company's Form 10-K (File No. 001-36571) filed on March 31, 2023)
10.54		Waiver and Consent to Term Loan Agreement with CRG Servicing LLC, dated May 19, 2023 (incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q (File No. 001-36571) filed on May 22, 2023)
10.55		Amendment No. 9 to Term Loan Agreement, dated October 18, 2023, between T2 Biosystems, Inc. and CRG Servicing LLC (incorporated by reference to Exhibit 10.5 of the Company's Form 10-Q (File No. 001-36571) filed on November 15, 2023)
10.56		Purchase Agreement, dated July 5, 2023, by and between the Company and the Purchasers party thereto (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on November 15, 2023) filed on July 6, 2023
10.57		Securities Purchase Agreement, dated July 3, 2023, by and between the Company and the Lenders party thereto (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K (File No. 001-36571) filed on November 15, 2023) filed on July 6, 2023
10.58		Securities Purchase Agreement, dated February 15, 2024 by and between the Company and the Lenders party thereto (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on February 15, 2024)
10.59		Equity Distribution Agreement, dated as of March 31, 2021, by and between T2 Biosystems, Inc. and Canaccord Genuity LLC. (incorporated by reference to Exhibit 1.2 to the Company's Registration Statement on Form S-3 (File No. 333-197193) filed on March 31, 2021)
10.60	#*	Letter Agreement, dated March 31, 2024, by and between T2 Biosystems, Inc. and John Sprague
10.61	#*	Letter Agreement, dated March 31, 2024, by and between T2 Biosystems, Inc. and Michael Gibbs
21.1	*	Subsidiaries of the Registrant.

23.1	*	Consent of BDO USA, P.C., Independent Registered Public Accounting Firm
31.1	*	Certification of principal executive officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	*	Certification of principal financial officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	**	Certification of the principal executive officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350.
32.2	**	Certification of the principal financial officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350.
97.1	#*	T2 Biosystems, Inc. Clawback Policy
101.INS	*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	*	Inline XBRL Taxonomy Extension Schema Document
101.CAL	*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Furnished herewith.

# Indicates management contract or compensatory plan.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, or the Securities Act.

Item 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of the 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, on April 1, 2024.

T2 BIOSYSTEMS, INC.

By: /S/ JOHN SPERZEL
Name: John Sperzel
Title: President, Chief Executive Officer and Director (principal executive officer)

April 1, 2024

By: /S/ JOHN M. SPRAGUE
Name: John M. Sprague
Title: Chief Financial Officer (principal financial officer and principal accounting officer)

April 1, 2024

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

Signature	Title	Date
/ S / JOHN SPERZEL **John Sperzel**	President, Chief Executive Officer and Director (principal executive officer)	April 1, 2024
/ S / JOHN M. SPRAGUE **John M. Sprague**	Chief Financial Officer (principal accounting officer)	April 1, 2024
/ S / LAURA ADAMS **Laura Adams**	Director	April 1, 2024
/ S / DR. NINFA M. SAUNDERS **Dr. Ninfa M. Saunders**	Director	April 1, 2024
/ S / ROBIN TOFT **Robin Toft**	Director	April 1, 2024
/ S / JOHN W. CUMMING **John W. Cumming**	Director	April 1, 2024
/ S / DAVID B. ELSBREE **David B. Elsbree**	Director	April 1, 2024
/ S / SEYMOUR LIEBMAN **Seymour Liebman**	Director	April 1, 2024

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