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 year ended December 31, 2022

☐ **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. ☐

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

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

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

As of June 30, 2022, 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 $30.9 million based on the closing price for the common stock of $8.10 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 27, 2023 was 20,275,428.

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 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 status as an early-stage commercial company;*
- *our expectation to incur losses in the future and our ability to utilize limited net operating losses against future profitability, if any;*
- *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;*
- *our future capital needs and our ability to raise additional funds;*
- *the performance of our diagnostics;*
- *our ability to compete in the highly competitive diagnostics market;*
- *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;*
- *our ability to recruit, train and retain key personnel;*
- *our dependence on third parties;*
- *manufacturing and other product risks, including unforeseen interruptions in the manufacturing of our products and backlogs in order fulfillment;*
- *the impact of cybersecurity risks, including ransomware, phishing, and data breaches on our information technology systems;*
- *the impact of short sellers and day traders on our share price;*
- *the impact of litigation, including our ability to adequately resolve current legal claims; and*

- *our ability to convert T2SARS-CoV-2 customers to our other test panels.*

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. 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 and Lyme disease, which represent areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics.

Our primary commercial products based on revenue for the year ended December 31, 2022 include the T2Dx® Instrument, the T2Candida® Panel, the T2Bacteria® Panel, the T2Resistance® Panel, and the T2SARS-CoV-2™ Panel.

History

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, which have the ability to rapidly identify the five most clinically relevant species of *Candida*, a fungal pathogen known to cause sepsis, directly from whole blood specimens. The T2Dx Instrument and T2Candida Panel were CE marked in the European Union, or 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 five of the most common and deadly sepsis-causing bacteria directly from whole blood specimens. The T2Bacteria Panel 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, it was CE marked in the EU. In December 2021, we initiated a U.S. clinical trial for the T2Resistance Panel.

In September 2019, the Biomedical Advanced Research and Development Authority, or BARDA, awarded us a milestone-based contract, with an initial value of $6 million, and a potential value of up to $62 million, 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 BARDA contract. In September 2021, BARDA exercised Option 2A valued at approximately $6.4 million to further advance the new product development initiatives. In March 2022, BARDA exercised Option 2B valued at approximately $4.4 million. In December 2021, we initiated the U.S. clinical trials for the T2Resistance and T2Biothreat Panels. 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 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 Emergency Use Authorization, or 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. We expect to continue to experience a decline in COVID-19 product sales tied to our T2SARS-CoV-2 Panel, and the focus of our go-to-market strategy continues to be increasing sales of our sepsis test panels, expanding the installed base of our T2Dx Instruments, and solidifying commercial plans for our T2Lyme Panel.

Clinical Need

Sepsis is the body's overwhelming and life-threatening response to infection that can lead to tissue damage, organ failure, and death. It is one of the leading causes of death in the United States, claiming more lives annually than the top three cancers combined: lung, colorectal and breast cancer, and it is the most expensive hospital-treated condition. Most commonly afflicting immunocompromised, critical care, and elderly patients, sepsis is a severe inflammatory response to a bacterial or fungal infection with a mortality rate of approximately 30%. Based on a 2020 study from the Department of Health and Human Services, or HHS, it was estimated that the annual cost of sepsis to the U.S. healthcare system was $62 billion. The rate of Medicare beneficiaries hospitalized with sepsis has increased by 40% from 2012 to 2018, the HHS study found. The United States Centers for Disease Control and Prevention, or CDC, estimates that sepsis causes more than 350,000 American deaths per year.

The most common cause of sepsis is bacterial, Gram positive and Gram negative pathogens, while *Candida* species are the most common cause of fungal sepsis. Early detection and identification of sepsis causing pathogens is critical for effective treatment and positive patient outcomes.

Today, sepsis-causing pathogens are typically detected through a series of blood cultures, post-blood culture species identification and antimicrobial susceptibility testing. These methods have substantial limitations including the risk of false negative test results, a delay in administration of targeted antimicrobial treatment, and the incurrence of unnecessary hospital expense. According to a study published in the Journal of Clinical Microbiology in 2010, targeted therapy for patients with bloodstream infections can be delayed up to 72 hours due to the wait time for blood culture results. In another study published in Clinical Infectious Diseases in 2012, the delayed administration of appropriate antifungal therapy was associated with higher mortality among patients with septic shock attributed to *Candida* infection.

In addition, the Survey of Physicians' Perspectives and Knowledge About Diagnostic Tests for Bloodstream Infections in 2015 reported that negative blood culture results are only trusted by 36% of those physicians. Without the ability to rapidly identify pathogens, physicians typically start treatment of at-risk patients with broad-spectrum antibiotics and switch therapies every 12 to 24 hours if a patient is not responding. These drugs, which can be costly, are often ineffective and unnecessary and have contributed to the spread of antimicrobial resistance. The speed to getting the patient on the right targeted therapy is critical. According to a study published by Critical Care Medicine in 2006, in sepsis patients with documented hypotension, administration of effective antimicrobial therapy within the first hour of detection was associated with a survival rate of 79.9% and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7.6%. *Candida* is the fourth leading hospital-acquired bloodstream infection, afflicting more than 135,000 patients per year in the United States, and the most lethal form of common bloodstream infections that cause sepsis, with an average mortality rate of approximately 40%. This high mortality rate is largely due to a delay in providing targeted therapy to the patient due to the elapsed time from *Candida* infection to positive diagnosis. According to a study published in Antimicrobial Agents and Chemotherapy, the *Candid*a mortality rate can be reduced from 40% to 11% with the initiation of targeted therapy within 12 hours of presentation of symptoms. Additionally, 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 more than $130,000 per patient. In a study published in the American Journal of Respiratory and Critical Care Medicine, 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, due to the high mortality rate associated with *Candida* infections, physicians often will place patients on antifungal drugs while they await blood culture diagnostic results which generally take at least five days to generate a negative test result. Antifungal drugs are toxic and may result in side effects and can cost over $50 per day. The speed to result of T2Candida, coupled with higher sensitivity as compared to blood culture, may help reduce the overuse of ineffective, or even unnecessary, antimicrobial therapy which may reduce side effects for patients, lower hospital costs and potentially counteract the growing resistance to antifungal therapy. The administration of inappropriate therapy is a driving force behind the spread of antimicrobial-resistant pathogens, which the CDC called "one of our most serious health threats." Currently, high risk patients are typically initially treated with broad spectrum antibiotic therapy that cover approximately 60% of patients with infections. Of the remaining 40% of patients, approximately 30% of the patients typically have a bacterial infection and 10% typically have *Candida* infections. T2Candida and T2Bacteria are designed to identify pathogens either resistant to, or not covered by, broad spectrum antibiotic therapy.

Products - Commercially Available

T2Dx Instrument

Our T2Dx Instrument, which is FDA-cleared for use with our T2Candida and T2Bacteria panels and CE marked in the EU for use with our T2Candida, T2Bacteria and T2Resistance Panels, 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 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. 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 incorporates a simple user interface and is designed to efficiently process up to seven specimens simultaneously.

The commercially available test panels designed to run on the T2Dx Instrument are T2Candida, T2Bacteria, T2Resistance, and T2SARS-CoV-2 panels, which are focused on identifying life-threatening pathogens associated with sepsis and COVID-19.

T2Candida Panel

Our T2Candida Panel, which is FDA-cleared in the U.S. and CE marked in the EU, is a direct-from-blood test that identifies the most lethal form of common blood stream infections that cause sepsis, candidemia, which has an average mortality rate of approximately 40%. T2Candida

identifies five species of *Candida*, directly from certain human whole blood specimens, including *Candida albicans, Candida tropicalis, Candida krusei, Candida glabrata, and Candida parapsilosis*. These species account for 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 the T2Candida Panel in the U.S. and in July 2014 the T2Candida Panel was CE marked in the EU.

In our pivotal clinical trial for T2Candida, we demonstrated that it delivered results in as few as three hours, with an average time to result during the trial of 4.2 hours, compared to the average time to result of one to six or more days typically required for blood-culture-based diagnostics. We believe the speed of T2Candida will enable physicians to potentially make treatment decisions and administer targeted treatment to patients in 4 to 6 hours versus 24 to 144 hours for blood culture. In the pivotal clinical trial, the T2Candida Panel also demonstrated overall sensitivity of 91.1% and overall specificity of 99.4%. Furthermore, 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 that economic 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 detection of 60% of the patients (33 cases) with blood culture.

We believe T2Candida can enable clinicians to administer the most effective therapy, faster, significantly improving patient outcomes and reducing hospital 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.

T2Bacteria Panel

Our T2Bacteria Panel, which is FDA-cleared in the U.S. and CE marked in the EU, is a direct-from-blood test that detects certain bacterial pathogens associated with sepsis that are frequently not covered by first-line antibiotics, often referred to as the “ESKAPE pathogens.” The T2Bacteria Panel is designed for the detection of most of the ESKAPE pathogens from human whole blood specimens: *Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Pseudomonas aeruginosa*, *Escherichia coli*, and the CE marked T2Bacteria Panel in addition identifies a sixth species, *Acinetobacter baumannii*, with a positive percent agreement ranging from 81.3% to 100% and the negative percent agreement ranging from 95.0% to 100.0%. The ESKAPE pathogens 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. These pathogens cause over 2 million illnesses and 23,000 deaths per year. In the pivotal clinical trial the T2Bacteria Panel also demonstrated overall sensitivity of 90% and overall specificity of 98%.

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 the T2Bacteria Panel decreased the time to species identification on average by 55 hours faster than blood culture. The rapid detection and identification of the pathogens by the T2Bacteria Panel 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. Seitz T et al presented on the Evaluation of the clinical impact of the T2MR for the Diagnosis of Blood Stream Infections, where the data showed that the use of T2Bacteria led to a shorter length of stay for T2Bacteria of 10 days as compared with the 13 days for blood culture. The T2Bacteria Panel can ensure prompt diagnosis, assist clinicians in making clinical decisions about patient management such as the escalation or de-escalation of therapy faster, with improvement in patient care and outcomes, by potentially shortening the time of exposure to ineffective antibiotics, which may reduce the chances of developing anti-microbial resistance. Our sepsis panels are to be used in conjunction with whole blood cultures, and detecting the ESKAPE pathogens directly from whole blood in 3-5 hours, potentially enables therapy targeted to these organisms, which are often resistant to common empiric therapies. Detecting these commonly resistant organisms in 3-5 hours pre-culture is more critical than rapidly

detecting those organisms which typically respond to common empiric therapies. In August 2019, CMS granted approval for a New Technology Add-on Payment, or NTAP, for the T2Bacteria Panel, effective October 1, 2019, which was extended through the 2022 fiscal year. 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." Effective fiscal year 2023, T2 Bacteria is no longer eligible for NTAP reimbursement.

We believe T2Bacteria can enable clinicians to achieve targeted antimicrobial therapy, faster, significantly improving patient outcomes and reducing hospital 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 antimicrobial drugs.

T2Resistance Panel

Our T2Resistance Panel, which is CE marked in the EU, is a direct-from-blood test 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. The T2Resistance Panel 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 is recognized by the WHO as "one of the biggest threats to global health, food security, and development today."

We believe the T2Resistance Panel 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. Most importantly, these tests have the potential to enable more patients to get on appropriate targeted therapy faster, and thereby reduce mortality and hospitalization costs. The T2Resistance Panel 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 2023, and we believe the data from this trial may enable submission of a marketing application to the FDA in 2023.

T2SARS-CoV-2 Panel

Our T2SARS-CoV-2 Panel, which is commercially available in the United States under an EUA is designed to detect SARS-CoV-2, the virus that is responsible for COVID-19 infections, in certain patients. The T2SARS-CoV-2 Panel provides sample-to-answer results in less than two hours, utilizing a nasopharyngeal swab sample. Clinical testing on known positive and negative patient samples showed a sensitivity of 95% and specificity of 100%. The T2SARS-CoV-2 Panel runs on our T2Dx Instrument, and is capable of performing seven tests simultaneously. The Company has conducted a number of *in silico* analyses which have demonstrated that the T2SARS-CoV-2 was capable of detecting currently known variants of the SARS-CoV-2 virus.

In March 2020, we announced that we had licensed certain technology for the development of a rapid test for COVID-19 from the Center for Discovery and Innovation, or CDI, at Hackensack Meridian Health. Under this license agreement, T2 Biosystems is authorized to use the CDI technology and adapt the CDI-developed COVID-19 test to the T2 Biosystems platform, and market and distribute the test in places of need amid the expanding pandemic. In August 2020, we received an EUA from the FDA to market 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. COVID-19 has since become a global pandemic infecting over 760 million individuals and causing over 6.8 million deaths as of March 31, 2023.

SARS-CoV-2 has a wide-ranging clinical manifestation that contributes to increased morbidity and mortality from mild symptoms to hypoxic respiratory failure, acute respiratory distress syndrome, thromboembolic disease, cytokine release syndrome, multiorgan failure, and in some, secondary infections. A study by David R. Little et al has shown that patients who are hospitalized with COVID-19 are more likely to develop sepsis and septic shock when compared to patients admitted with influenza during the 2016, 2017, or 2018 flu seasons. COVID-19 pneumonia typically presents with fever, cough and dyspnea and this has led to the use of empirical antibiotics in patients by the physicians while waiting for laboratory and radiological results further compounding the problem of rational antimicrobial agent usage.

In a multicenter clinical study published in 2021 of hospitalized patients that were tested for COVID-19, the investigators found that SARS-CoV-2 positive patients were almost 2 times as likely to have a secondary pathogen detected during hospital onset period (42.4% vs 22.2%). There was also an increase in length of hospital stay for COVID-19 positive patients with a secondary positive pathogen detected vs patients with a negative pathogen specimen (13.7 vs 8.2 days). The data from the study additionally showed that 6 out of the top 10 pathogens detected by

blood cultures of admitted patients are identified by the T2Bacteria and T2Candida panels. The existing reimbursement codes support our sepsis products and COVID-19 product and we anticipate the same for our product candidates in development.

Products - in Development

T2Biothreat Panel

Our T2Biothreat Panel is a direct-from-blood test panel that is designed to run on the T2Dx Instrument and to simultaneously detect six biothreat pathogens identified as threats by the U.S. Government, including *Bacillus anthracis*, *Burkholderia mallei*, *Burkholderia pseudomallei*, *Francisella tularensis*, *Richettsia prowazekii* and *Yersinia pestis.* The T2Biotreat Panel is indicated as an aid in the diagnosis of anthrax, tularemia, melioidosis, glanders, typhus fever and plague. In December 2021, the Company initiated a U.S. clinical evaluation for the T2Biothreat Panel that includes positive samples being prepared and analyzed at a high-containment Biosafety Level 3 laboratory and negative samples being analyzed at a clinical site. The clinical evaluation was completed in 2022, and we believe the data from this evaluation will enable submission of a marketing application to the FDA in the first half of 2023.

T2Lyme Panel

Our T2Lyme Panel is a direct-from-blood test panel designed to run on the T2Dx Instrument to identify the bacteria that cause Lyme disease. We believe the T2Lyme Panel may benefit from similar advantages provided by our technology, including the potential for high sensitivity, high specificity, ease of use and rapid time to result. T2Lyme is designed to provide accurate and timely diagnosis of Lyme disease causing pathogens, 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, also known as LymeX, a partnership between the U.S Department of Health and Human Services and the Steven & Alexandra 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*, *Borrelia af*zelii, and *Borrelia garinii*, directly from human whole blood. We are currently exploring commercial opportunities with partners and plan to commence a U.S. clinical trial to support submission a marketing application to the FDA

T2Cauris

Our T2Cauris™ Panel is designed to provide direct detection of the emerging superbug *Candida auris* in patient skin, patient blood, and hospital environmental samples and is now available for RUO. The CDC evaluated the T2Cauris™ Panel swab test on patient skin samples and published their findings in *Mycoses*. We currently intend to complete development of the T2Cauris Panel and include the detection of *Candida auris* on our FDA-cleared and CE marked T2Candida Panel.

Candida auris is a multi-drug resistant pathogen recognized by the CDC as a serious global health threat because it can be resistant to all three major classes of antifungal drugs and is difficult to identify. The CDC has also reported that more than one-in-three patients with *Candida auris* infections have died. Unlike most other species of *Candida*, *Candida auris* can spread quickly in a hospital making rapid identification and hospital environment surveillance a critical component of containing these outbreaks. Existing laboratory methods that detect *Candida auris*, including blood culture, suffer from prolonged detection times and low accuracy, which exacerbates the challenge in the fight to contain the superbug. Recently, reported cases have surged internationally, and the CDC has reported a significant increase in infected patients in the United States. According to the European Centre for Disease Prevention and Control, hospital outbreaks have occurred in the United Kingdom and Spain. Because *Candida auris* can be resistant to most treatment options and can spread so quickly, these hospital outbreaks have been difficult to contain by even the most enhanced control measures.

The goals of the CDC collaboration were to use the T2Dx Instrument to (i) validate the detection of *Candida auris* from patient skin samples and hospital environmental samples, (ii) validate a process for surveillance of *Candida auris* in healthcare facilities from skin and

environmental samples, and (iii) assist state and local public health labs in combating the outbreak. In a study presented at ASM Microbe 2018 regarding the detection of *Candida auris*, it was found that our technology provided accurate diagnostic results from patient skin samples.

Comprehensive Sepsis Panel

Our comprehensive sepsis panel is a direct-from-blood test panel that is designed to run on our next generation instrument. The new test panel is designed to detect greater than 95% of all bloodstream infections caused by bacterial and *Candida* species, and antibiotic resistant markers identified as threats by the CDC, in a single test and to provide a time to result of approximately 3 hours. We believe this test panel, if successfully developed and authorized by the FDA, could be positioned as the primary test for patients at risk of sepsis, and substantially change the blood culture based laboratory workflow.

Next Generation Instrument

Our next-generation instrument, which is being developed in conjunction with our comprehensive sepsis panel, is designed to be fully automated, on-demand, and random access. This design is similar to our current T2Dx Instrument but incorporates faster turnaround times and is designed to detect an increased number of pathogens and resistance genes from a single, whole blood sample.

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 broad utilization among new and existing customers, and 2) expanding our T2Dx Instrument installed base by selling or placing new instruments.

  In 2022, we entered into contracts for 51 T2Dx Instruments, including 27 instruments in the U.S. and 24 outside the U.S. Our installed base of T2Dx Instruments at the end of 2022 was 181, including 106 in the U.S. and 75 internationally. We generated sepsis and related revenue of $8.4 million representing an increase of 17% compared to the prior year.

  We continue to expand our international distribution network which allows our products to be marketed and sold in more countries. Hospitals around the world face similar challenges when caring for patients suspected of sepsis and we are leaning into this opportunity. In 2022, we entered into exclusive distribution agreements with distributors in South Africa, and countries in Scandinavian and Baltic regions.

- ***Enhancing our Operations***. To sustain growth and drive adoption and utilization of our products over the long-term we continue to implement changes to our operations that enable a more efficient business model.

  During the second quarter of 2022, we reduced our overall cost structure, including reductions in headcount, which now stands at 150 employees, and operating expenses. As part of the headcount reductions, we also revised our hiring plans and eliminated several open roles, including the position of Chief Operations Officer.

  During 2022, we also made process improvements to the T2Bacteria and T2Candida Panels to reduce manufacturing costs and gain manufacturing efficiencies. We believe these improvements will contribute to improved product gross margins, which we expect to begin positively impacting our financial statements in 2023.

  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***. We are continuing to prioritize the programs under our milestone-based product development contract awarded by BARDA, which is valued at up to $62 million. The four products that we are advancing under the BARDA contract are the T2Resistance Panel, the T2Biothreat Panel, the comprehensive sepsis panel, and the next-generation instrument.

  We are currently operating in Option 3 of our BARDA contract, having successfully met all development milestones under the Base Phase, Option 1, Option 2A, and Option 2B. In March of 2023 we executed a no-cost extension with BARDA, under Option 3, to allow time for the completion of the T2Resistance U.S. clinical trial. In December 2021, we initiated the U.S. clinical trials for the T2Resistance Panel and the T2Biothreat Panel. The clinical trials are designed to evaluate the performance of the T2Resistance and T2Biothreat panels and support submission of marketing applications to the FDA.

  The T2Resistance Panel, which runs on our T2Dx Instrument, is a direct-from-blood test panel that simultaneously detects thirteen antibiotic resistance genes from both Gram-positive and Gram-negative bacterial pathogens, which are known to cause antibiotic-resistant infections that may lead to sepsis. It provides accurate results in 3-5 hours without the need to wait days for a positive blood culture. The T2Resistance Panel, which is currently marketed and sold in the EU under a CE-mark, was granted Breakthrough Device designation from the FDA, which offers manufacturers an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, and may help manufacturers receive feedback from the FDA in a timely way. All submissions for devices designated as Breakthrough Devices will receive priority review,

meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources at FDA, as needed. The clinical trial for the T2Resistance Panel, includes up to 1,500 patients across 10 U.S. hospitals, is estimated to cost T2 Biosystems $2.5 million and is expected to be completed in 2023, and we believe the data from this trial may enable filing a submission to the FDA in 2023.

The T2Biothreat Panel, which also runs on our T2Dx Instrument, is a direct-from-blood test panel that is designed to provide results in 3-5 hours, and to simultaneously detect six biothreat pathogens identified as threats by the CDC. The clinical evaluation was completed in 2022, and we believe the data from this evaluation will enable filing a submission to the FDA in early 2023.

The comprehensive sepsis panel is a direct-from-blood test panel that is designed to run on our next generation instrument. This test panel is designed to detect greater than 95% of all bloodstream infections caused by bacterial and *Candida* species, and antibiotic resistant markers identified as threats by the CDC, in a single test and to provide a time to result of approximately 3 hours. We believe this test panel, if successfully developed and authorized by the FDA, could be positioned as the primary test for patients at risk of sepsis, and substantially change the blood culture based laboratory workflow.

The next-generation instrument, which is being developed in conjunction with our comprehensive sepsis panel, is designed to be fully-automated, on-demand, and random access. This design is similar to our current T2Dx Instrument but incorporates faster turnaround times and is designed to detect an increased number of pathogens and resistance genes from a single, whole blood sample.

Sales, Marketing and Distribution

We are working to drive awareness and adoption of our products with a direct sales force that targets hospitals that treat critical care patients. At the end of 2022, our commercial organization consisted of 38 people, including sales, marketing, medical affairs, service and support.

Our sales team employs a strategic approach focusing on clinical value of our products highlighting clinical data, clinical performance of our products, improved patient outcomes and the 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 diagnostics and empiric therapy practices.

Today, our team markets and sells the T2Dx Instrument, T2Bacteria, T2Candida and T2SARS-CoV-2 products directly to hospitals in the United States. If these institutions optimize the full extent of our technology, we expect a positive network effect in the hospital community, accelerating 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, contributing positively to their adoption.

Outside of the United States, we have received marketing authorizations or certifications in the EU, Australia, and certain countries in the Middle East and Africa, and expect to seek regulatory authorizations or certifications in additional international markets. We market our products primarily through distribution partners who utilize a similar model as our sales approach in the United States. We have affixed a CE mark on our products as follows: T2Candida and T2Dx Instrument in July 2014, T2Bacteria in September 2017, and T2Resistance in November 2019. As of the end of 2022, 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 in infectious diseases and/or microbiology. We continue to develop partner relationships in other key international markets and plan to further expand our distribution channels in other key markets around the world. We have employed a small regionally-focused commercial team of business managers and field service personnel primarily to support the efforts of our distributors.

Medical and Clinical Affairs

We continue to educate physicians, key decision makers and thought leaders through publishing scientific data in peer-reviewed journals, presenting at major industry conferences and conducting and supporting clinical studies. Our clinical and medical affairs teams are 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 2022, our products were mentioned in over 52 publications, posters, and presentations.

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. 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 T2Candida and T2Bacteria to these decision-makers.

Manufacturing

We manufacture our proprietary T2Dx Instrument and our sepsis test panels at our manufacturing facilities in Lexington, MA and Wilmington, MA. 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.

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 35 issued U.S. patents and over 15 pending U.S. patent applications, including provisional and non-provisional filings. 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 T2Candida, T2Bacteria, T2Resistance, T2Cauris products, and our T2Lyme product candidates, as well as protection of certain aspects of the conduct of the assays and detection of analytes. The issued patents in our patent families that cover T2Candida and T2Bacteria are expected to expire between 2023 and 2034, while additional pending applications covering T2Candida and T2Bacteria would be expected, if issued, to expire as late as 2037. The issued patents in our patent families that cover T2Lyme are expected to expire between 2023 and 2034, while additional pending applications covering T2Lyme would be expected, if issued, to expire as late as 2037. In all cases, the expiration dates are subject to any extension that may be available under applicable law.

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 “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 products are used across all T2 Biosystems' product lines. 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 biotechnology products 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 the Company a milestone-based contract, with an initial value of $6.0 million, and a potential value of up to $62.0 million, if BARDA awards all contract options. BARDA operates within the Office of the Assistant Secretary for Preparedness and Response, or ASPR, at HHS. If BARDA awards 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, the Company completed the initial award and BARDA exercised the first contract option valued at $10.5 million. In September 2021, BARDA exercised Option 2A valued at approximately $6.4 million. In March 2022, BARDA exercised Option 2B valued at approximately $4.4 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 next generation instrument, T2Biothreat, T2Resistance and comprehensive sepsis panel. In May 2022, BARDA exercised Option 3 valued at approximately $3.7 million to further advance the U.S. clinical trials for the T2Resistance® Panel and T2Biothreat Panel and submitting applications to the FDA for U.S. regulatory clearance for those product candidates. Should BARDA reduce, cancel or not grant additional milestone projects, our ability to continue our future product development may be impacted.

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 whole blood, at limits of detection as low as 1 CFU/mL, without the need of culturing colony growth, we compete with commercial diagnostics companies for the limited resources of our customers. Our principal competition is from a number of companies that offer platforms and applications in our target sepsis markets, 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 in complex and high volume samples, including whole blood, eliminating the need for sample extraction and purification;
- our products' ability to detect a broad range of targets, providing a wide variety of potential applications both within and outside of the *in vitro* diagnostics market;
- our products' ability to provide rapid and highly-sensitive diagnostic results, which can provide timely information to assist physicians and hospitals to make therapeutic decisions that can improve patient outcomes and reduce healthcare costs;
- our ability to develop easily operable products for end users;
- 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; and
- our applications may provide substantial economic benefits to hospitals that can accrue the savings related to the rapid treatment of sepsis patients.

In addition to identifying sepsis-causing pathogens, we can also identify the existence of the SARS-CoV-2 virus. Competition for molecular testing of the SARS-CoV-2 virus includes the same large commercial organizations named above, and extends to other large companies like Abbott, Roche, Bio-Rad, PerkinElmer, Hologic, Thermo Fisher and others.

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 Pre-market Clearance and Approval Requirements

Each medical device we seek to commercially distribute in the United States must first receive 510(k) clearance, *de novo* classification, or 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. 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

Certain of our products have received 510(k) clearance from the FDA. 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 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 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.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process. For example, in September 2019, the FDA issued revised final guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintains a list of device types appropriate for the "safety and performance based" pathway and continues to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as recommended testing methods, where feasible.

Pre-market Approval Process

Class III devices require PMA approval before they can be marketed, although some pre-amendment Class III devices for which FDA has not yet required a PMA are cleared through the 510(k) process. 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 extensive data, including data from pre-clinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. After a PMA application is submitted and filed by the FDA, the FDA begins an in-depth review of the submitted information, which typically takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the QSR, which imposes elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval or requirements to conduct additional clinical studies post-approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as an original PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel. 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 a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

De novo Classification Process

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in July 2012, a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, FDA is required to classify the device within 120 days following receipt of the *de novo* application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the *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. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

Regardless of the degree of risk 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. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects. During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA'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 prioritized review of premarket submissions.

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 has 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.

Although the US Department for Human and Health Services has announced that it will be allowing the COVID-19 Public Health Emergency to expire on May 11, 2023, this expiration does not affect the FDA EUA process or the devices that are currently available through the EUA process. At present, there are no plans that have been announced by FDA to discontinue the EUA process, which would affect the company's ability to distribute the T2SARS-CoV-2 Panel as well as allow the Company to keep product that has already been sold to remain at those commercial inventories. It is expected that FDA will request those companies, like ours, that have products authorized under the COVID-19 EUA to have their products cleared under the premarket notification or premarket approval process if they wish to continue to distribute products commercially. It is also expected that FDA will provide at least 180 days to transition from EUA authorization to standard regulatory pathways.

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.

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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:

- including Medical Device Reporting, which requires manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury, or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.
- 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 and the 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 inspections by the FDA. 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 the company 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 the company 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 the company on August 12, 2022. While the T2Bacteria, T2Candida 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 the company must now pursue conformity routes for each product as the company continues to complete the transition to EU IVDR. This work was delayed by the company's Notified Body accreditation to certify to EU IVDR on February 25, 2023. The company 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 the federal government and the states and foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, 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 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. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the

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 civil False Claims Act prohibits, among other things, knowingly presenting or causing the presentation of a false or fraudulent claim for payment to, or approval by, the U.S. government. 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. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government intervenes and is ultimately successful in obtaining redress in the matter, or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. The federal government is using the 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.

The Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the 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 civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

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 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 of HIPAA's 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 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, including our T2SARS-CoV-2 Panel 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 the Company a milestone-based contract, with an initial value of $6.0 million, and a potential value of up to $62.0 million, if BARDA awards all contract options (the "U.S. Government Contract"). BARDA operates within the Office of the ASPR at HHS. If BARDA awards 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 Option 2A valued at approximately $6.4 million. 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 further advance the U.S. clinical trials for the T2Resistance Panel and T2Biothreat Panel and file submissions to the FDA for U.S. regulatory clearance for those products.

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 T2Biothreat, T2Resistance and our next generation instrument and comprehensive sepsis panel. The modification does not change the overall total potential value of the BARDA contract.

The Company recorded research and contribution revenue of $11.0 million and $11.4 million for the years ended December 31, 2022 and 2021, respectively, under the BARDA contract.

Human Capital Resources

At T2 Biosystems, employees are integral to the Company's 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, 2022, we had a total of 158 employees, including 110 employees working on-site, and 48 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 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, 2022 was $11.9 million, which will not be sufficient to fund our current operating plan for at least a year from issuance of these financial statements. While we completed an underwritten public offering in February 2023 in which the Company raised approximately $12 million in gross proceeds, before underwriting discounts and commissions and offering expenses, absent any reductions in current operating expenses, the Company believes it will require additional financing during the first half of 2023. 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 $5.0 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 30, 2024. There can be no assurances that we will be able to refinance on terms favorable or at all. The amounts involved in any such transactions, individually or in the aggregate may be material.

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 are issued. Management's plans to alleviate the conditions that raise substantial doubt include raising additional capital, earning payments pursuant to our contract with BARDA, 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 these financial statements.

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

If we fail to regain or maintain compliance with the continued listing requirements of The Nasdaq Capital Market, Nasdaq may take steps to delist our common stock.

On June 9, 2022, we received a letter from the Nasdaq notifying us that the Nasdaq had granted our request to be transferred to The Nasdaq Capital Market, effective at the open of trading on June 13, 2022, and our request for an exception to the Bid Price Rule was granted until November 1, 2022.

On October 11, 2022, at the annual meeting of stockholders, our stockholders approved an amendment to our restated certificate of incorporation to effect a reverse stock split of our common stock. Following the receipt of the stockholders' approval, our board of directors approved the reverse stock split at the ratio of 1 post-split share for every 50 pre-split shares, which was effective as of October 12, 2022. On October 31, 2022, we received a letter from Nasdaq informing us that we regained compliance with the Bid Price Rule. However, there is no assurance that the market price per share of our common stock will continue to remain in excess of the $1.00 minimum bid price as required by Nasdaq, or that we will otherwise meet the requirements of Nasdaq for continued inclusion for trading on The Nasdaq Capital Market.

On November 22, 2022, we received a letter from Nasdaq indicating that, for the last thirty consecutive business days, the Market Value of Listed Securities, as defined by Nasdaq ("MVLS") had been below the $35 million minimum requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have been provided an initial period of 180 calendar days, or until May 22, 2023, to regain compliance. The letter states that the Nasdaq staff will provide written notification that we have achieved compliance with Rule 5550(b)(2) if at any time before May 22, 2023, our MVLS closes at $35 million or more for a minimum of ten consecutive business days. The letter has no immediate effect on the listing or trading of our common stock. If compliance in

not achieved by May 22, 2023, we expect that Nasdaq would provide written notification to us that our securities are subject to delisting. We will continue to monitor our MVLS and consider our available options to regain compliance with the Nasdaq minimum MVLS requirements, which may include applying for an additional extension of the compliance period or appealing to a Nasdaq Hearings Panel.

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 minimum bid price requirement would stabilize the market price or improve the liquidity of our common stock, prevent our common stock from falling below the minimum bid price 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, 2022 and expect to incur losses in the future. Our accumulated deficit as of December 31, 2022 was $534.2 million and we incurred net losses of $62.0 million and $49.2 million for the years ended December 31, 2022 and 2021, 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.

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 $1,000,000 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, 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. 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 sales and marketing 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.

The COVID-19 pandemic has had, and may continue to have, an adverse impact on our business, including our marketing and research activities, and results of operations.

The global outbreak of COVID-19 continues to and has had adverse effects on general commercial activity and the global economy, including research, manufacturing and distributions.

We have a significant development contract with a United States government agency and should the agency reduce, cancel or not grant additional milestone projects, our ability to continue our future product development may be impacted. The COVID-19 pandemic also caused us to reassess our build plan and evaluate inventories accordingly.

In addition, the trading prices for our and other life sciences companies' stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. The extent to which COVID-19 may continue to impact our business, research and development programs and operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, supply chain disruptions, and the effectiveness of actions taken in the United States and other countries to contain and manage the disease. In addition, if we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted, which could have a material adverse effect on our business and our financial results.

Until we achieve scale in our business model our revenue will be primarily generated from the T2Dx Instrument, T2Candida, T2Bacteria, T2Resistance and T2SARS-CoV-2 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 T2SARS-CoV-2 in 2020 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, T2Resistance and T2SARS-CoV-2 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, T2Resistance and T2SARS-CoV-2 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 sell them in the US in the third quarter of 2014, applied the CE mark to the T2Bacteria Panel in 2018, applied the CE mark to T2Resistance in 2019, and received EUA to sell T2SARS-CoV-2 in August 2020, we have limited experience marketing and selling our products. As of December 31, 2021, our commercial organization consisted of 31 people, including 22 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 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.

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, or the COVID-19 pandemic 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. In February 2023, we experienced a raw material issue that was identified during our routine internal quality inspection that limited our ability to manufacture sufficient volume of certain consumable products to meet customer demand. We have resumed manufacturing and shipping these products in March 2023. To the extent we experience similar issues in the future, it 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. We also compete with numerous companies that provide COVID-19 diagnostic testing in hospitals, including, but not limited to Roche, Abbott Laboratories, bioMerieux, Inc. and Cepheid.

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, T2Candida, T2Bacteria, T2Resistance and T2SARS-CoV-2 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.

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 $1,000,000 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, 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 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.

Provisions of our debt instruments may restrict our ability to pursue our business strategies.

Our credit facilities require 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. If we default, which includes a material adverse change, under our credit facilities, and such event of default was not cured or waived, the lenders 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.

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.

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, 2022, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of $256.7 million, which are available to offset future taxable income, if any, of which $34.9 million begin to expire in 2026 and $221.8 million carry forward indefinitely. Since 2020 and through 2022, 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. In August 2019, we were the subject of a ransomware attack that resulted in the encryption of certain data stored on our computer network. Although we did not pay the ransom; the attack did not materially affect business operations; and there was no evidence of a loss of data or inappropriate disclosure of confidential or proprietary information, we did incur additional cost, expense and the diversion of time and resources to recover from the attack and the Company's management concluded that our disclosure controls and procedures were not effective at that time due to a material weakness in our internal control over the quality, frequency and periodic testing of the backup of our Information System data. We have strengthened our network security and infrastructure following the attack, however, 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. 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. 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. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. However, some devices are automatically subject to the PMA pathway regardless of the level of risk they pose because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that FDA review such devices in accordance with the *de novo* classification procedure, which allows a manufacturer whose novel device would otherwise require the submission and approval of a PMA prior to marketing to request down-classification of the device on the basis that the device presents low or moderate risk. If the FDA agrees with the down-classification, the applicant will then receive approval to market the device. This device type can then be used as a predicate device for future 510(k) submissions. 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 recently evolved. On May 26, 2022, the EU In Vitro Diagnostic Medical Devices Regulation, or IVDR, entered into force, which repeals and replaces the EU In Vitro Diagnostic Medical Devices Directive (*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 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.

Moreover, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, on February 23, 2022, the FDA issued a proposed rule to amend the QSR, which establishes current good manufacturing practice requirements for medical device manufacturers, to align more closely with ISO:13485 (2016), as established by the International Organization for Standardization. This proposal has not yet been finalized or adopted. Accordingly, it is unclear the extent to which this or any other proposals, if adopted, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create competition that may negatively affect our business.

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. 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 are regulated by the FDA as medical devices, and 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. Although medical devices are subject to stringent FDA oversight, 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 viewed by the FDA as adulterated and misbranded under the FDCA, and subject to FDA enforcement action. The FDA has indicated that when determining the intended use of a product labeled RUO, 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. 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 until we are in compliance with applicable regulations, 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.

We are subject to extensive regulatory requirements in connection with the EUA we received for our T2SARS-CoV-2 Test Panel. If we fail to comply with these requirements, or if the FDA otherwise determines that the conditions no longer warrant such authorization, we will be unable to market our products pursuant to this authorization and our business may be harmed.

In August 2020, the FDA granted an EUA to our T2SARS-CoV-2 Panel, authorizing its commercial sale and use 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, for the duration of the COVID-19 public health emergency, without the need to obtain premarket clearance or approval under the FDA's standard review pathways. The FDA has also established certain conditions which must be met in order to maintain authorization under this EUA. The requirements that apply to the manufacture and sale of these products may be unclear and are subject to change.

Under section 564 of the FDCA, the FDA has authority to issue an EUA under certain circumstances, such as during a public health emergency, pursuant to a declaration by the Secretary of the Department of Health and Human Services, or HHS, 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 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 for a specific product. 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 chemical, biological, radioactive or nuclear agent, or 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. These standards for marketing authorization are lower than if the FDA had reviewed our test under its traditional marketing authorization pathways, and we cannot assure you that the T2SARS-CoV-2 Panel would be cleared or approved under those more onerous clearance and approval standards.

Moreover, the FDA's policies regarding EUAs can change unexpectedly, and the FDA may revoke an EUA where it determines that the underlying health emergency no longer exists or warrants such authorization or if problems are identified with the authorized product. We cannot predict how long our EUA will remain in place. FDA policies regarding diagnostic tests, therapies and other products used to diagnose, treat or mitigate COVID-19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence. For example, in December 2021, the FDA issued a draft guidance describing a potential transition plan for the regulation and distribution of emergency-use-authorized medical devices in the event that the current EUA declaration is terminated. Changes to FDA regulations or requirements could require changes to our authorized test, necessitate additional measures or make it impractical or impossible for us to market our test. The termination of an EUA for our T2SARS-CoV-2 Panel would adversely impact our business, financial condition and results of operations.

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.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical studies. 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.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business

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 but the COVID-19 pandemic has significantly slowed down their designation process. Without IVDR designation, notified bodies may not yet start certifying devices in accordance with the new regulation. As only a few notified bodies has 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, including our T2SARS-CoV-2 Panel, 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 35 issued U.S. patents and over 15 pending U.S. patent applications, including provisional and non-provisional filings. 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.

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 Hackensack Meridian Health, 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 patents we 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 these patents against third-party infringement, we cannot be certain that MGH will elect to enforce these patents 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 patents 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

An active trading market for our common stock may not be sustained.

Since our initial listing on The Nasdaq Global Market in August 2014, the trading market in our common stock has historically been limited. The listing of our common stock on The Nasdaq Global Market does not assure that a meaningful, consistent and liquid trading market currently exists. We cannot predict whether a more 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:

- 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 Global 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.

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.

General Risk Factors

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 2. PROPERTY

Our corporate headquarters is located in Lexington, Massachusetts, where we currently lease approximately 32,000 square feet of office space of which 11,000 square feet was vacated in 2020, 12,200 square feet of laboratory space and 11,000 square feet of 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.

We believe the Landlord's claims are without merit and we intend to vigorously contest the claim.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II.

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOC KHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders

Our common stock has been quoted on The Nasdaq Capital Market under the symbol "TTOO" and has been trading since August 7, 2014. On March 27, 2023, there were 14 holders of record of our common stock.

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 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 T2SARS-CoV-2™ Panel.

We have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit at December 31, 2022 was $534.2 million and we have experienced cash outflows from operating activities over the past years. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations. We have incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution of our FDA-cleared products, the T2Dx Instrument, T2Candida Panel and T2Bacteria 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, T2Candida, T2Bacteria, T2Resistance, T2SARS-CoV-2 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.

The COVID-19 pandemic has impacted and may continue to impact the Company's operations as the pandemic shifts to an endemic health threat. Customers have significantly reduced their purchases of the Company's COVID-19 tests and the Company has forecasted no COVID-19 test sales in 2023.

We believe that our cash, cash equivalents, and restricted cash of $11.9 million at December 31, 2022 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 2023. Certain elements of our operating plan cannot be considered probable. During the year ended December 31, 2022, 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 Term Loan Agreement with CRG Servicing LLC ("CRG") (the "Term Loan Agreement") (See Note 6 of the notes to our consolidated financial statements) has a minimum liquidity covenant which requires the Company to maintain a minimum cash balance of $5.0 million. There can be no assurances that it will continue to be in compliance with the cash covenant in future periods without additional funding. In November 2022, CRG amended the Term Loan Agreement, extending the interest only period and maturity to December 30, 2024.

On March 30, 2023, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1). Under Nasdaq rules, we have 180 calendar days (September 26, 2023) to regain compliance by increasing the stock price to over $1.00.

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, earning payments pursuant to our contract with BARDA, 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 the 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 these consolidated 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, to increase test use by our existing hospital customers, and to convert T2SARS-CoV-2 customers to sepsis testing. 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.

We have a significant development contract with BARDA and should BARDA reduce, cancel or not grant additional milestone projects, our ability to continue certain future product development programs may be impacted.

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. We have a significant development contract with BARDA and should BARDA reduce, cancel or not grant additional milestone projects, our ability to continue our future product development may be impacted.

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.

Interest income

Interest income consists of interest earned on our cash and cash equivalents.

Interest expense

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

Change in fair value of derivative instrument

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 derivative warrant liability

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 income

Other income consists of dividend and other investment income.

Other expense

Other expense consists of non-recurring expenses, including issuance costs allocated to the derivative warrant liability.

Other gains/losses

Other gains/losses consists of 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, 2022 and 2021

	Year ended December 31,		
	2022	2021	Change
		(in thousands)	
Revenue:			
Product revenue	$ 11,259	$ 16,646	$ (5,387)
Contribution revenue	11,046	11,412	(366)
Total revenue	22,305	28,058	(5,753)
Costs and expenses:			
Cost of product revenue	21,101	20,703	398
Research and development	25,775	21,801	3,974
Selling, general and administrative	30,625	28,527	2,098
Total costs and expenses	77,501	71,031	6,470
Loss from operations	(55,196)	(42,973)	(12,223)
Other income (expense):			
Interest income	8	112	(104)
Interest expense	(6,084)	(7,596)	1,512
Change in fair value of derivative instrument	(1,088)	1,010	(2,098)
Change in fair value of warrant liability	326	—	326
Other income	125	218	(93)
Other expense	(15)	—	(15)
Other gains/losses	(79)	(12)	(67)
Total other expense	(6,807)	(6,268)	(539)
Net loss	$ (62,003)	$ (49,241)	$ (12,762)

Product revenue

During the year ended December 31, 2022, product revenue was $11.3 million, compared to $16.6 million for the year ended December 31, 2021, a decrease of $5.4 million. The decrease was driven by lower consumable sales of $6.3 million due to a decrease in sales of our T2SARS-CoV-2 product, and lower revenue under our service agreements of $0.1 million, offset by higher T2Dx instrument sales of $1.1 million.

Contribution revenue

Contribution revenue, all from the BARDA contract, was $11.0 million for the year ended December 31, 2022, compared to $11.4 million for the year ended December 31, 2021, a decrease of $0.4 million. The decrease was driven by decreased contract activity.

Cost of product revenue

During the year ended December 31, 2022, cost of product revenue was $21.1 million, compared to $20.7 million for the year ended December 31, 2021, an increase of $0.4 million. The increase was driven by $5.6 million of higher costs due to the effect of a change in build plan and manufacturing inefficiencies, $1.8 million of costs related to higher instrument sales, $0.3 million of higher shipping and other costs, and a $0.1 million impairment charge, partially offset by $6.8 million of decreased costs related to lower consumable sales, $0.3 million of lower service and repair costs and $0.3 million of lower royalties.

Research and development expenses

Research and development expenses were $25.7 million for the year ended December 31, 2022, compared to $21.8 million for the year ended December 31, 2021, an increase of $4.0 million. The increase was driven by clinical related expenses of $2.6 million for our T2Resistance Panel 510(k) Study and T2Biothreat Panel, internal usage of $1.9 million primarily for T2Resistance research and development projects, higher payroll related expenses of $0.5 million and stock based compensation expenses of $0.1 million due to a higher 2022 year-to-date average headcount, higher materials costs of $0.3 million and consulting expenses of $0.1 million primarily for BARDA, partially offset by a decrease of $1.5 million in lab and facility expenses related to less IT support services and less BARDA lab expenses.

Selling, general and administrative expenses

Selling, general and administrative expenses were $30.7 million for the year ended December 31, 2022, compared to $28.5 million for the year ended December 31, 2021, an increase of $2.2 million. The increase was driven by a $1.0 million estimated liability recorded for our Billerica, Massachusetts lease, a $0.7 million increase in payroll related expenses due to higher year-to-date average headcount, $0.6 million of increased travel primarily from higher average sales headcount, tradeshows and conferences, $0.3 million of increased marketing expenses primarily for tradeshows and conferences and higher consulting expenses of $0.5 million, partially offset by lower stock based compensation expenses of $0.7 million primarily due to the $0.8 million equity modification recorded in the third quarter of 2021 upon a previous director’s resignation, lower director fees of $0.1 million that were paid as a result of the aforementioned director's resignation and other expenses of $0.1 million primarily related to less IT support services.

Interest income

Interest income was immaterial for the year ended December 31, 2022 and $0.1 million for the year ended December 31, 2021. The decrease of $0.1 million was due to the maturity of our marketable securities.

Interest expense

Interest expense was $6.1 million for the year ended December 31, 2022, compared to $7.6 million for the year ended December 31, 2021. Interest expense decreased by $1.5 million primarily due to the February 2022 and November 2022 amendments to the CRG Term Loan Agreement which extended the interest only period and maturity date.

Change in fair value of derivative instrument

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 $1.1 million of expense for the year ended December 31, 2022. The change in fair value of the derivative instrument was a $1.0 million reduction of expense for the year ended December 31, 2021 as we achieved the only remaining revenue covenant in June 2021 and had sufficient cash and cash equivalents that the minimum liquidity covenant would not be triggered, relieving the derivative liability.

Change in fair value of derivative warrant liability

The change in fair value of the derivative warrant liability associated with the Securities Purchase Agreement (See Note 6 of the notes to our consolidated financial statements) was a $0.3 million reduction of expense for the year ended December 31, 2022. There was no derivative warrant liability recorded at December 31, 2021.

Other income

Other income was expense of $0.1 million for the ended December 31, 2022 primarily due to the loss recorded upon issuance of the Series A redeemable convertible preferred stock and warrant compared to income of $0.2 million for the year ended December 31, 2021 primarily from a one-time payment.

Other expense

Other expense related to the issuance costs allocated to the derivative warrant liability was immaterial for the year ended December 31, 2022. Other expense was not recorded for the year ended December 31, 2021.

Other gains/losses

Other gains/losses of $0.1 million for the year ended December 31, 2022 primarily due to the initial loss on issuance of Series A redeemable convertible preferred stock and derivative warrant liability. Other gains/losses were immaterial for the year ended December 31, 2021.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of December 31, 2022 and 2021, we had an accumulated deficit of $534.2 million and $472.2 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 2023. 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.

In July 2021, our shareholders approved of an increase in the number of authorized shares of our common stock from 200,000,000 to 400,000,000.

Equity Distribution Agreement

On March 31, 2021, we entered into a Sales Agreement ("Sales Agreement") with Canaccord Genuity LLC, as agent ("Canaccord"), pursuant to which we 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. We sold 366,188 shares of common stock for net proceeds of $20.0 million during the year ended December 31, 2021. We sold 4,306,879 shares under the Sales Agreement for net proceeds of $29.2 million after expenses during the year ended December 31, 2022.

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

Plan of operations and future funding requirements

As of December 31, 2022 and 2021 we had unrestricted cash and cash equivalents of approximately $10.3 million and $22.2 million, respectively. Our marketable securities of $10.0 million as of December 31, 2021 were held in U.S. treasury securities. 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.

The COVID-19 pandemic has impacted and may continue to impact the Company's operations as the pandemic shifts to an endemic health threat. Customers have begun to reduce their purchases of the Company's Covid test products and the Company believes this trend will continue.

Going Concern

We believe that our cash, cash equivalents, and restricted cash of $11.9 million at December 31, 2022 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 2023. Certain elements of our operating plan cannot be considered probable.

The Term Loan Agreement with CRG Servicing LLC ("CRG") (Note 6) has a minimum liquidity covenant which requires the Company to maintain a minimum cash balance of $5.0 million. There can be no assurances that the Company will continue to be in compliance with the cash covenant in future periods without additional funding. In February 2022, CRG amended the Term Loan Agreement, extending the interest only period and maturity to December 30, 2023. In November 2022, CRG amended the Term Loan Agreement, extending the interest only period and maturity to December 30, 2024.

The Nasdaq Stock Market LLC ("Nasdaq") has $1.00 minimum bid price and $35 million minimum market value rules. Since 2021 the Company has violated, appealed to Nasdaq and cured its violation of these rules several times.

On November 22, 2022, the Company received notice from the Nasdaq indicating that the Company was in violation of the $35 million minimum market value rule. The Company has until May 22, 2023, to regain compliance which includes a closing market value of $35 million or more for a minimum of ten consecutive business days. If compliance in not achieved by May 22, 2023, the Company believes the Nasdaq will

notify the Company that its securities are subject to delisting. The Company is considering applying for an extension to the compliance period or appealing to a Nasdaq Hearings Panel.

On March 30, 2023, we received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1). Under Nasdaq rules, we have 180 calendar days (September 26, 2023) to regain compliance by increasing the stock price to over $1.00.

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, earning payments pursuant to our contract with BARDA, 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 the 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 these consolidated 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,	
	2022	2021
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (50,629)	$ (38,874)
Investing activities	9,659	24,791
Financing activities	29,054	20,535
Net increase in cash, cash equivalents and restricted cash	$ (11,916)	$ 6,452

Net cash used in operating activities

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 of $2.1 million, non-cash lease expense of $1.2 million, a change in fair value of the derivative instrument 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 operating activities was $38.9 million for the year ended December 31, 2021, and consisted primarily of a net loss of $49.2 million, an adjustment for non-cash items including stock-based compensation expense of $7.1 million, non-cash interest expense of $3.8 million, depreciation and amortization expense of $1.3 million, non-cash lease expense of $1.3 million, a change in fair value of derivative of $1.0 million, amortization of bond premium of $0.2 million, and a net change in operating assets and liabilities of $2.2 million. The net change in operating assets and liabilities was primarily driven by a decrease in operating lease liabilities of $1.2 million, a decrease in deferred revenue of $0.1 million, an increase in prepaid expenses and other current assets of $0.5 million primarily related to deposits made and software subscription renewals, and an increase in inventories of $1.9 million due to bulk materials purchases for favorable pricing, partially offset by an increase in accounts payable of $0.8 million due to timing of payments, and an increase in accrued expenses of $0.8 million, mostly due to increased employee costs.

Net cash used in investing activities

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 investing activities was $24.8 million for the year ended December 31, 2021, and consisted of $25.3 million of proceeds from the maturities of marketable securities, offset by $0.5 million of costs to acquire property and equipment.

Net cash provided by financing activities

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.

Net cash provided by financing activities was $20.5 million for the year ended December 31, 2021, and consisted primarily of net proceeds of $20.0 million under the Sales Agreement, and net proceeds of $0.6 million from the exercise of stock options and employee stock purchase plan.

Borrowing Arrangements

Term Loan Agreement

In December 2016, we entered into a Term Loan Agreement with CRG. We borrowed $40.0 million pursuant to the Term Loan Agreement, which has a six-year term with three years (through December 30, 2019) of interest-only payments, which period was extended to four years (through December 30, 2020) upon achieving the Approval Milestone, after which quarterly principal and interest payments would be due through the December 30, 2022 maturity date. In February 2022, we amended our agreement with CRG to extend the maturity date from December 30, 2022 to December 30, 2023. In November 2022, CRG amended the Term Loan Agreement, extending the interest only period and maturity to December 30, 2024. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of (a) prior to the Approval Milestone, 12.50%, 4.0% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount and (b) following the Approval Milestone, 11.50%, 3.5% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. In addition, if we achieve certain financial performance metrics, the loan will convert to interest-only until the December 30, 2024 maturity, at which time all unpaid principal and accrued unpaid interest will be due and payable. We are required to pay CRG a financing fee based on the loan principal amount drawn. We are also required to pay a final payment fee of 8%, subsequently amended to 10%, of the principal outstanding upon repayment. We are accruing the final payment fee as interest expense and it is included as a non-current liability at December 31, 2022 and December 31, 2021 on the balance sheet to conform to the classification of the associated debt in those periods.

The Term Loan Agreement with CRG is classified as a non-current liability at December 31, 2022 as the Company amended the agreement in November 2022, which extended the maturity date to December 30, 2024 and obtained a waiver for default in January 2023. The Term Loan Agreement with CRG is classified as a non-current liability at December 31, 2021 as the Company amended the agreement in February 2022, which extended the maturity date to December 30, 2023. We have assessed the classification of the note payable as non-current based on facts and circumstances as of the date of this filing. Management continues to reassess at each balance sheet and filing date based on facts and circumstances and can provide no assurances regarding the probability of meeting its minimum liquidity covenant in future periods.

We may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Term Loan Agreement at any time upon prior notice subject to a certain prepayment fee during the first five years of the term and no prepayment fee thereafter. As security for our obligations under the Term Loan Agreement, we entered into a security agreement with CRG whereby we granted a lien on substantially all of its assets, including intellectual property. The Term Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type, including a requirement to maintain a minimum cash balance of $5.0 million.

In 2019, the Term Loan Agreement was amended to reduce minimum revenue targets, extend the interest-only period and extend the principal repayment. The final payment fee was increased from 8% to 10% of the principal amount outstanding upon repayment. We issued to CRG warrants to purchase 11,365 shares of the Company's common stock ("New Warrants") (See Note 6 of the notes to our consolidated financial statements) at an exercise price of $77.50, with typical provisions for termination upon a change of control or a sale of all or substantially all of our assets. We also reduced the exercise price for the warrants previously issued to CRG to purchase an aggregate of 10,579 shares of our common stock to $77.50. All of the New Warrants are exercisable any time prior to September 9, 2029, and all of the previously issued warrants are exercisable any time prior to December 30, 2026.

In January 2021, the Term Loan Agreement was amended to extend the interest-only payment period through December 30, 2022, to extend the initial principal repayment to December 30, 2022, and to significantly reduce the revenue covenant for the 24-month period beginning on

January 1, 2020. We did not pay or provide any consideration in exchange for this amendment. We accounted for the January 2021 amendment as a modification to the Term Loan Agreement. In June 2021, the Company satisfied the only remaining revenue covenant which was for the 24-month period beginning on January 1, 2020.

In February 2022, the Term Loan Agreement was amended to extend the interest-only payment period through December 30, 2023, and to extend the initial principal repayment to December 30, 2023. In November 2022, CRG amended the Term Loan, extending the interest only period and maturity to December 30, 2024.

We did not pay or provide any consideration in exchange for these amendments. As the effective borrowing rate under the amended agreements was less than the effective borrowing rate under the previous agreement, a concession was deemed to have been granted under ASC 470-60. As a concession was granted, the agreements were accounted for as troubled debt restructurings under ASC 470-60. The amendments did not result in a gain on restructuring as the future undiscounted cash outflows required under the amended agreements exceed the carrying value of the debt immediately prior to the amendment.

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 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 will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default. CRG has not exercised its right under this clause.

We assessed the terms and features of the Term Loan Agreement, including the interest-only period dependent on the achievement of the Approval Milestone and the acceleration of the obligations under the Term Loan Agreement under an event of default, of the Term Loan Agreement in order to identify any potential embedded features that would require bifurcation. In addition, under certain circumstances, a default interest rate of an additional 4.0% per annum will apply at the election of CRG on all outstanding obligations during the occurrence and continuance of an event of default, we concluded that the features of the Term Loan Agreement are not clearly and closely related to the host instrument, and represent a single compound derivative that is required to be re-measured at fair value on a quarterly basis.

The fair value of the derivative at December 31, 2022 is $1.1 million and is classified as a non-current liability on the balance sheet at December 31, 2022 to match the classification of the related Term Loan Agreement. At December 31, 2021, we had no derivative liability.

Contingent Liabilities and Commitments, Including Tax Matters

We have net deferred tax assets of $87.8 million as of December 31, 2022, 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, 2022, we had federal NOL carryforwards of $256.7 million available to reduce future taxable income, if any. Out of the total NOL carryforwards of $256.7 million, $34.9 million begin to expire in 2026 and $221.8 million carryforward indefinitely. As of December 31, 2022, we had state NOL carryforwards of $303.0 million, of which $233.8 million expire at various dates through 2042 and $69.2 million is carried forward indefinitely. As of December 31, 2022, we had federal tax credit carryforwards of $0.5 million and state tax credit carryforwards of $0.7 million which expire at various dates through 2042 and 2037, respectively.

In 2022, we completed a study which identified an additional ownership change in 2022. 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 at December 31, 2022. We disagree with Landlord’s allegations and actions and believes that the Landlord is in breach of certain of its materials obligations under the lease. We have filed 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 and intend to vigorously defend ourselves and pursue all legal remedies available under applicable laws. We believe we will continue to meet our current manufacturing needs with our operations at our 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.

See Note 2 of the notes to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K for additional information on our accounting policies and significant judgments.

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, 2022 and 2021, 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 then ended, 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, 2022 and 2021, 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, has experienced cash outflows from operating activities over the past year, has uncertainties related to achieving a debt covenant – which contains a minimum cash balance – in the future, 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 Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates 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 the critical audit matter 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 matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of certain inventories

As described in Note 2, the Company performs an assessment of the recoverability of capitalized inventory during each reporting period, which includes evaluation of any excess and obsolete inventories, 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. The Company classifies certain inventories, including raw material and work-in-process inventories, used for reagent rentals or internal use purposes such as testing, as a component of property and equipment based on the Company's business model and forecast.

We identified the estimation of the valuation of certain inventories as a critical audit matter. Management applies significant judgment in determining the net realizable value of inventories specifically related to estimated future average selling prices of certain inventories. Auditing these elements required significant auditor judgment and subjectivity including the nature and extent of audit effort required to address these matters.

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

- Testing management’s process for developing the net realizable value estimate of certain inventories; evaluating the appropriateness of management’s estimated net realizable value methodology; testing the completeness, accuracy, and relevance of underlying data used in the estimate of net realizable value of certain inventories.
- Evaluating management’s assumptions related to future average selling prices by considering current and past average selling prices, including actual selling prices subsequent to year end.

/s/ BDO USA, LLP
We have served as the Company's auditor since 2018.
Boston, Massachusetts
March 31, 2023

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 10,329	$ 22,245
Marketable securities	—	9,996
Accounts receivable	2,163	5,134
Inventories	4,285	3,909
Prepaid expenses and other current assets	2,582	3,110
Total current assets	19,359	44,394
Property and equipment, net	4,533	4,675
Operating lease right-of-use assets	8,741	9,766
Restricted cash	1,551	1,551
Other assets	143	153
Total assets	$ 34,327	$ 60,539
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,296	$ 2,832
Accrued expenses and other current liabilities	7,269	7,164
Operating lease liability	1,352	1,174
Warrant liability	39	—
Deferred revenue	172	518
Total current liabilities	10,128	11,688
Notes payable	49,651	47,790
Operating lease liabilities, net of current portion	8,214	9,359
Deferred revenue, net of current portion	52	28
Derivative liability	1,088	—
Accrued interest on term loan	4,849	4,577
Total liabilities	73,982	73,442
Commitments and contingencies (see Notes 12 & 13)		
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 7,716,519 and 3,328,017 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	8	3
Additional paid-in capital	494,556	459,314
Accumulated other comprehensive loss	—	(4)
Accumulated deficit	(534,219)	(472,216)
Total stockholders' deficit	(39,655)	(12,903)
Total liabilities and stockholders' deficit	$ 34,327	$ 60,539

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,	
	2022	**2021**
Revenue:		
Product revenue	$ 11,259	$ 16,646
Contribution revenue	11,046	11,412
Total revenue	22,305	28,058
Costs and expenses:		
Cost of product revenue	21,101	20,703
Research and development	25,775	21,801
Selling, general and administrative	30,625	28,527
Total costs and expenses	77,501	71,031
Loss from operations	(55,196)	(42,973)
Other income (expense):		
Interest income	8	112
Interest expense	(6,084)	(7,596)
Change in fair value of derivative instrument	(1,088)	1,010
Change in fair value of warrant liability	326	—
Other income	125	218
Other expense	(15)	—
Other losses	(79)	(12)
Total other expense	(6,807)	(6,268)
Net loss	$ (62,003)	$ (49,241)
Deemed dividend on Series A redeemable convertible preferred stock	$ (330)	$ -
Net loss attributable to common stockholders	$ (62,333)	$ (49,241)
Net loss per share — basic and diluted	$ (12.22)	$ (15.50)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	5,100,395	3,177,228
Other comprehensive loss:		
Net loss	$ (62,003)	$ (49,241)
Net unrealized gain (loss) on marketable securities arising during the period	2	(4)
Less: net realized gain (loss) on marketable securities included in net loss	2	(9)
Total other comprehensive gain (loss), net of taxes	4	(13)
Comprehensive loss	$ (61,999)	$ (49,254)

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)

	Series A Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	—	—	2,961,579	$ 3	- $ 431,689	- $ (422,975)	- $ 9	- $ 8,726
Stock-based compensation expense	—	—	—	—	7,090	—	—	7,090
Issuance of common stock from vesting of restricted stock, exercise of stock options and employee stock purchase plan	—	—	30,247	—	567	—	—	567
Issuance of common stock from secondary public offerings, net of offering costs of $0.8 million	—	—	336,188	—	19,968	—	—	19,968
Unrealized loss on marketable securities	—	—	—	—	—	—	(13)	(13)
Reverse stock split rounding adjustment	—	—	3	—	—	—	—	—
Net loss	—	—	—	—	—	(49,241)	—	(49,241)
Balance at December 31, 2021	—	—	3,328,017	3	459,314	(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	—	—	92,336	—	165	—	—	165
Shares surrendered for income taxes	—	—	(10,781)	—	(243)	—	—	(243)
Issuance of common stock from secondary offering, net of offering costs	—	—	4,306,897	5	29,157	—	—	29,162
Issuance of Series A convertible preferred stock	3,000	—	—	—	—	—	—	—
Deemed dividend for Series A convertible preferred stock	—	330	—	—	(330)	—	—	(330)
Redemption of Series A redeemable convertible preferred stock	(3,000)	(330)	—	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	—	—	—	4	4
Reverse stock split rounding adjustment	—	—	50	—	—	—	—	—
Net loss	—	—	—	—	—	(62,003)	—	(62,003)
Balance at December 31, 2022	—	—	7,716,519	$ 8	$ 494,556	$ (534,219)	$ —	$ (39,655)

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (62,003)	$ (49,241)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,047	1,270
Amortization of bond premium	—	152
Amortization of operating lease right-of-use assets	1,224	1,268
Stock-based compensation expense	6,493	7,090
Change in fair value of derivative instrument	1,088	(1,010)
Change in fair value of warrant liability	(326)	—
Loss (gain) on sales of marketable securities	2	(14)
Loss on issuance of Series A redeemable convertible preferred stock and derivative warrant liability	65	—
Impairment of property and equipment	151	—
Non-cash interest expense	2,133	3,782
Changes in operating assets and liabilities:		
Accounts receivable	2,971	(35)
Prepaid expenses and other assets	471	(467)
Inventories	(949)	(1,940)
Accounts payable	(1,566)	761
Accrued expenses and other liabilities	261	769
Deferred revenue	(322)	(108)
Operating lease liabilities	(1,369)	(1,151)
Net cash used in operating activities	(50,629)	(38,874)
Cash flows from investing activities		
Proceeds from maturities of marketable securities	—	25,251
Proceeds from sales of marketable securities	9,998	—
Purchases and manufacture of property and equipment	(339)	(460)
Net cash provided by investing activities	9,659	24,791
Cash flow from financing activities		
Proceeds from issuance of shares from employee stock purchase plan and stock option exercises	165	567
Proceeds from issuance of Series A redeemable convertible preferred stock and derivative warrant liability	300	—
Payment of employee restricted stock tax withholdings	(243)	—
Proceeds from issuance of common stock in public offerings, net of offering costs	29,162	19,968
Redemption of Series A redeemable convertible preferred stock	(330)	—
Net cash provided by financing activities	29,054	20,535
Net (decrease) increase in cash, cash equivalents and restricted cash	(11,916)	6,452
Cash, cash equivalents and restricted cash at beginning of period	23,796	17,344
Cash, cash equivalents and restricted cash at end of period	$ 11,880	$ 23,796

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,	
Reconciliation of cash, cash equivalents and restricted cash at end of period	**2022**	**2021**
Cash and cash equivalents	$ 10,329	$ 22,245
Restricted cash	1,551	1,551
Total cash, cash equivalents and restricted cash	$ 11,880	$ 23,796

	Year ended December 31,	
	2022	**2021**
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 3,917	$ 3,814
Supplemental disclosures of noncash activities		
Transfer of T2 owned instruments and components from inventory	$ 573	$ 1,667
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	$ 117	$ 80

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 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

At December 31, 2022, the Company had cash, cash equivalents, and restricted cash of $11.9 million, an accumulated deficit of $534.2 million, stockholders’ deficit of $39.7 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 8), private placements of redeemable convertible preferred stock and through debt financing arrangements. In February 2023, we raised $12.0 million through a common stock and warrants sale.

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 2023, 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.

The COVID-19 pandemic has impacted and may continue to impact the Company’s operations as the pandemic shifts to an endemic health threat. Customers have begun to reduce their purchases of the Company’s COVID-19 Test and the Company has not forecasted any COVID-19 test sales in 2023.

The Company has a significant development contract with the Biomedical Advanced Research and Development Authority (“BARDA”) and should BARDA reduce, cancel or not grant additional milestone projects, the Company’s ability to continue its future product development may be hindered.

The Company’s T2Dx Instrument and T2Candida and T2Bacteria Panels are authorized for use in the United States by the Food and Drug Administration, or FDA. In June 2020 the FDA extended Emergency Use Authorization, or EUA, to the Company’s T2SARS-CoV-2 Panel. The Company believes the FDA will rescind the EUA for all COVID-19 diagnostic tests, and has indicated that it will provide a 180 day transition period. The Company believes the market for its T2SARS-CoV-2 panel is declining.

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 $11.9 million at December 31, 2022 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 2023, 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 Term Loan Agreement with CRG Servicing LLC ("CRG") (the "Term Loan Agreement") (Note 6) has a minimum liquidity covenant which requires the Company to maintain a minimum cash balance of $5.0 million. There can be no assurances that it will continue to be in compliance with the cash covenant in future periods without additional funding. In November 2022, CRG amended the Term Loan Agreement, extending the interest only period and maturity to December 30, 2024.

The Nasdaq Stock Market LLC ("Nasdaq") has $1.00 minimum bid price and $35 million minimum market value rules. Since 2021, the Company has failed to comply with Nasdaq listing requirements but subsequently regained compliance.

On November 22, 2022, the Company received notice from the Nasdaq indicating that the Company was in violation of the $35 million minimum market value rule. The Company has until May 22, 2023, to regain compliance which includes a closing market value of $35 million or more for a minimum of ten consecutive business days. If compliance in not achieved by May 22, 2023, the Company believes the Nasdaq will notify the Company that its securities are subject to delisting. Although we believe the Company may regain compliance organically, the Company plans to apply to the Nasdaq Hearings Panel for an extension to the compliance period.

On March 30, 2023, the Company received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for its common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1). Under Nasdaq rules, the Company has 180 calendar days (September 26, 2023) to regain compliance by increasing the stock price to over $1.00.

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, earning payments pursuant to the Company's contract with BARDA, 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 adequately reduce 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, 2022, the Company effected a 50 for 1 reverse stock split. One share of common stock was issued for every 50 shares of issued and outstanding, fractional shares were settled in cash and adjustment made for 50 shares of rounding. After the reverse split the Company had 7,059,144 shares of common stock issued and outstanding. All references to share and per share amounts (excluding authorized shares) in the consolidated financial statements and accompanying notes have been retroactively restated to for the reverse split.

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.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation. 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.

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. International sales to any customer in a single country did not exceed 10% of total revenue in any year. Total international sales were approximately $3.9 million, or 18% of total revenue in 2022, and $2.3 million, or 8% of total revenue, in 2021.

As of December 31, 2022 and 2021, the Company had outstanding receivables of $0.4 million and $0.6 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 and marketable securities are financial instruments that potentially subject the Company to concentrations of credit risk. At December 31, 2022 and 2021, substantially all of the Company's cash and cash equivalents and the marketable securities at December 31, 2021 were deposited in accounts at two financial institutions, with the majority of marketable securities invested in certificates of deposit and U.S. treasury securities. 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 customers that represent greater than 10% of revenue for the period presented:

	Year Ended December 31,	
	2022	2021
Customer A	50%	41%
Customer B	5%	15%

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

	December 31, 2022	December 31, 2021
Customer A	32%	37%
Customer B	7%	22%

Customer A is a U.S. government customer (BARDA). Customer B is a U.S. healthcare system comprised of multiple hospitals.

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 government securities as of December 31, 2021. There were no cash equivalents at 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 gains (losses) 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, 2022 and 2021.

The Company had no marketable securities at December 31, 2022. The following tables summarize the Company's marketable securities at December 31, 2021 (in thousands):

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	10,000	—	(4)	9,996
Total	$ 10,000	$ —	$ (4)	$ 9,996

The following table summarizes the maturities of the Company's marketable securities at December 31, 2021 (in thousands):

	December 31, 2021	
	Amortized Cost	Fair Value
Due in less than 1 year	$ 10,000	$ 9,996
Total	$ 10,000	$ 9,996

Accounts Receivable

The Company's accounts receivable consists of amounts due from product sales to commercial customers and unbilled amounts due from its development contract with BARDA. 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 and did not have an allowance for doubtful accounts at December 31, 2021. The Company has an allowance for doubtful accounts of $0.1 million for one customer at December 31, 2022 and bad debt expense is classified as a selling, general and administrative expense.

Inventories

Inventories are stated at the lower of cost or net realizable value. The Company determines the 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. 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, which for the T2Dx Instrument, T2Candida and T2Bacteria was upon the achievement of regulatory clearance and upon EUA for T2SARS-CoV-2, 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, which for the T2Dx Instrument was upon the achievement 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.

Instruments, including raw materials and work-in-process inventories, used for reagent rentals and internal use purposes such as testing, are classified as T2-owned instruments and components in property and equipment.

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

	December 31, 2022	December 31, 2021
Raw materials	$ 2,004	$ 1,591
Work-in-process	1,176	953
Finished goods	1,105	1,365
Total inventories, net	$ 4,285	$ 3,909

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, 2022 and 2021 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. At December 31, 2022, 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 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 the liability for the warrant issued in conjunction with the Series A redeemable convertible preferred stock is a derivative instrument. The warrant liability is classified on the consolidated balance sheets as current because cash 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 liability in the period of change in the consolidated statements of operations and comprehensive loss. See Notes 3 and 7.

The Company has identified a single compound derivative liability related to its Term Loan Agreement with CRG, that is classified as non-current on the consolidated balance sheets to match the classification of the related Term Loan Agreement. Changes in fair value are recognized in change in fair value of derivative instrument in the period of change in the consolidated statements of operations and comprehensive loss. See Notes 6 and 10.

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

Classification of Series A Redeemable Convertible Preferred Stock

The Company has 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 mezzanine equity because it was redeemable at the option of the holders in certain events. The Series A redeemable convertible preferred stock was redeemed on October 26, 2022 (see Note 7).

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 but subject to penalty. As a result of the penalty, the customers are deemed reasonably certain of not exercising their termination rights resulting in a lease term of generally three years. 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 and thus 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.

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 nonlease 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 is 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 is earned under a cost-sharing arrangement in which the Company is reimbursed for direct costs incurred plus allowable indirect costs. The government contract revenue is recognized as the related reimbursable expenses are incurred. The cost reimbursement that is reported as revenue is presented gross of the related reimbursable expenses in the Company's consolidated statements of operations; the related reimbursable expenses are expensed as incurred as research and development expense. The Company accounts 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 Company has a significant development contract with BARDA and should BARDA reduce, cancel or not grant additional milestone projects, the Company's ability to continue future product development may be adversely impacted. Refer to Note 16 for further details regarding the development contract with BARDA.

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,	
	2022	2021
Product revenue		
Instruments	$ 2,302	$ 1,238
Consumables	8,185	14,576
Instrument rentals	78	6
Service	694	826
Total product revenue	11,259	16,646
Contribution revenue	11,046	11,412
Total revenue	$ 22,305	$ 28,058

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, 2022. 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 $0.1 million as of December 31, 2022. The Company expects to recognize 63% 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

At December 31, 2022, the Company recorded $0.1 million of contract assets within other assets on the balance sheet. The 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 Company did not record any contract assets at December 31, 2021.

The Company’s contract liabilities consist of upfront payments for research and development contracts and maintenance services on instrument sales. Contract liabilities are classified in deferred revenue as current or noncurrent based on the timing of when revenue is expected to be recognized. At December 31, 2022 and 2021, the Company had contract liabilities of $0.2 million and $0.5 million, respectively. Revenue recognized in the year-ended December 31, 2022 relating to contract liabilities at December 31, 2021 was $0.5 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.

At December 31, 2022, capitalized costs to obtain contracts of less than $0.1 million was included in prepaid and other current assets. At December 31, 2021, capitalized costs to obtain contracts of $0.1 million were included in prepaid and other current assets and less than $0.1 million in other non-current assets. The company amortized costs of less than $0.1 million during the year ended December 31, 2022 and $0.1 million during the year ended December 31, 2021.

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, including capitalized T2 owned instruments and components and capitalized costs to fulfill a contract, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indications of impairment exist, projected future undiscounted cash flows associated with the asset or asset group are compared to the carrying amount to determine whether the asset’s value is recoverable. During this review, the Company reevaluates the significant assumptions used in determining the original cost and estimated lives of long-lived assets. Although the assumptions may vary from asset to asset, they generally include operating results, changes in the use of the asset, cash flows and other indicators of value. Management then determines whether the remaining useful life continues to be appropriate or whether there has been an impairment of long-lived assets based primarily upon whether expected future undiscounted cash flows are sufficient to support the assets’ recovery. If impairment exists, the Company would adjust the carrying value of the asset to fair value, generally determined by a discounted cash flow analysis. If the carrying value of the asset exceeds such projected undiscounted cash flows, the asset will be written down to its estimated fair value. The Company recorded impairment expense of $0.2 million during the year ended December 31, 2022, and did not record any impairment expense during the year ended December 31, 2021.

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, 2022 and 2021 was $0.1 million.

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 9 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

The Company applies the two-class method for computing earnings per share because the Series A redeemable convertible preferred stock issued in 2022 and the warrants issued with that preferred stock are participating securities. Under the two-class method, net loss for the period is allocated between common stockholders and the participating securities according to dividends declared, if any, and participation rights in undistributed earnings. Because the Company incurred a net loss for the year ended December 31, 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 2022. No participating securities were outstanding during 2021.

Basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. In 2022, accretion of the carrying amount of the Company's Series A redeemable convertible preferred stock to its redemption amount was treated as a deemed dividend to the preferred stockholders and increased the amount of the net loss attributable to common stockholders.

Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding for the dilutive effect of common stock equivalents that were outstanding during the period, determined using either the if-converted method (for its Series A redeemable, convertible preferred stock) or the treasury-stock method. For purposes of the diluted net loss per share calculation, stock options and unvested restricted stock, restricted stock contingently issuable upon achievement of certain market conditions, the Series A redeemable convertible preferred stock and the warrants issued with Series A redeemable convertible preferred stock are considered to be common stock equivalents but

have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. In periods in which the Company recognizes gains due to changes in the fair value of its warrant liability, the Company will further assess whether the effect of adjusting its computation of diluted net loss per share to include the potential common shares and reverse the gain associated with the warrant would result in a more diluted net loss per share, and modify the computation if necessary. Because all common stock equivalents were excluded from the calculation of diluted net loss per share, basic and diluted net loss per share applicable to common stockholders were the same for all periods presented.

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 the year ended December 31, 2022 as compared to less than $0.1 million for the year ended December 31, 2021. Amounts are recorded in other gains (losses) 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 the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

Accounting Standards Adopted

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)—Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06")*, which simplifies accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. The standard is effective for smaller reporting companies for fiscal years beginning after December 15, 2023 and interim periods within those fiscal years. The Company early adopted the standard as of January 1, 2022. The adoption did not have a material impact on the Company's financial statements.

In May 2021, the FASB issued ASU No. 2021-04, Earnings Per Share (Topic 260), *Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40) Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options ("ASU 2021-04")* which clarifies and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after a modification or exchange. This standard is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply this standard prospectively to modifications or exchanges occurring on or after the effective date of this standard. The Company adopted this standard as of January 1, 2022. The adoption did not have a material impact on the Company's financial statements.

In July 2021, the FASB issued ASU 2021-05, *Lessors-Certain Leases with Variable Lease Payments.* This ASU requires a lessor to classify a lease with variable payments that do not depend on an index or rate ("variable payments") as an operating lease on the commencement date of the lease if (a) the lease would have been classified as a sales-type lease or direct financing lease and (b) the lessor would have recognized a selling loss at lease commencement. This ASU is effective for fiscal years beginning after December 15, 2021 for lessors that have adopted ASC 842, with early adoption permitted. The Company adopted this standard as of January 1, 2022. The adoption did not have a material impact on the Company's financial statements.

In November 2021, the FASB issued ASU 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance.* This ASU requires certain disclosures when companies (a) have received government assistance and (b) use a grant or contribution accounting model by analogy to other accounting guidance. A company that has received government assistance must provide disclosures related to the nature of the transaction, accounting policies used to account for the transaction, and the amounts and line items on the financial statements that are affected by the transaction. This ASU is effective for fiscal years beginning after December 15, 2021, with early adoption permitted, and can be applied either prospectively or retrospectively. The Company adopted this standard as of January 1, 2022 on a prospective basis. The adoption did not have a material impact on the Company's financial statements.

Accounting Standards Issued, To Be Adopted

On September 29, 2022, the FASB issued ASU 2022-04, *Liabilities-Supplier Finance Programs (Subtopic 405-50) Disclosure of Supplier Finance Program Obligations.* 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 will be effective for the Company for fiscal years beginning after December 15, 2022, 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 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, 2022 and 2021 (in thousands):

	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 liability	$ 39	$ —	$ 39	$ —
Derivative liability	1,088	—	—	1,088
	$ 1,127	$ —	39	1,088

	Balance at December 31, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
US Treasury securities	9,996	9,996	—	—
	$ 9,996	$ 9,996	$ —	$ —

The Company's cash equivalents and available-for-sale marketable securities are comprised of government securities. The Company also maintains money market accounts classified as restricted cash, which are Level 1 assets, for $1.6 million at December 31, 2022 and 2021 (Note 4).

The Company estimated the fair value of the warrant liability (Note 7) 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 warrant liability at December 31, 2022 was determined using the following assumptions:

Risk-free interest rate	3.99 %
Expected dividend yield	0.00 %
Expected volatility	115.00 %
Expected term	5.13 %

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 at December 31, 2022 is $1.1 million and is classified as a non-current liability on the balance sheet at December 31, 2022 consistent with the classification of the related Term Loan Agreement. The likelihood of paying contingent interest within the next twelve months was also deemed remote at December 31, 2021 and the fair value of a derivative liability was estimated as zero.

The estimated fair value of the derivative at December 31, 2022 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 2023	30 %

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

Balance at December 31, 2020	$	1,010
Change in fair value of derivative liability		(1,010)
Balance at December 31, 2021		—
Change in fair value of derivative liability		1,088
Balance at December 31, 2022	$	1,088

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. 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 the fair value for December 31, 2022.

4. Restricted Cash

The Company is required to maintain security deposits for its office lease agreements. At December 31, 2022 and 2021, the Company had lease security deposits, invested in money market accounts, aggregating $1.6 million. In January 2023 one of these deposits of $1.0 million was claimed by a landlord as compensation for a lease dispute (see Note 13).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, 2022	December 31, 2021
Office and computer equipment	3	$ 757	$ 749
Software	3	783	783
Laboratory equipment	5	5,570	5,507
Furniture	5-7	197	197
Manufacturing equipment	5	1,454	1,445
Manufacturing tooling and molds	0.5-5	494	478
T2-owned instruments and components	5	4,052	5,327
Leased T2-owned instruments	5	1,014	886
Leasehold improvements	Lesser of useful life or remaining lease term	3,784	3,768
Construction in progress	n/a	685	512
		18,790	19,652
Less accumulated depreciation and amortization		(14,257)	(14,977)
Property and equipment, net		4,533	$ 4,675

Construction in progress includes $0.8 million and $1.4 million of T2-owned instrument raw materials and work-in-process at December 31, 2022 and 2021, respectively. Depreciation expense, a component of cost of product revenue, from instruments under the T2-owned reagent rental pool was $0.1 million and $0.2 million for the year ended December 31, 2022 and 2021, respectively. 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 $1.0 million and $1.3 million was charged to operations for the years ended December 31, 2022 and 2021, respectively.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2022	December 31, 2021
Accrued payroll and compensation	$ 2,930	$ 3,687
Accrued clinical trial and development expenses	1,097	1,250
Accrued professional services	1,626	384
Accrued interest	1,009	974
Other accrued expenses	607	869
Total accrued expenses and other current liabilities	$ 7,269	$ 7,164

Accrued professional services includes a $1.0 million estimated liability related to the Billerica, Massachusetts lease (Note 12).

6. Notes Payable

Future principal payments on the notes payable as of December 31, 2022 are as follows (in thousands):

Year ended December 31,	
2023	—
2024	53,453
2025	—
2026	—
Total including PIK interest, before unamortized discount and issuance costs	53,453
Less: unaccrued paid-in-kind interest	(3,647)
Less: unamortized discount and deferred issuance costs	(155)
Total notes payable	$ 49,651

Term Loan Agreement

In December 2016, the Company entered into a Term Loan Agreement with CRG and borrowed $40.0 million. The Agreement initially had a six-year term, and provided for quarterly interest-only payments through December 30, 2020 and quarterly principal and interest payments hereafter through maturity. The Company issued warrants to CRG to purchase a total of 10,579 shares of the Company's common stock, exercisable any time prior to December 30, 2026 at a price of $77.50 per share. The Agreement has been subsequently amended as described below.

Interest on borrowings, as amended, accrue 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. The Company paid CRG a financing fee based on the loan principal amount drawn and the fee is being amortized over the loan term as debt discount interest expense. A final fee payment of 10% (initially 8%, then amended) is due at maturity based on the principal outstanding at maturity. The final fee is accrued as interest expense and recorded as a non-current liability consistent with the classification of the associated debt.

In connection with a 2019 amendment of the Term Loan Agreement, the Company issued to CRG warrants to purchase 11,365 shares of the Company's common stock ("New Warrants") exercisable any time prior to September 9, 2029at an exercise price of $77.50 per share.

The Company may prepay principal at any time partially or in full without 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. Also at CRG's discretion, a default interest rate of an additional 4.0% per annum may apply during the occurrence and continuance of an event of default. In January 2023, CRG waived certain specified events of default associated with the Company's issuance of shares of Series A convertible preferred stock in August 2022 and the subsequent redemption.

Amendments

In 2019, the Term Loan Agreement was amended to reduce minimum revenue targets, extend the interest-only period, extend the principal repayment period and to increase the final payment fee from 8% to 10%. The Company issued the New Warrants to CRG, with provisions for termination upon a change of control or a sale of all or substantially all of the assets of the Company. The Company also reduced the exercise price for the warrants previously issued to CRG to purchase an aggregate of 10,579 shares of the Company's common stock to $77.50. The New Warrants are exercisable any time prior to September 9, 2029, and all of the previously issued warrants are exercisable any time prior to December 30, 2026.

In January 2021, the Term Loan Agreement was amended to extend the interest-only payment period until December 30, 2022, extend the initial principal repayment until December 30, 2022, and to reduce the minimum product revenue target for the twenty-four month period beginning on January 1, 2020. The Company did not pay or provide any consideration in exchange for this amendment. The Company accounted for the January 2021 amendment as a modification to the Term Loan Agreement. In June 2021, the Company satisfied the remaining revenue covenant.

In February 2022, the Term Loan Agreement was amended to extend the interest-only and the principal maturity dates to December 30, 2023. The Company did not pay or provide any consideration in exchange for this amendment. As the effective borrowing rate under the amended agreement is less than the effective borrowing rate under the previous agreement, a concession was deemed granted as per ASC Topic 470-60, *Debt: Troubled Debt Restructurings by Debtors ("ASC 470-60)*, and the amendment was accounted for as a troubled debt restructuring. The future undiscounted cash outflows required under the amended agreement exceed the carrying value of the debt immediately prior to the amendment and the amendment did not result in a gain on restructuring.

In November 2022, CRG amended the Term Loan Agreement, extending the interest only period and principal maturity to December 30, 2024. No consideration was given in exchange for the amendment. There were no costs paid to the lender or third parties in association with the amendment. Because a concession was granted, the agreement was accounted for as a troubled debt restructuring under ASC 470-60. The future undiscounted cash outflows required under the amended agreement exceed the carrying value of the debt immediately prior to the amendment and the amendment did not result in a gain on restructuring

7. Series A Redeemable Convertible Preferred Stock

On August 15, 2022, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement"), pursuant to which we entered into a private placement transaction for an aggregate of 3,000 shares of Series A redeemable convertible preferred stock with a par value of $0.001 per share and a warrant to purchase up to an aggregate of 42,857 shares of common stock of the Company at an exercise price of $7.50 per share (such number of shares and exercise price are adjusted for the reverse stock split described in Notes 1 and 2) for an aggregate subscription amount equal to $0.3 million, before deducting estimated offering expenses payable by the Company. Pursuant to the Purchase Agreement, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series A convertible preferred stock with the Secretary of State of the State of Delaware designating the rights, preferences and limitations of the Series A redeemable convertible preferred stock.

Series A Redeemable Convertible Preferred Stock

The Series A redeemable convertible preferred stock was issued at a price of $100 per share (the Stated Value).

Conversion -The Series A redeemable convertible preferred stock was convertible at the option of the holder, at any time after the date of the reverse stock split proposed by the Board of Directors, into that number of shares of common stock (subject to certain beneficial ownership limitations) determined by dividing the stated value of the Series A redeemable convertible preferred stock share by the conversion price then in effect, rounded down to the nearest whole share (with cash paid in lieu of any fractional shares). The initial conversion price was $7.00 per share, adjusted for the reverse stock split that was effected on October 12, 2022 (the "Conversion Price"). The Conversion Price was subject to adjustment (1) upon occurrence of any subsequent stock splits or stock dividends and (2) upon subsequent issue or sale by the Company of any common stock, convertible securities or option for a price per share less than the Conversion Price in effect immediately prior to such issue or sale.

Redemption – The Series A redeemable convertible preferred stock did not contain any mandatory redemption provisions. Beginning on the date of the reverse stock split (1) the Company could redeem in cash all or any portion of the Series A redeemable convertible preferred stock at a price per share equal to one hundred and five percent (105%) of the Stated Value and (2) each holder of Series A preferred stock could require the Company to redeem in cash all or any portion of the Series A redeemable convertible preferred stock held by such holder at a price per share equal to one hundred and ten percent (110%) of the Stated Value. In addition, an automatic redemption by the Company at a price per

share equal to one hundred and ten percent (110%) of the Stated Value would have been triggered by the delisting of the Company's common shares.

Dividend Rights-Holders of the Series A redeemable convertible preferred stock were entitled to receive dividends on shares of Series A redeemable convertible preferred stock equal (on an as-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.

Voting Rights -The Series A redeemable convertible preferred stock had no voting rights other than the right to vote on certain specified matters related to the proposal to approve the reverse stock split of the Company's outstanding common stock.

Status of Converted or Redeemed Series A Preferred Stock -If any shares of Series A Preferred Stock shall be converted, redeemed or reacquired by the Company, such shares shall resume the status of authorized but unissued shares of Preferred Stock and shall no longer be designated as Series A Preferred Stock.

As of September 30, 2022, the Company determined that the Series A redeemable convertible preferred stock was currently redeemable; therefore, the Company adjusted the carrying amount of the preferred stock on the balance sheet to its redemption value, which was equal to its liquidation value under the terms of the certificate of designation.

On October 26, 2022, the private investor in the Company's Series A redeemable convertible preferred stock redeemed all 3,000 shares of the Series A redeemable convertible preferred stock for an aggregate amount of $0.3 million. No gain or loss was recognized as a result of the redemption.

Warrant

In connection with the execution of the Securities Purchase Agreement, the Company issued a warrant to purchase 42,857 shares of the Company's common stock (the "Warrant") at an exercise price equal to $7.50 per share, subject to adjustments noted below. The Warrant will become exercisable on February 15, 2023 and has a term ending February 15, 2028. At issuance, the Company determined that the Warrant should be classified as a derivative liability because such Warrant could require cash redemption in certain circumstances. The gross proceeds were allocated between the derivative warrant liability and the preferred stock with allocation to the derivative warrant liability being equal to the fair value. The fair value of the derivative warrant liability exceeded the proceeds of $0.3 million, resulting in a day one loss of $0.1 million. The Warrant is carried at fair value, with changes in fair value recognized in earnings each reporting period.

The exercise price of the Warrant and the number of shares issuable upon exercise will be adjusted proportionately upon the occurrence of any subsequent stock dividend or stock split of the Company's common stock. In addition, if at any time the Company grants, issues or sells any common stock equivalents or rights to purchase stock, warrants, securities or other property pro rata to holders of any class of shares of common stock (the "Purchase Rights"), then the Warrant holder will be entitled to acquire, upon the terms applicable to the Purchase Rights, the aggregate Purchase Rights which the holder could have acquired if the holder had held the number of shares of common stock acquirable upon complete exercise of the Warrant (subject to certain beneficial ownership limitations). Furthermore, after the issuance of the Warrant and while it is outstanding, if the Company declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of common stock, by way of return of capital or otherwise (a "Distribution"), the Warrant holder will be entitled to participate in that Distribution to the same extent that the holder would have participated if the holder had held the number of shares of common stock acquirable upon complete exercise of the Warrant (subject to certain beneficial ownership limitations).

After the occurrence of a Fundamental Transaction, as defined, then, upon any subsequent exercise of the Warrant the holder will, at its option, have the right to receive for each warrant share that would have been issuable upon such exercise immediately prior to the occurrence of the Fundamental Transaction the number of shares of common stock (or its equivalent) of the successor or acquiring corporation or of the Company, if it is the surviving corporation, or such other consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of common stock for which the Warrant is exercisable immediately prior to the Fundamental Transaction. For purposes of any such exercise, the determination of the exercise price will be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of common stock in such Fundamental Transaction, and the Company will apportion the exercise price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of common stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Warrant holder will be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction.

While any Warrant is outstanding, if the Company issues or sells, any common stock, convertible securities or options, for a consideration per share (the "New Issuance Price") less than a price equal to the exercise price of the Warrant in effect immediately prior to such issue or sale (a "Dilutive Issuance"), then immediately after the Dilutive Issuance, the exercise price then in effect will be reduced to an amount equal to the New Issuance Price. 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 Note 16). Consequently, the exercise price of the existing Warrant was adjusted to $0.54 effective as of February 17, 2023.

If at the time of a Warrant's exercise there is no effective registration statement registering, or no current prospectus available for, the resale of the warrant shares by the holder, then the Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise".

8. 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. The number of shares was increased by our shareholders in July 2021, from 200,000,000 shares.

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, 2022, a total of 179,641 shares, 201,998 shares, and 64,801 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

The Company entered into a Sales Agreement with Canaccord Genuity (the "Sales Agreement"), through which the Company may sell up to $75.0 million of gross proceeds of common stock. 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 Sales Agreement for its services. Legal and accounting fees from sales under the Sales Agreement are charged to share capital. Under the Sales Agreement the Company sold 4,306,897 shares of common stock in 2022 for net proceeds of $29.2 million, and 336,188 shares of common stock in 2021 for net proceeds of $20.0 million. Subsequent to December 31, 2022, the Company sold 653,122 shares of common stock for proceeds of $1.0 million under the Sales Agreement.

9. 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 June 2021, 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) 16,470 (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 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 700,000 shares may be issued upon the exercise of incentive stock options. As of December 31, 2022, there were 66,224 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 192,500 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, 2022, there were 94,476 shares available for future grant under the Inducement Plan.

Stock Options

During the years ended December 31, 2022 and 2021, the Company granted options with an aggregate fair value of $0.6 million and $1.8 million, respectively, 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 at December 31, 2021	197,171	$ 143.96	7.09	51
Granted	33,520	21.50		
Forfeited	(37,611)	38.70		
Canceled	(13,439)	117.93		
Outstanding at December 31, 2022	179,641	145.09	5.93	
Exercisable at December 31, 2022	133,727	179.55	5.18	
Vested or expected to vest at December 31, 2022	174,164	$ 148.41	5.85	

There were no options exercised in the year ended December 31, 2022 and 2,405 options exercised in the year ended December 31, 2021. The total intrinsic value of options exercised in the year ended December 31, 2021 was immaterial. The weighted-average fair values of options granted in the years ended December 31, 2022 and 2021 were $17.58 and $44.67 per share, respectively, and were calculated using the following estimated assumptions:

	Year ended December 31,	
	2022	2021
Weighted-average risk-free interest rate	2.27%	1.02%
Expected dividend yield	0.00%	0.00%
Expected volatility	106%	105%
Expected terms	5.2 years	5.8 years

The total fair values of stock options that vested during the years ended December 31, 2022 and 2021 were $1.7 million and $2.6 million, respectively.

As of December 31, 2022, there was $1.5 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 1.8 years as of December 31, 2022.

Restricted Stock Units

During the year ended December 31, 2022, 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 $3.7 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
Nonvested at December 31, 2021	142,434	$ 91.77
Granted	176,975	21.05
Vested	(62,712)	82.50
Forfeited	(54,699)	48.26
Nonvested at December 31, 2022	201,998	$ 44.47

As of December 31, 2022, there was $6.4 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 1.5 years as of December 31, 2022.

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, 2022 and 2021 was approximately $0.1 million and $0.4 million, respectively. During the year ended December 31, 2022, 29,624 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,	
	2022	2021
Weighted-average risk-free interest rate	0.82%	0.07%
Expected dividend yield	0.00%	0.00%
Expected volatility	105.93%	103.00%
Expected terms	0.5 years	0.5 years

The 2014 ESPP, which was amended and restated effective August 6, 2020, provides for the granting of up to 90,479 shares of the Company’s common stock to eligible employees. At December 31, 2022, there were 22,849 shares available 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,	
	2022	2021
Cost of product revenue	$ 367	$ 339
Research and development	1,017	975
Selling, general and administrative	5,079	5,743
Total stock-based compensation expense	$ 6,463	$ 7,057

For the years ended December 31, 2022 and 2021, stock-based compensation expense capitalized as part of inventory or T2-owned instruments and components was immaterial.

In July 2021, a previous director of the Company resigned. In conjunction with his resignation, all of the director's outstanding options vested in full and the exercise term was extended to the final expiration date for each respective outstanding option. Additionally, the non-vested restricted stock units granted to the director in June 2021 vested in full upon his resignation. These were accounted for as Type I equity modifications for the accelerated vesting and Type III equity modifications for the extended exercise period and resulted in an increase of $0.8 million to stock-based compensation expense for the year ended December 31, 2021. Included within selling, general and administrative above for the year ended December 31, 2021 is $0.6 million and $0.2 million related to the Type I modification and the Type III modification, respectively, from the director's resignation.

10. Net Loss Per Share

The Company applies the two-class method for computing earnings per share because the Series A redeemable convertible preferred stock issued during 2022 and the warrants issued with that preferred stock are participating securities. Under the two-class method, net income for the period is allocated between common stockholders and the participating securities according to dividends declared, if any, and participation rights in undistributed earnings. Because the Company incurred a net loss for the year ended December 31, 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. No participating securities were outstanding during 2021.

For 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 method, because their effect would have been anti-dilutive for the periods presented:

	Year ended December 31,	
	2022	2021
Options to purchase common shares	179,641	197,171
Restricted stock units	201,998	142,434
Warrants to purchase common stock	64,801	21,945
Total	446,440	361,550

The Series A redeemable convertible preferred stock was issued and redeemed in 2022 and is not considered in the calculation of diluted net loss per share because its effect is anti-dilutive.

11. Income Taxes

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

	Year Ended December 31,	
	2022	2021
Tax at statutory rates	21.0%	21.0%
State income taxes	4.6	4.8
Stock-based compensation	(2.4)	(2.8)
Permanent differences	0.1	(0.1)
Research and development credits	1.7	2.7
Other	0.1	(0.3)
Limitations on credits and net operating losses	(20.1)	(0.1)
Change in valuation allowance	(4.9)	(25.2)
Effective tax rate	0.0%	0.0%

The significant components of the Company's deferred tax asset consist of the following at December 31, 2022 and 2021 (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 72,360	$ 73,372
Tax credits	1,012	2,783
Other temporary differences	3,745	3,183
Start-up expenditures	2,068	2,392
Capitalized research and development expenses	5,793	—
Stock option expenses	3,025	3,305
Lease liability	2,494	2,791
Total deferred tax assets	90,497	87,826
Deferred tax asset valuation allowance	(87,843)	(84,797)
Net deferred tax assets	2,654	3,029
Deferred tax liabilities:		
Right of use asset	(2,279)	(2,587)
Prepaid expenses	(375)	(442)
Net deferred taxes	$ —	$ —

In 2022 and 2021, 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 2022 deferred tax assets. The valuation allowance decreased by $3.0 million and increased $12.4 million for the years ended December 31, 2022 and 2021, respectively. The decrease in the 2022 valuation allowance is primarily attributable to the current 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, partially offset by current year net operating losses, capitalized research and development ("R&D") expenses, and tax credits that require additional valuation allowance in 2022. The increase in the 2021 valuation allowance is primarily attributable to the current year losses and tax credit carryforwards.

As of December 31, 2022, the Company had federal and state net operating losses of $256.7 million and $303.0 million, respectively, which are available to offset future taxable income, if any, of which $34.9 million of federal and $233.8 million of state carryforwards will expire in varying amounts through 2037 and 2042, respectively. Additionally, $221.8 million of federal net operating loss carryforwards and $69.2 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 $0.5 million and $0.7 million, respectively. The federal credits will expire at various dates through 2042 if not utilized. Approximately $0.3 million of the state credits will expire at various dates through 2037 if not utilized, and approximately $0.4 million of the credits have no expiration date.

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 at December 31, 2022 and December 31, 2021 regarding whether there may have been a Section 382 ownership change. The study concluded that ownership changes have occurred in the past, and the most recent change was during 2022. The Company has reduced its net operating loss and tax credit carryforwards to the amounts that are utilizable after accounting for the annual limitations and expiration dates of the attributes.

The Company has no balance of gross unrecognized tax benefits as of December 31, 2022. 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. At December 31, 2022 and 2021, 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, 2022. The statute of limitations for assessment by federal and state tax jurisdictions in which the Company has business operations is open for tax years ended December 31, 2018 and after. The tax years open to examination vary by jurisdiction.

12. 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 at December 31, 2022 and 2021.

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 an agreement to rent additional office space in Lexington, Massachusetts. In April 2015, the Company entered into an amendment to extend the term to December 31, 2017. In connection with this agreement, the Company paid a security deposit of $50,000, which is recorded as a component of other assets in the consolidated balance sheets. In May 2015, the Company entered into an amendment to expand existing manufacturing facilities in Lexington, Massachusetts. In September 2017, the Company entered into an amendment to extend the term to December 31, 2021. In June 2020, the Company vacated this office space and determined that subleasing it to a tenant was unlikely due to the impact of the COVID-19 pandemic on the local commercial real estate sub-lease market. The lease terminated on December 31, 2021.

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 at 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 at December 31, 2022 and 2021 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 at December 31, 2022 and 2021. 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 at December 31, 2022 is a $1.0 million estimated liability pertaining to this lease. Subsequent to December 31, 2022, 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 16).

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):

Lease cost	Year Ended December 31, 2022	Year Ended December 31, 2021
Operating lease cost	2,402	2,401
Variable lease cost	915	698
Total lease cost	$ 3,317	$ 3,099

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

Other information	Year Ended December 31, 2022	Year Ended December 31, 2021
Weighted-average remaining lease term - operating leases (in years)	5.5	6.4
Weighted-average discount rate - operating leases	12.0%	11.9%

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, 2022 Operating Leases
2023	$ 2,403
2024	2,487
2025	2,331
2026	1,893
2027	1,950
Thereafter	2,008
Total lease payments	$ 13,072
Less: effect of discounting	(3,506)
Present value of lease liabilities	$ 9,566

The following table summarizes the presentation of the Company's operating leases in its consolidated balance sheets (in thousands):

Leases	Classification	December 31, 2022	December 31, 2021
Assets			
Operating lease assets	Operating lease assets	$ 8,741	$ 9,766
Total lease assets		$ 8,741	$ 9,766
Liabilities			
Current			
Operating	Accrued expenses and other current liabilities	$ 1,352	$ 1,174
Noncurrent			
Operating	Noncurrent operating lease liabilities	8,214	9,359
Total lease liabilities		$ 9,566	$ 10,533

13. 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, 2022 and 2021, 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

The Company has been in an ongoing dispute with the landlord of the Billerica, Massachusetts lease (Note 16).

Leases

Refer to Note 12, 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 1,693 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, 2022 and 2021 were $0.1 million and $0.2 million, respectively.

Resignation of Board Member

In July 2021, John McDonough resigned as a director of the Company. He was a Class I Director and Chairman of the Board. Upon his resignation, the Board appointed John Sperzel, the Company's CEO, as Chairman of the Board. In conjunction with his resignation, the Company paid Mr. McDonough $240,000, which represented the aggregate cash retainer that he would have received for his service had he continued to serve through the second quarter of 2024. All of Mr. McDonough's outstanding options vested in full immediately prior to his resignation and can be exercised until the final expiration date set forth in each respective option agreement. The restricted stock units granted to Mr. McDonough on June 25, 2021 vested in full immediately prior to the resignation. Refer to Note 9, Stock-Based Compensation, for more information.

14. 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 $244,000 and $192,000 for the years ended December 31, 2022 and 2021, respectively.

15. US Government Contract

In September 2019, the Biomedical Advanced Research and Development Authority ("BARDA") awarded the Company a milestone-based 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 awards all contract options. 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 awards 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 T2NxT, T2Biothreat, T2Resistance and T2AMR. The modification does 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 is providing 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 will be 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 $11.0 million and $11.4 million for the years ended December 31, 2022 and 2021, respectively, under the BARDA contract.

The Company had unbilled accounts receivable of $0.7 million and $1.9 million at December 31, 2022 and 2021, respectively, under the BARDA contract.

16. Subsequent Events

Issuance of Common Shares and Warrants

On February 17, 2023, the Company sold 9,018,519 shares of $0.001 par value common stock, 2,092,592 pre-funded warrants and 22,222,222 warrants to purchase common stock through an underwritten offering by Craig-Hallum Capital Group LLC. The shares, warrants and pre-funded warrants were sold for $1.08 per share. Gross offering proceeds were $12.0 million and net proceeds after underwriting commissions and offering costs were $11.9 million.

The pre-funded warrants are exercisable anytime without expiration at the holder's option for cash at $0.001 per share or cashless for shares equal to 50% of warrants exercised. Common shares issuable on the exercise of the pre-funded warrants are subject to adjustment for stock dividends and stock splits and other transactions affecting common shares.

The warrants are exercisable commencing March 17, 2023, through February 17, 2028 at the holder's option for cash at $1.08 per share or cashless for shares equal to 50% of warrants exercised. Common shares issuable on the exercise of the pre-funded warrants are subject to adjustment for stock dividends and stock splits and other transactions affecting common shares.

Billerica Lease Agreement

The Company 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. 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. The Company and the Landlord have had ongoing communications. On January 17, 2023, the Landlord terminated the Lease and alleged the Company 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 Company's $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. 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 disagrees with Landlord's allegations and actions and believes that the Landlord is in breach of certain of its materials obligations under the lease. 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.

Bid Price

On March 30, 2023, the Company received a letter from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for its common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1). Under Nasdaq rules, the Company has 180 calendar days (September 26, 2023) to regain compliance by increasing the stock price to over $1.00.

Letter Agreements

On March 30, 2023, the Company entered into letter agreements with Mr. Sprague, Mr. Giffin, 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, 2023, and the second installment, in the amount of $40,000, shall be paid within five business days following November 15, 2023. 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, 2022. 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, 2022, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, the Company's disclosure controls and procedures were effective.

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, 2022. 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 concluded that our internal control over financial reporting was effective as of December 31, 2022.

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 30, 2023, the Company entered into letter agreements with Mr. Sprague, Mr. Giffin, 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, 2023, and the second installment, in the amount of $40,000, shall be paid within five business days following November 15, 2023. 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 eight 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 - 2022	59
Ninfa Saunders	Director	2020	Class II - 2022	71
Thierry Bernard	Director	2020	Class II - 2022	58
John Cumming	Director	2014	Class III - 2023	77
David Elsbree	Director	2014	Class III - 2023	75
Seymour Liebman	Director	2016	Class I - 2024	73
Laura Adams	Director	2021	Class I - 2024	66
Robin Toft	Director	2020	Class I - 2024	62

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.

Thierry Bernard has served as a member of our Board of Directors since June 2020. Mr. Bernard has been employed by Qiagen NV, a provider of sample and assay technologies for molecular diagnostics, applied testing, and academic and pharmaceutical research since February 2015 and was named Chief Executive Officer in March 2020. From August 2014 to February 2015, Mr. Bernard was employed by Daktari Diagnostics, a point of care diagnostics company, where he served as Chief Executive Officer. From April 1998 to August 2014, Mr. Bernard was employed by bioMérieux, an in vitro diagnostics company, where he served in roles of increasing responsibility, most recently as Corporate Vice President, Global Commercial Operations, Investor Relations and the Greater China Region. He has earned a BS International Economics & Finance from Sciences Po Paris, an MSc Administration & Economics from the College of Europe, an MSc International Economics from the London School of Economics, a DESS Comercio Exterior from Universidad de Barcelona and a degree from the Advanced Management Program (AMP) 177 at Harvard Business School. Mr. Bernard's extensive knowledge of and experience with diagnostic product companies contributed to our Board of Directors' conclusion that he 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 currently serves as Chief Executive Officer and Managing Director of Cumming & Associates LLC, a strategic advisory firm serving the healthcare industry. 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	64	Chief Financial Officer
Michael Gibbs, Esq.	52	Senior Vice President and General Counsel
Brett Giffin	64	Chief Commercial Officer
Roger Smith, Ph.D.	58	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 by the Company on behalf of its directors and officers 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, 2022, there has been compliance with all Section 16(a) filing requirements applicable to such Reporting Persons, except that one Form 4 for Ms. Ahuja, Ms. Adams, Mr. Sperzel, Mr. Gibbs and Mr. Sprague, two Form 4's for Mr. Barclay, and three 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 2022 Annual Meeting of Stockholders.

Audit Committee and Audit Committee Financial Expert

David Elsbree, Ninfa Saunders and Thierry Bernard currently serve on the audit committee, which is chaired by David Elsbree. Our Board of Directors has determined that each member of the audit committee is currently, and was during 2022, “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 2022, our named executive officers and their positions as of December 31, 2022 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 2022 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 had considered the adviser independence factors required under SEC rules as they relate to Arnosti Consulting and does not believe Arnosti Consulting's work in 2022 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 2022 Mr. Sperzel's annual base salary was $575,000 (unchanged from 2021). Mr. Sprague's annual base salary was $370,000 (increased from $360,000) and Mr. Gibbs' base salary was $375,000 (increased from $356,000). Base salary increases were effective March 1, 2022.

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 2022, 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 2022 annual cash incentive compensation program were established in January 2022 by our compensation committee and generally related to the attainment of clinical, business development and financing milestones and certain publication, commercialization and operational goals. The determination of 2022 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 2022 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 2022 as set forth in the "Non-Equity Incentive Plan Compensation" column of our 2022 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.

We awarded restricted stock unit awards to our named executive officers in 2022 in the following amounts:

Named Executive Officer	February 2022 RSUs Granted (#)(1)
John Sperzel	48,000
John Sprague	12,000
Michael Gibbs	12,000

(1) The RSUs vest in three substantially equal annual installments occurring on the first three anniversaries of February 20, 2022.

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 lesser.

2022 Summary Compensation Table

Name and Principal Position	Year	Salary ($)(1)	Stock Awards ($)(2)	Option Awards ($)(3)	Non-Equity Incentive Plan Compensation ($)(4)	All Other Compensation ($)(5)	Total ($)
John Sperzel,	2022	575,000	1,119,840	—	287,500	3,000	1,985,340
President, Chief Executive Officer and Chairman of the Board of Directors	2021	562,500	2,480,000	—	460,000	3,000	3,505,500
John Sprague,	2022	368,333	279,960	—	111,000	3,000	762,293
Chief Financial Officer							
Michael Gibbs,	2022	371,833	279,960	—	112,500	3,000	767,293
SVP and General Counsel	2021	353,333	1,084,152	—	170,880	3,000	1,611,365

(1) Amounts in this column represent base salaries earned for 2022 and 2021 rather than 2022 and 2021 annual base salary rates.
(2) 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 9 to the audited consolidated financial statements included in this Annual Report on Form 10-K.
(3) 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.
(4) Represents Company matching contributions under our 401(k) plan.

Outstanding Equity Awards at Fiscal Year-End Table—2022

	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							
	01/08/2020	43,750	16,250	57.50	01/08/2030		
	02/24/2021					13,334	18,934
	02/20/2022					48,000	68,160
John Sprague							
	01/30/2018	4,500	—	254.00	03/01/2028		
	02/21/2019	1,150	50	186.00	02/21/2029		
	09/10/2019	1,000	—	71.50	09/10/2029		
	02/21/2019					—	—
	02/24/2021					5,829	8,277
	02/20/2022					12,000	17,040
Michael Gibbs							
	12/01/2014	899	—	850.50	12/01/2024		
	01/20/2016	1,199	—	451.00	01/20/2026		
	02/09/2017	699	—	283.50	02/09/2027		
	03/01/2018	1,799	—	254.00	03/01/2028		
	02/21/2019	1,150	50	186.00	02/21/2029		
	09/10/2019	999	—	71.50	09/10/2029		
	03/24/2020	1,375	625	19.50	03/24/2030		
	02/21/2019					—	—
	03/14/2020					334	474
	02/24/2021					5,829	8,277
	02/20/2022					12,000	17,040

(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. Sprague with a vesting commencement date of January 30, 2018 vest as to 25% of the shares subject to the option on the first anniversary of the vesting commencement date and as to the remaining shares subject to the option in substantially equal monthly installments over the ensuing 36 months. The unvested options for Mr. Sprague and Mr. Gibbs (a) granted on September 10, 2019 vest in substantially equal monthly installments over the 36 month period from the vesting commencement date, and (b) granted on all other dates vest in substantially equal monthly installments over the 48 month period from the vesting commencement date; in each case, subject to Mr. Sprague's and 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 granted on 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 granted on 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. All unvested restricted stock units for Mr. Gibbs granted on March 24, 2020 vest in three substantially equal annual installments beginning on March 24, 2021, 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 30, 2022 of $1.42.

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.

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 six 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. 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 2022.

Director Compensation Table—2022

	Fees Earned or Paid in Cash ($)(1)	Stock Awards ($)(2)(3)	Total ($)
John W. Cumming	96,000	10,400	106,400
David B. Elsbree	60,000	9,200	69,200
Seymour Liebman	40,006	9,200	49,206
Thierry Bernard	50,006	9,200	59,206
Dr. Ninfa M. Saunders	50,006	9,200	59,206
Robin Toft	60,000	9,200	69,200
Laura Adams	40,000	9,200	49,200

(1) Messrs. Liebman, Bernard and Saunders each elected to receive the $40,000 2022 annual retainer for board service in the form of restricted stock units and, as a result, were each issued 1,550 restricted stock units on January 1, 2022 that vested in a single installment on January 1, 2023. Amounts in this column include the value of the $40,000 2022 annual retainer forgone in lieu of restricted stock units for each of Messrs. Liebman, Bernard and Saunders.

(2) Messrs. Elsbree, Liebman, Bernard, Saunders and Toft were granted $9,200 in the form of restricted stock units, and, as a result, were each issued 2,300 restricted stock units on October 11, 2022 that vest in a single installment on the earlier of the first anniversary of the grant date or the date of the next annual meeting of stockholders.

(3) Mr. Cumming was granted $10,400 in the form of restricted stock units, and, as a result, was issued 2,600 restricted stock units on October 11, 2022 that vest in a single installment on the earlier of the first anniversary of the grant date or the date of the next annual meeting of stockholders.

The table below shows the aggregated numbers of outstanding option awards (exercisable and unexercisable) and unvested stock awards held as of December 31, 2022 by each non-employee director.

	Option Awards Outstanding at 2022 Fiscal Year End	Unvested Stock Awards Outstanding at 2022 Fiscal Year End
John W. Cumming	2,467	2,600
David B. Elsbree	2,467	2,300
Seymour Liebman	1,763	3,850
Thierry Bernard	—	4,304
Dr. Ninfa M. Saunders	—	4,304
Robin Toft	—	2,754
Laura Adams	—	3,764

We maintain a non-employee director compensation program pursuant to which all non-employee directors were paid cash compensation as set forth below for 2022:

	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 provides for an annual equity grant of restricted stock units to continuing non-employee directors who have been serving for at least six months. The non-employee director compensation program was updated, effective March 2022, as to the restricted stock unit awards for the continuing non-employee directors. 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. Such grant shall be 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.

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, 2022.

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)	286,710	(2)	$ 237.55	(3)	89,073	(4)
Equity compensation plans not approved by security holders (5)	94,929	(6)	62.59	(7)	94,476	
Total	381,639		$ 145.09		183,549	

(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 10,053 outstanding options to purchase shares of our common stock under the 2006 Plan, 74,659 outstanding options to purchase shares of our common stock under the 2014 Plan, and 201,998 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, 2022. 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 in 2015 and ending on and including 2026. The annual increase in the number of shares is currently 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. Pursuant to the terms of the 2014 ESPP, as amended in August 2020, the aggregate number of shares that may be issued pursuant to rights granted under the 2014 ESPP shall be 90,478 shares. As of December 31, 2022, a total of 22,849 shares of stock were available for issuance under the 2014 ESPP, 15,600 of which were subject to purchase with respect to the purchase period in effect as of December 31, 2022, which purchase period ends on May 15, 2023.

(5) Consists of the Inducement Award Plan. See Note 9 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, 2022, 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.

The table lists applicable percentage ownership based on 7,716,519 shares of our common stock outstanding as of December 31, 2022. 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, 2022, 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.

Name of Beneficial Owner	Amount and Nature of Ownership	Percentage of Class
5% or Greater Stockholders		
None		
Named Executive Officers and Directors		
John Sperzel (1)	73,352	1.0 %
Michael Gibbs (2)	18,500	*
John Sprague (3)	16,661	*
John W. Cumming (4)	5,123	*
David B Elsbree (5)	7,991	*
Seymour Liebman (6)	129,121	1.7 %
Thierry Bernard (7)	4,569	*
Dr. Ninfa M. Saunders (7)	4,569	*
Robin Toft (8)	3,019	*
Laura Adams (9)	732	*
All executive officers and directors as a group (11 persons) (10)	267,224	3.5 %

* Less than 1%.

(1) Consists of (a) 4,435 shares of common stock, (b) options to purchase 46,250 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, 2022 and (c) 22,667 restricted stock units vesting within 60 days of December 31, 2022.

(2) Consists of (a) 3,333 shares of common stock, (b) options to purchase 8,253 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, 2022 and (c) 6,914 restricted stock units vesting within 60 days of December 31, 2022.

(3) Consists of (a) 3,047 shares of common stock, (b) options to purchase 6,700 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, 2022, and (c) 6,914 restricted stock units vesting within 60 days of December 31, 2022.

(4) Consists of (a) 2,656 shares of common stock and (b) options to purchase 2,467 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, 2022.

(5) Consists of (a) 5,524 shares of common stock and (b) options to purchase 2,467 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, 2022.

(6) 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 121,106 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 Chairman of the Board of BriefCam, a Canon Inc. company 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) 4,702 shares of common stock, (b) options to purchase 1,763 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, 2022, and (c) 1,550 restricted stock units vesting within 60 days of December 31, 2022.

(7) Consists of (a) 3,019 shares of common stock and (b) 1,550 restricted stock units vesting within 60 days of December 21, 2022 for Mr. Bernard and Ms. Saunders.

(8) Consists of 3,019 shares of common stock for Ms. Toft.

(9) Consists of 732 shares of common stock for Ms. Adams.

(10) Consists of (a) 156,846 shares of common stock, (b) 67,900 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, 2022 and (c) 42,478 restricted stock units vesting within 60 days of December 31, 2022.

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, 2022 in which any related person or related person affiliate has a direct or indirect material interest and the amount involved exceeds $120,000.

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 Ninfa Saunders, Thierry Bernard, Laura Adams, Seymour Liebman and Robin Toft), except John Sperzel, are independent, as determined in accordance with Nasdaq rules. 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, LLP ("BDO"), our independent registered public accounting firm, and its affiliates for the fiscal years ended December 31, 2022 and 2021.

	Fiscal 2022	Fiscal 2021
Audit Fees	$ 793,692	$ 730,265
Tax Fees	58,000	51,975
Total	$ 851,692	$ 782,240

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, LLP 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, LLP 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, LLP 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, 2022 and 2021 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 LLP, Independent Registered Public Accounting Firm (BDO USA, LLP; Boston, Massachusetts; PCAOB ID# 243)

   Consolidated Balance Sheets as of December 31, 2022 and 2021

   Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2022 and 2021

   Consolidated Statements of Series A Redeemable Convertible Preferred Stock and Stockholders' Deficit for the years ended December 31, 2022 and 2021

   Consolidated Statements of Cash Flows for the years ended December 31, 2022 and 2021

   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		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, effective as of June 14, 2020 (incorporated by reference to Exhibit 10.4 of the Company's Form 10-Q (File No. 001-36571) filed on August 12, 2020)
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	†	Contract, dated as of September 6, 2019, by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q/A (File No. 001-36571) filed on November 18, 2019)
10.39	†	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)
10.40	#	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)
10.41	†	Amendment of Solicitation/Modification of Contract, dated as of September 30, 2020 by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q (File No. 001-36571) filed on November 5, 2020)
10.42		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)
10.43		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)
10.44		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)
10.45	†	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)

10.46		Amendment of Solicitation/Modification of Contract, dated as of April 30, 2021 by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q (File No. 001-36571) filed on May 13, 2021)
10.47		T2 Biosystems, Inc. 2014 Incentive Award Plan, as amended and restated (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-36571) filed on June 28, 2021)
10.48	†	Lease, dated September 3, 2021, by and between T2 Biosystems, Inc. and Farley White Concord Road, LLC (incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q (File No. 001-36571) filed on November 4, 2021)
10.49		Amendment of Solicitation/Modification of Contract, dated as of September 30, 2021 by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q (File No. 001-36571) filed on November 4, 2021)
10.50		Amendment of Solicitation/Modification of Contract, dated as of October 25, 2021 by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (incorporated by reference to Exhibit 10.3 of the Company's Form 10-Q (File No. 001-36571) filed on November 4, 2021)
10.51	#*	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
10.52	#*	Employment Offer Letter, dated as of November 2, 2021, by and between the Company and Brett Giffin
10.53	#*	Change of Control Severance Agreement, dated March 21, 2022 by and between the Company and John Sprague
10.54	#*	Change of Control Severance Agreement, dated March 21, 2022 by and between the Company and Michael Gibbs
10.55	#*	Change of Control Severance Agreement, dated March 21, 2022 by and between the Company and Brett Giffin
10.56	*	Amendment No. 7 to Term Loan Agreement, dated February 15, 2022, between T2 Biosystems, Inc. and CRG Servicing LLC
10.57	†	Amendment of Solicitation/Modification of Contract, dated as of March 31, 2022 by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q (File No. 001-36571) filed on May 12, 2022)
10.58	†	Amendment of Solicitation/Modification of Contract, dated as of April 22, 2022 by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (incorporated by reference to Exhibit 10.3 of the Company's Form 10-Q (File No. 001-36571) filed on May 12, 2022)
10.59		Securities Purchase Agreement, dated as of August 15, 2022 (incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q (File No. 001-36571) filed on August 16, 2022)
10.60	†	Amendment of Solicitation/Modification of Contract, dated as of July 26, 2022 by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q (File No. 001-36571) filed on August 16, 2022)
10.61		Registration Rights Agreement, dated as of August 15, 2022 (incorporated by reference to Exhibit 10.3 of the Company's Form 10-Q (File No. 001-36571) filed on August 16, 2022)
10.62	†	Amendment of Solicitation/Modification of Contract, dated as of September 29, 2022 by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (incorporated by reference to Exhibit 10.4 of the Company's Form 10-Q (File No. 001-36571) filed on November 14, 2022)
10.63	†	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)
10.64	*	Amendment No. 6 to Commercial Lease between Columbus Day Realty, Inc. and T2 Biosystems, Inc. dated September 26, 2022
10.65	†*	Amendment of Solicitation/Modification of Contract, dated as of March 20, 2023 by and between the Company and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services
10.66	*	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
10.67	#*	Letter Agreement, dated March 30, 2023, by and between T2 Biosystems, Inc. and John Sprague
10.68	#*	Letter Agreement, dated March 30, 2023, by and between T2 Biosystems, Inc. and Michael Gibbs

10.69	#*	Letter Agreement, dated March 30, 2023, by and between T2 Biosystems, Inc. and Brett Giffin
21.1	*	Subsidiaries of the Registrant.
23.1	*	Consent of BDO USA, LLP, 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.
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 March 31, 2023.

T2 BIOSYSTEMS, INC.

By: /S/ JOHN SPERZEL
Name: John Sperzel
Title: President, Chief Executive Officer and Director (principal executive officer)

March 31, 2023

By: /S/ JOHN M. SPRAGUE
Name: John M. Sprague
Title: Chief Financial Officer (principal financial officer and principal accounting officer)

March 31, 2023

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)	March 31, 2023
/ S / JOHN M. SPRAGUE **John M. Sprague**	Chief Financial Officer (principal accounting officer)	March 31, 2023
/ S / LAURA ADAMS **Laura Adams**	Director	March 31, 2023
/ S / THIERRY BERNARD **Thierry Bernard**	Director	March 31, 2023
/ S / DR. NINFA M. SAUNDERS **Dr. Ninfa M. Saunders**	Director	March 31, 2023
/ S / ROBIN TOFT **Robin Toft**	Director	March 31, 2023
/ S / JOHN W. CUMMING **John W. Cumming**	Director	March 31, 2023
/ S / DAVID B. ELSBREE **David B. Elsbree**	Director	March 31, 2023
/ S / SEYMOUR LIEBMAN **Seymour Liebman**	Director	March 31, 2023

Exhibit 4.4

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED UNDER SECTION 12 OF THE EXCHANGE ACT

General

As of December 31, 2022, T2 Biosystems, Inc. had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). References herein to "we," "us," "our" and the "Company" refer to T2 Biosystems, Inc. and not to any of its subsidiaries.

The following description of our common stock and certain provisions of our amended and restated certificate of incorporation (our "charter") and amended and restated bylaws ("bylaws") are summaries and are qualified in their entirety by reference to the full text of our amended and restated certificate of incorporation and our amended and restated bylaws, each of which have been publicly filed with the Securities and Exchange Commission (the "SEC"). We encourage you to read our amended and restated certificate of incorporation and our amended and restated bylaws and the applicable provisions of the Delaware General Corporation Law (the "DGCL") for additional information.

Common Stock

Our board of directors is authorized to direct us to issue up to 400,000,000 shares of common stock, $0.001 par value. Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of shareholders and do not have any cumulative voting rights. An election of directors by our stockholders is determined by a plurality of the votes cast by the stockholders entitled to vote in the election. Subject to the supermajority votes for some matters, other matters are decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our restated certificate of incorporation.

Dividend

Holders of our common stock are entitled to receive proportionately any dividends as may be declared by the board of directors, subject to any preferential dividend rights of any outstanding preferred stock that we may designate and issue in the future. The Company has not paid cash dividends on any of its shares of capital stock.

Other Rights and Preferences

Our common stock has no preemptive, subscription, redemption or conversion rights or sinking fund provisions.

Liquidation

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock.

Fully Paid and Non-Assessable

All outstanding shares of common stock are fully paid and non-assessable.

Preferred Stock

Our board of directors is authorized to direct us to issue up to 10,000,000 shares of preferred stock in one or more series without shareholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock.

Staggered Board

Our board of directors is divided into three classes. The directors in each class serve for a three year term, one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Anti-Takeover Effects of Delaware Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. Under Section 203, we would generally be prohibited from engaging in any business combination with any interested stockholder for a period of three years following the time that this stockholder became an interested stockholder unless:

- prior to this time, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers, and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Under Section 203, a “business combination” includes:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder, subject to limited exceptions;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

T2 BIOSYSTEMS, INC.
INDUCEMENT AWARD PLAN
(as amended and restated effective February 16, 2023)

ARTICLE 1.

PURPOSE

The purpose of the T2 Biosystems, Inc. Inducement Award Plan (as it may be amended or restated from time to time, the "Plan") is to promote the success and enhance the value of T2 Biosystems, Inc. (the "Company") by linking the individual interests of eligible individuals to those of Company stockholders and by providing such individuals with an incentive for outstanding performance to generate superior returns to Company stockholders. The Plan is further intended to provide flexibility to the Company in its ability to motivate, attract, and retain the services of persons who are expected to make important contributions to the Company whose judgment, interest, and special effort the successful conduct of the Company's operation will be largely dependent. This Plan constitutes an amendment and restatement of the T2 Biosystems, Inc. Inducement Award Plan.

ARTICLE 2.

DEFINITIONS AND CONSTRUCTION

Wherever the following terms are used in the Plan they shall have the meanings specified below, unless the context clearly indicates otherwise. The singular pronoun shall include the plural where the context so indicates.

2.1 "Administrator" shall mean the entity that conducts the general administration of the Plan as provided in Article 11. With reference to the duties of the Committee under the Plan which have been delegated to one or more persons pursuant to Section 11.6, or as to which the Board has assumed, the term "Administrator" shall refer to such person(s) unless the Committee or the Board has revoked such delegation or the Board has terminated the assumption of such duties.

2.2 "Applicable Accounting Standards" shall mean Generally Accepted Accounting Principles in the United States, International Financial Reporting Standards or such other accounting principles or standards as may apply to the Company's financial statements under United States federal securities laws from time to time.

2.3 "Applicable Law" shall mean any applicable law, including without limitation: (i) provisions of the Code, the Securities Act, the Exchange Act and any rules or regulations thereunder; (ii) corporate, securities, tax or other laws, statutes, rules, requirements or regulations, whether federal, state, local or foreign; and (iii) rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded.

2.4 "Automatic Exercise Date" shall mean, with respect to an Option or a Stock Appreciation Right, the last business day of the applicable Option Term or Stock Appreciation

Right Term that was established by the Administrator for such Option or Stock Appreciation Right (*e.g.*, the last business day prior to the tenth anniversary of the date of grant of such Option or Stock Appreciation Right if the Option or Stock Appreciation Right initially had a ten-year Option Term or Stock Appreciation Right Term, as applicable); provided that with respect to an Option or Stock Appreciation Right that has been amended pursuant to this Plan so as to alter the applicable Option Term or Stock Appreciation Right Term, "Automatic Exercise Date" shall mean the last business day of the applicable Option Term or Stock Appreciation Right Term that was established by the Administrator for such Option or Stock Appreciation Right as amended.

2.5 "Award" shall mean an Option, a Restricted Stock award, a Restricted Stock Unit award, a Performance Award, a Dividend Equivalents award, a Stock Payment award or a Stock Appreciation Right, which may be awarded or granted under the Plan (collectively, "Awards").

2.6 "Award Agreement" shall mean any written notice, agreement, terms and conditions, contract or other instrument or document evidencing an Award, including through electronic medium, which shall contain such terms and conditions with respect to an Award as the Administrator shall determine consistent with the Plan.

2.7 "Board" shall mean the Board of Directors of the Company.

2.8 "Change in Control" shall mean and includes each of the following:

(a) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission or a transaction or series of transactions that meets the requirements of clause (i) and (ii) of paragraph (c) below) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than the Company, any of its Subsidiaries, an employee benefit plan maintained by the Company or any of its Subsidiaries or a "person" that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company's securities outstanding immediately after such acquisition; or

(b) During any period of two consecutive years, individuals who, at the beginning of such period, constitute the Board together with any new Director(s) (other than a Director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in Section 2.8(a) or Section 2.8(c)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the Directors then still in office who either were Directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or

(c) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or

substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(i) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the "Successor Entity")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction, and

(ii) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this Section 2.8(c)(ii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction.

In addition, if a Change in Control constitutes a payment event with respect to any portion of an Award that provides for the deferral of compensation and is subject to Section 409A of the Code, the transaction or event described in subsection (a), (b), (c) or (d) with respect to such Award (or portion thereof) must also constitute a "change in control event," as defined in Treasury Regulation Section 1.409A-3(i)(5) to the extent required by Section 409A.

The Committee shall have full and final authority, which shall be exercised in its discretion, to determine conclusively whether a Change in Control of the Company has occurred pursuant to the above definition, and the date of the occurrence of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

2.9 "Code" shall mean the Internal Revenue Code of 1986, as amended from time to time, together with the regulations and official guidance promulgated thereunder.

2.10 "Committee" shall mean the Compensation Committee of the Board, or another committee or subcommittee of the Board or the Compensation Committee, appointed as provided in Section 11.1.

2.11 "Common Stock" shall mean the common stock of the Company, par value $0.001 per share.

2.12 "Company" shall have the meaning set forth in Article 1.

2.13 "Consultant" shall mean any consultant or adviser engaged to provide services to the Company or any Subsidiary that qualifies as a consultant under the applicable rules of the Securities and Exchange Commission for registration of shares on a Form S-8 Registration Statement.

2.14 "Director" shall mean a member of the Board, as constituted from time to time.

2.15 "Dividend Equivalent" shall mean a right to receive the equivalent value (in cash or Shares) of dividends paid on Shares, awarded under Section 8.2.

2.16 "DRO" shall mean a domestic relations order as defined by the Code or Title I of the Employee Retirement Income Security Act of 1974, as amended from time to time, or the rules thereunder.

2.17 "Effective Date" shall mean the day that the Plan is approved by the Board.

2.18 "Eligible Individual" shall mean any individual hired as a new Employee or rehired as an Employee following a bona fide period of interruption of employment if such person is granted an Award as a material inducement to his or her entering into employment with the Company or a Subsidiary (within the meaning of the NASDAQ Rule 5635(c)(4)).

2.19 "Employee" shall mean any officer or other employee (as determined in accordance with Section 3401(c) of the Code) of the Company or of any Subsidiary.

2.20 "Equity Restructuring" shall mean a nonreciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split, spin-off, rights offering or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind of Shares (or other securities of the Company) or the share price of Common Stock (or other securities) and causes a change in the per share value of the Common Stock underlying outstanding Awards.

2.21 "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended from time to time.

2.22 "Expiration Date" shall have the meaning given to such term in Section 12.1.

2.23 "Fair Market Value" shall mean, as of any given date, the value of a Share determined as follows:

(a) If the Common Stock is listed on any (i) established securities exchange (such as the New York Stock Exchange, the NASDAQ Global Market and the NASDAQ Global Select Market), (ii) national market system or (iii) automated quotation system, its Fair Market Value shall be the closing sales price for a Share as quoted on such exchange or system for such date or, if there is no closing sales price for a Share on the date in question, the closing sales price for a Share on the last preceding date for which such quotation exists, as reported in *The Wall Street Journal* or such other source as the Administrator deems reliable;

(b) If the Common Stock is not listed on an established securities exchange, national market system or automated quotation system, but the Common Stock is regularly quoted by a recognized securities dealer, its Fair Market Value shall be the mean of the high bid and low asked prices for such date or, if there are no high bid and low asked prices for a Share on such date, the high bid and low asked prices for a Share on the last preceding date for which such

information exists, as reported in *The Wall Street Journal* or such other source as the Administrator deems reliable; or

(c) If the Common Stock is neither listed on an established securities exchange, national market system or automated quotation system nor regularly quoted by a recognized securities dealer, its Fair Market Value shall be established by the Administrator in good faith.

2.24 "Holder" shall mean a person who has been granted an Award.

2.25 "Independent Director" means a Director who qualifies as "independent" within the meaning of NASDAQ Rule 5635(c)(4) or any successor rule, as such rule may be amended from time to time.

2.26 "NASDAQ Rule 5635(c)(4)" means NASDAQ Rule 5635(c)(4), or any successor rule, and all guidance and other interpretative authority thereunder, as such rule, guidance and other authority may be amended from time to time

2.27 "Non-Employee Director" shall mean a Director of the Company who is not an Employee.

2.28 "Option" shall mean a right to purchase Shares at a specified exercise price, granted under Article 5. An Option under the Plan will not qualify as an incentive stock option pursuant to Section 422 of the Code.

2.29 "Option Term" shall have the meaning set forth in Section 5.6.

2.30 "Parent" shall mean any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities ending with the Company if each of the entities other than the Company beneficially owns, at the time of the determination, securities or interests representing at least fifty percent (50%) of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

2.31 "Performance Award" shall mean a cash bonus award, stock bonus award, performance award or other incentive award that is paid in cash, Shares or a combination of both, awarded under Section 8.1.

2.32 "Performance Criteria" shall mean the criteria (and adjustments) that the Committee selects for an Award for purposes of establishing the Performance Goal or Performance Goals for a Performance Period, determined as follows:

(a) The Performance Criteria that shall be used to establish Performance Goals may include, but are not limited to: (i) net earnings (either before or after one or more of (A) interest, (B) taxes, (C) depreciation, (D) amortization and (E) non-cash equity-based compensation expense); (ii) gross or net sales or revenue; (iii) net income (either before or after taxes); (iv) adjusted net income; (v) operating earnings or profit (either before or after taxes); (vi) cash flow (including, but not limited to, operating cash flow and free cash flow) and cash flow return on capital; (vii) return on assets; (viii) return on capital (or invested capital) and cost of capital); (ix) return on stockholders' equity; (x) total stockholder return; (xi) return on sales; (xii) gross or net

profit or operating margin; (xiii) costs, reductions in costs and cost control measures; (xiv) expenses; (xv) working capital; (xvi) earnings or loss per share; (xvii) adjusted earnings or loss per share; (xviii) price per share or dividends per share (or appreciation in and/or maintenance of such price or dividends); (xix) regulatory achievements or compliance (including, without limitation, regulatory body approval for commercialization of a product); (xx) implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments of critical projects; (xxi) market share; (xxii) economic value; (xxiii) revenue; (xxiv) revenue growth; (xxv) productivity; (xxvi) operating efficiency; (xxvii) economic value-added; (xxviii) return on net assets; (xxix) funds from operations; (xxx) funds available for distributions; (xxxi) sales unit volume; (xxxii) licensing revenue; (xxxiii) brand recognition and acceptance; (xxxiv) inventory, inventory turns or cycle time; (xxxv) market penetration and geographic business expansion; (xxxvi) customer satisfaction/growth and customer service; (xxxvii) employee satisfaction, recruitment and maintenance of personnel, and human resources management; (xxxviii) supervision of litigation and other legal matters; (xxxix) strategic partnerships and transactions; (xxxx) financial ratios (including those measuring liquidity, activity, profitability or leverage); (xxxxi) supply chain achievements; (xxxxii) debt levels or reductions; (xxxxiii) sales-related goals; (xxxxiv) financing and other capital raising transactions; (xxxxv) year-end cash; (xxxxvi) acquisition activity; (xxxxvii) investment sourcing activity; and (xxxxiii) marketing initiatives, any of which may be measured either in absolute terms or as compared to any incremental increase or decrease or as compared to results of a peer group or to market performance indicators or indices.

(b) The Administrator, in its discretion, may adjust the Performance Criteria for any Performance Period for such factors as the Administrator may determine, including, without limitation, in recognition of unusual or non-recurring events affecting the Company or changes in Applicable Law or Applicable Accounting Standards.

2.33 "Performance Goals" shall mean, for a Performance Period, one or more goals established in writing by the Administrator for the Performance Period based upon one or more Performance Criteria. Depending on the Performance Criteria used to establish Performance Goals, Performance Goals may be expressed in terms of overall Company performance or the performance of a Subsidiary, division, business unit, or an individual. The achievement of each Performance Goal shall be determined, to the extent applicable, with reference to Applicable Accounting Standards.

2.34 "Performance Period" shall mean one or more periods of time, which may be of varying and overlapping durations, as the Administrator may select, over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Holder's right to, and the payment of, an Award.

2.35 "Performance Stock Unit" shall mean a Performance Award awarded under Section 8.1 which is denominated in units of value including dollar value of Shares.

2.36 "Permitted Transferee" shall mean, with respect to a Holder, any "family member" of the Holder, as defined in the instructions to use the Form S-8 Registration Statement under the Securities Act, or any other transferee specifically approved by the Administrator after taking into account Applicable Law.

2.37 "Plan" shall have the meaning set forth in Article 1.

2.38 "Restricted Stock" shall mean Common Stock awarded under Article 6 that is subject to certain restrictions and may be subject to risk of forfeiture or repurchase.

2.39 "Restricted Stock Unit" shall mean the right to receive Shares awarded under Article 7.

2.40 "Securities Act" shall mean the Securities Act of 1933, as amended.

2.41 "Shares" shall mean shares of Common Stock.

2.42 "Stock Appreciation Right" shall mean a stock appreciation right granted under Article 9.

2.43 "Stock Appreciation Right Term" shall have the meaning set forth in Section 9.4.

2.44 "Stock Payment" shall mean (a) a payment in the form of Shares, or (b) an option or other right to purchase Shares, as part of a bonus, deferred compensation or other arrangement, awarded under Section 8.3.

2.45 "Subsidiary" shall mean any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing at least 50% of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

2.46 "Termination of Service" shall mean:

(a) As to a Consultant, the time when the engagement of a Holder as a Consultant to the Company or a Subsidiary is terminated for any reason, with or without cause, including, without limitation, by resignation, discharge, death, disability or retirement, but excluding terminations where the Consultant simultaneously commences or remains in employment or service with the Company or any Subsidiary.

(b) As to a Non-Employee Director, the time when a Holder who is a Non-Employee Director ceases to be a Director for any reason, including, without limitation, a termination by resignation, failure to be elected, death, disability or retirement, but excluding terminations where the Holder simultaneously commences or remains in employment or service with the Company or any Subsidiary.

(c) As to an Employee, the time when the employee-employer relationship between a Holder and the Company or any Subsidiary is terminated for any reason, including, without limitation, a termination by resignation, discharge, death, disability or retirement; but excluding terminations where the Holder simultaneously commences or remains in employment or service with the Company or any Subsidiary.

The Administrator, in its discretion, shall determine the effect of all matters and questions relating to any Termination of Service, including, without limitation, the question of whether a Termination of Service resulted from a discharge for cause and all questions of whether particular leaves of absence constitute a Termination of Service. For purposes of the Plan, a Holder's employee-employer relationship or consultancy relations shall be deemed to be terminated in the event that the Subsidiary employing or contracting with such Holder ceases to remain a Subsidiary following any merger, sale of stock or other corporate transaction or event (including, without limitation, a spin-off).

ARTICLE 3.

SHARES SUBJECT TO THE PLAN

3.1 Number of Shares.

(a) Subject to Sections 3.1(b) and 12.2, the aggregate number of Shares which may be issued or transferred pursuant to Awards under the Plan is 692,500 Shares.

(b) To the extent all or a portion of an Award is forfeited, expires, lapses for any reason, or is settled for cash without the delivery of Shares to the Holder, any Shares subject to such Award or portion thereof shall, to the extent of such forfeiture, expiration, lapse or cash settlement, again be available for the grant of an Award under the Plan. Any Shares repurchased by or surrendered to the Company under Section 6.4 so that such Shares are returned to the Company shall again be available for the grant of an Award under the Plan. The payment of Dividend Equivalents in cash in conjunction with any outstanding Awards shall not be counted against the Shares available for issuance under the Plan.

3.2 Stock Distributed. Any Shares distributed pursuant to an Award may consist, in whole or in part, of authorized and unissued Common Stock, treasury Common Stock or Common Stock purchased on the open market.

ARTICLE 4.

GRANTING OF AWARDS

4.1 Participation. The Administrator may, from time to time, select from among all Eligible Individuals, those to whom an Award shall be granted and shall determine the nature and amount of each Award, which shall not be inconsistent with the requirements of the Plan. No Eligible Individual shall have any right to be granted an Award pursuant to the Plan.

4.2 Award Agreement. Each Award shall be evidenced by an Award Agreement that sets forth the terms, conditions and limitations for such Award, which may include the term of the Award, the provisions applicable in the event of the Holder's Termination of Service, and the Company's authority to unilaterally or bilaterally amend, modify, suspend, cancel or rescind an Award.

4.3 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan, the Plan, and any Award granted or awarded to any individual who is then subject to

Section 16 of the Exchange Act, shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including Rule 16b-3 of the Exchange Act and any amendments thereto) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, the Plan and Awards granted or awarded hereunder shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

4.4 At-Will Employment; Voluntary Participation. Nothing in the Plan or Award Agreement shall confer upon any Holder any right to continue in the employ of, or as a Director or Consultant for, the Company or any Subsidiary, or shall interfere with or restrict in any way the rights of the Company and any Subsidiary, which rights are hereby expressly reserved, to discharge any Holder at any time for any reason whatsoever, with or without cause, and with or without notice, or to terminate or change all other terms and conditions of employment or engagement, except to the extent expressly provided otherwise in a written agreement between the Holder and the Company or any Subsidiary. Participation by each Holder in the Plan shall be voluntary and nothing in the Plan shall be construed as mandating that any Eligible Individual shall participate in the Plan.

4.5 Stand-Alone and Tandem Awards. Awards granted pursuant to the Plan may, in the discretion of the Administrator, be granted either alone, in addition to, or in tandem with, any other Award granted pursuant to the Plan. Awards granted in addition to or in tandem with other Awards may be granted either at the same time as or at a different time from the grant of such other Awards.

ARTICLE 5.

OPTIONS

5.1 Granting of Options to Eligible Individuals. The Administrator is authorized to grant Options to Eligible Individuals from time to time, in its discretion, on such terms and conditions as it may determine, which shall not be inconsistent with the Plan.

5.2 Option Exercise Price. The exercise price per Share subject to each Option shall be set by the Administrator, but shall not be less than 100% of the Fair Market Value of a Share on the date the Option is granted unless otherwise determined by the Administrator.

5.3 Option Vesting.

(a) The period during which the right to exercise, in whole or in part, an Option vests in the Holder shall be set by the Administrator and the Administrator may determine that an Option may not be exercised in whole or in part for a specified period after it is granted. Such vesting may be based on service with the Company or any Subsidiary or any other criteria selected by the Administrator, including Performance Goals or Performance Criteria. At any time after the grant of an Option, the Administrator, in its discretion and subject to whatever terms and conditions it selects, may accelerate the period during which an Option vests.

(b) No portion of an Option which is unexercisable at a Holder's Termination of Service shall thereafter become exercisable, except as may be otherwise provided by the

Administrator either in the Award Agreement evidencing the grant of an Option or by action of the Administrator following the grant of the Option. Unless otherwise determined by the Administrator in the Award Agreement or by action of the Administrator following the grant of the Option, the portion of an Option that is unexercisable at a Holder's Termination of Service shall automatically expire thirty (30) days following such Termination of Service.

5.4 Manner of Exercise. All or a portion of an exercisable Option shall be deemed exercised upon delivery of all of the following to the Secretary of the Company, the stock administrator of the Company or such other person or entity designated by the Administrator, or his, her or its office, as applicable:

(a) A written or electronic notice complying with the applicable rules established by the Administrator stating that the Option, or a portion thereof, is exercised. The notice shall be signed by the Holder or other person then entitled to exercise the Option or such portion of the Option.

(b) Such representations and documents as the Administrator, in its discretion, deems necessary or advisable to effect compliance with Applicable Law. The Administrator may, in its discretion, also take whatever additional actions it deems appropriate to effect such compliance including, without limitation, placing legends on share certificates and issuing stop-transfer notices to agents and registrars.

(c) In the event that the Option shall be exercised by any person or persons other than the Holder, appropriate proof of the right of such person or persons to exercise the Option, as determined in the discretion of the Administrator.

(d) Full payment of the exercise price and applicable withholding taxes for the shares with respect to which the Option, or portion thereof, is exercised, in a manner permitted by Section 10.1 and Section 10.2.

5.5 Partial Exercise. An exercisable Option may be exercised in whole or in part. However, an Option shall not be exercisable with respect to fractional Shares unless otherwise determined by the Administrator and the Administrator may require that, by the terms of the Option, a partial exercise must be with respect to a minimum number of shares.

5.6 Option Term. The term of each Option (the "Option Term") shall be set by the Administrator in its discretion; provided, however, that the Option Term shall not be more than ten (10) years from the date the Option is granted. The Administrator shall determine the time period, including the time period following a Termination of Service, during which the Holder has the right to exercise the vested Options, which time period may not extend beyond the last day of the Option Term. Except as limited by the requirements of Section 409A of the Code or the first sentence of this Section 5.6, the Administrator may extend the Option Term of any outstanding Option, and may extend the time period during which vested Options may be exercised, in connection with any Termination of Service of the Holder, and may amend, subject to Section 11.2, any other term or condition of such Option relating to such a Termination of Service.

5.7 Expiration of Option Term: Automatic Exercise of In-The-Money Options. Unless otherwise determined by the Administrator (in an Award Agreement or otherwise) or as otherwise directed by an Option Holder in writing to the Company, each Option outstanding on the Automatic Exercise Date with an exercise price per share that is less than the Fair Market Value per share of Common Stock as of such date shall automatically and without further action by the Option Holder or the Company be exercised on the Automatic Exercise Date. In the discretion of the Administrator, payment of the exercise price of any such Option shall be made pursuant to Section 10.1(b) or Section 10.1(c) and the Company or any Subsidiary shall deduct or withhold an amount sufficient to satisfy all taxes associated with such exercise in accordance with Section 10.2. Unless otherwise determined by the Administrator, this Section 5.7 shall not apply to an Option if the Holder of such Option incurs a Termination of Service on or before the Automatic Exercise Date. For the avoidance of doubt, no Option with an exercise price per share that is equal to or greater than the Fair Market Value per share of Common Stock on the Automatic Exercise Date shall be exercised pursuant to this Section 5.7.

ARTICLE 6.

RESTRICTED STOCK

6.1 Award of Restricted Stock.

(a) The Administrator is authorized to grant Restricted Stock to Eligible Individuals, and shall determine the terms and conditions, including the restrictions applicable to each award of Restricted Stock, which terms and conditions shall not be inconsistent with the Plan, and may impose such conditions on the issuance of such Restricted Stock as it deems appropriate.

(b) The Administrator shall establish the purchase price, if any, and form of payment for Restricted Stock; provided, however, that if a purchase price is charged, such purchase price shall be no less than the par value, if any, of the Shares to be purchased, unless otherwise permitted by Applicable Law. In all cases, legal consideration shall be required for each issuance of Restricted Stock.

6.2 Rights as Stockholders. Subject to Section 6.4, upon issuance of Restricted Stock, the Holder shall have, unless otherwise provided by the Administrator, all the rights of a stockholder with respect to said Shares, subject to the restrictions in each individual Award Agreement, including the right to receive all dividends and other distributions paid or made with respect to the Shares; provided, however, that, in the discretion of the Administrator, any extraordinary distributions with respect to the Shares shall be subject to the restrictions set forth in Section 6.3.

6.3 Restrictions. All shares of Restricted Stock (including any shares received by Holders thereof with respect to shares of Restricted Stock as a result of stock dividends, stock splits or any other form of recapitalization) shall, in the terms of each individual Award Agreement, be subject to such restrictions and vesting requirements as the Administrator shall provide. Such restrictions may include, without limitation, restrictions concerning voting rights and transferability and such restrictions may lapse separately or in combination at such times and pursuant to such circumstances or based on such criteria as selected by the Administrator,

including, without limitation, criteria based on the Holder's duration of employment, directorship or consultancy with the Company, Performance Goals, Performance Criteria, Company performance, individual performance or other criteria selected by the Administrator. By action taken after the Restricted Stock is issued, the Administrator may, on such terms and conditions as it may determine to be appropriate, accelerate the vesting of such Restricted Stock by removing any or all of the restrictions imposed by the terms of the applicable Award Agreement. Unless otherwise determined by the Administrator, Restricted Stock may not be sold or encumbered until all restrictions are terminated or expire.

6.4 Repurchase or Forfeiture of Restricted Stock. Except as otherwise determined by the Administrator at the time of the grant of the Award or thereafter, (a) if no price was paid by the Holder for the Restricted Stock, upon a Termination of Service during the applicable restriction period, the Holder's rights in unvested Restricted Stock then subject to restrictions shall lapse, and such Restricted Stock shall be surrendered to the Company and cancelled without consideration, and (b) if a price was paid by the Holder for the Restricted Stock, upon a Termination of Service during the applicable restriction period, the Company shall have the right to repurchase from the Holder the unvested Restricted Stock then subject to restrictions at a cash price per share equal to the price paid by the Holder for such Restricted Stock or such other amount as may be specified in the applicable Award Agreement.

6.5 Certificates for Restricted Stock. Restricted Stock granted pursuant to the Plan may be evidenced in such manner as the Administrator shall determine. Certificates or book entries evidencing shares of Restricted Stock shall include an appropriate legend referring to the terms, conditions, and restrictions applicable to such Restricted Stock. The Company, in its discretion, may (a) retain physical possession of any stock certificate evidencing shares of Restricted Stock until the restrictions thereon shall have lapsed and/or (b) require that the stock certificates evidencing shares of Restricted Stock be held in custody by a designated escrow agent (which may but need not be the Company) until the restrictions thereon shall have lapsed and that the Holder deliver a stock power, endorsed in blank, relating to such Restricted Stock.

6.6 Section 83(b) Election. If a Holder makes an election under Section 83(b) of the Code to be taxed with respect to the Restricted Stock as of the date of transfer of the Restricted Stock rather than as of the date or dates upon which the Holder would otherwise be taxable under Section 83(a) of the Code, the Holder shall be required to deliver a copy of such election to the Company promptly after filing such election with the Internal Revenue Service.

ARTICLE 7.

RESTRICTED STOCK UNITS

7.1 Grant of Restricted Stock Units. The Administrator is authorized to grant Awards of Restricted Stock Units to any Eligible Individual selected by the Administrator in such amounts and subject to such terms and conditions as determined by the Administrator.

7.2 Purchase Price. The Administrator shall specify the purchase price, if any, to be paid by the Holder to the Company with respect to any Restricted Stock Unit award; provided,

however, that value of the consideration shall not be less than the par value of a Share, unless otherwise permitted by Applicable Law.

7.3 Vesting of Restricted Stock Units. At the time of grant, the Administrator shall specify the date or dates on which the Restricted Stock Units shall become fully vested and nonforfeitable, and may specify such conditions to vesting as it deems appropriate, including, without limitation, vesting based upon the Holder's duration of service to the Company or any Subsidiary, Company performance, individual performance or other specific criteria, in each case on a specified date or dates or over any period or periods, as determined by the Administrator.

7.4 Maturity and Payment. At the time of grant, the Administrator shall specify the maturity date applicable to each grant of Restricted Stock Units, which shall be no earlier than the vesting date or dates of the Award and may be determined at the election of the Holder (if permitted by the applicable Award Agreement); provided that, except as otherwise set forth in an applicable Award Agreement, the maturity date relating to each Restricted Stock Unit shall not occur following the later of (a) the 15th day of the third month following the end of the calendar year in which the applicable portion of the Restricted Stock Unit vests; or (b) the 15th day of the third month following the end of the Company's fiscal year in which the applicable portion of the Restricted Stock Unit vests. On the maturity date, the Company shall, subject to Section 10.4, transfer to the Holder one unrestricted, fully transferable Share for each Restricted Stock Unit scheduled to be paid out on such date and not previously forfeited, or in the discretion of the Administrator, an amount in cash equal to the Fair Market Value of such Shares on the maturity date or a combination of cash and Common Stock as determined by the Administrator.

7.5 No Rights as a Stockholder. Unless otherwise determined by the Administrator, a Holder of Restricted Stock Units shall possess no incidents of ownership with respect to the Shares represented by such Restricted Stock Units, unless and until such Shares are transferred to the Holder pursuant to the terms of this Plan and the Award Agreement.

ARTICLE 8.

PERFORMANCE AWARDS, DIVIDEND EQUIVALENTS, STOCK PAYMENTS

8.1 Performance Awards. The Administrator is authorized to grant Performance Awards, including Awards of Performance Stock Units and other Awards determined in the Administrator's discretion from time to time, to any Eligible Individual. The value of Performance Awards, including Performance Stock Units, may be linked to the attainment of the Performance Goals or other specific criteria, whether or not objective, determined by the Administrator, in each case on a specified date or dates or over any period or periods and in such amounts as may be determined by the Administrator.

8.2 Dividend Equivalents.

(a) Dividend Equivalents may be granted by the Administrator based on dividends declared on the Common Stock, to be credited as of dividend payment dates with respect to dividends with record dates that occur during the period between the date an Award is granted to a Holder and the date such Award vests, is exercised, is distributed or expires, as determined by

the Administrator. Such Dividend Equivalents shall be converted to cash or additional Shares by such formula and at such time and subject to such restrictions and limitations as may be determined by the Administrator.

8.3 Stock Payments. The Administrator is authorized to make Stock Payments to any Eligible Individual. The number or value of Shares of any Stock Payment shall be determined by the Administrator and may be based upon one or more Performance Goals or any other specific criteria, including service to the Company or any Subsidiary, determined by the Administrator. Shares underlying a Stock Payment which is subject to a vesting schedule or other conditions or criteria set by the Administrator shall not be issued until those conditions have been satisfied. Unless otherwise provided by the Administrator, a Holder of a Stock Payment shall have no rights as a Company stockholder with respect to such Stock Payment until such time as the Stock Payment has vested and the Shares underlying the Award have been issued to the Holder. Stock Payments may, but are not required to, be made in lieu of base salary, bonus, fees or other cash compensation otherwise payable to such Eligible Individual.

8.4 Purchase Price. The Administrator may establish the purchase price of a Performance Award or Shares distributed as a Stock Payment award; provided, however, that value of the consideration shall not be less than the par value of a Share, unless otherwise permitted by Applicable Law.

ARTICLE 9.

STOCK APPRECIATION RIGHTS

9.1 Grant of Stock Appreciation Rights.

(a) The Administrator is authorized to grant Stock Appreciation Rights to Eligible Individuals from time to time, in its discretion, on such terms and conditions as it may determine, which shall not be inconsistent with the Plan.

(b) A Stock Appreciation Right shall entitle the Holder (or other person entitled to exercise the Stock Appreciation Right pursuant to the Plan) to exercise all or a specified portion of the Stock Appreciation Right (to the extent then exercisable pursuant to its terms) and to receive from the Company an amount determined by multiplying the difference obtained by subtracting the exercise price per share of the Stock Appreciation Right from the Fair Market Value on the date of exercise of the Stock Appreciation Right by the number of Shares with respect to which the Stock Appreciation Right shall have been exercised, subject to any limitations the Administrator may impose. Unless otherwise determined by the Administrator, the exercise price per Share subject to each Stock Appreciation Right shall be set by the Administrator, but shall not be less than 100% of the Fair Market Value on the date the Stock Appreciation Right is granted.

9.2 Stock Appreciation Right Vesting.

(a) The period during which the right to exercise, in whole or in part, a Stock Appreciation Right vests in the Holder shall be set by the Administrator, and the Administrator may determine that a Stock Appreciation Right may not be exercised in whole or in part for a specified period after it is granted. Such vesting may be based on service with the Company or any

Subsidiary, Performance Criteria, Performance Goals or any other criteria selected by the Administrator. At any time after grant of a Stock Appreciation Right, the Administrator, in its discretion and subject to whatever terms and conditions it selects, may accelerate the period during which a Stock Appreciation Right vests.

(b) No portion of a Stock Appreciation Right which is unexercisable at a Holder's Termination of Service shall thereafter become exercisable, except as may be otherwise provided by the Administrator in an Award Agreement or by action of the Administrator following the grant of the Stock Appreciation Right. Unless otherwise determined by the Administrator in the Award Agreement or by action of the Administrator following the grant of the Stock Appreciation Right, the portion of a Stock Appreciation Right which is unexercisable at a Holder's Termination of Service shall automatically expire thirty (30) days following such Termination of Service.

9.3 Manner of Exercise. All or a portion of an exercisable Stock Appreciation Right shall be deemed exercised upon delivery of all of the following to the Secretary of the Company, the stock administrator of the Company, or such other person or entity designated by the Administrator, or his, her or its office, as applicable:

(a) A written or electronic notice complying with the applicable rules established by the Administrator stating that the Stock Appreciation Right, or a portion thereof, is exercised. The notice shall be signed by the Holder or other person then entitled to exercise the Stock Appreciation Right or such portion of the Stock Appreciation Right.

(b) Such representations and documents as the Administrator, in its discretion, deems necessary or advisable to effect compliance with Applicable Law. The Administrator, in its discretion, may also take whatever additional actions it deems appropriate to effect such compliance, including, without limitation, placing legends on share certificates and issuing stop-transfer notices to agents and registrars.

(c) In the event that the Stock Appreciation Right shall be exercised by any person or persons other than the Holder, appropriate proof of the right of such person or persons to exercise the Stock Appreciation Right, as determined in the discretion of the Administrator.

(d) Full payment of the exercise price and applicable withholding taxes for the Shares with respect to which the Stock Appreciation Right, or portion thereof, is exercised, in a manner permitted by Section 10.1 and Section 10.2.

9.4 Stock Appreciation Right Term. The term of each Stock Appreciation Right (the "Stock Appreciation Right Term") shall be set by the Administrator in its discretion; provided, however, that the Stock Appreciation Right Term shall not be more than ten (10) years from the date the Stock Appreciation Right is granted. The Administrator shall determine the time period, including the time period following a Termination of Service, during which the Holder has the right to exercise the vested Stock Appreciation Rights, which time period may not extend beyond the last day of the Stock Appreciation Right Term applicable to such Stock Appreciation Right. Except as limited by the requirements of Section 409A of the Code or the first sentence of this Section 9.4, the Administrator may extend the Stock Appreciation Right Term of any outstanding Stock Appreciation Right, and may extend the time period during which vested Stock Appreciation

Rights may be exercised, in connection with any Termination of Service of the Holder, and may amend, subject to Section 11.2, any other term or condition of such Stock Appreciation Right relating to such a Termination of Service.

9.5 Payment. Payment of the amounts payable with respect to Stock Appreciation Rights pursuant to this Article 9 shall be in cash, Shares (based on Fair Market Value as of the date the Stock Appreciation Right is exercised), or a combination of both, as determined by the Administrator.

9.6 Expiration of Stock Appreciation Right Term: Automatic Exercise of In-The-Money Stock Appreciation Rights. Unless otherwise determined by the Administrator (in an Award Agreement or otherwise) or as otherwise directed by a Stock Appreciation Right Holder in writing to the Company, each Stock Appreciation Right outstanding on the Automatic Exercise Date with an exercise price per share that is less than the Fair Market Value per share of Common Stock as of such date shall automatically and without further action by the Stock Appreciation Right Holder or the Company be exercised on the Automatic Exercise Date. In the discretion of the Administrator, the Company or any Subsidiary shall deduct or withhold an amount sufficient to satisfy all taxes associated with such exercise in accordance with Section 10.2. Unless otherwise determined by the Administrator, this Section 9.6 shall not apply to a Stock Appreciation Right if the Holder of such Stock Appreciation Right incurs a Termination of Service on or before the Automatic Exercise Date. For the avoidance of doubt, no Stock Appreciation Right with an exercise price per share that is equal to or greater than the Fair Market Value per share of Common Stock on the Automatic Exercise Date shall be exercised pursuant to this Section 9.6.

ARTICLE 10.

ADDITIONAL TERMS OF AWARDS

10.1 Payment. The Administrator shall determine the methods by which payments by any Holder with respect to any Awards granted under the Plan shall be made, including, without limitation: (a) cash or check, (b) Shares (including, in the case of payment of the exercise price of an Award, Shares issuable pursuant to the exercise of the Award) held for such period of time as may be required by the Administrator in order to avoid adverse accounting consequences, in each case, having a Fair Market Value on the date of delivery equal to the aggregate payments required, (c) delivery of a written or electronic notice that the Holder has placed a market sell order with a broker acceptable to the Company with respect to Shares then issuable upon exercise or vesting of an Award, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the aggregate payments required; provided that payment of such proceeds is then made to the Company upon settlement of such sale, or (d) any other form of legal consideration acceptable to the Administrator in its discretion. The Administrator shall also determine the methods by which Shares shall be delivered or deemed to be delivered to Holders. Notwithstanding any other provision of the Plan to the contrary, no Holder who is a Director or an "executive officer" of the Company within the meaning of Section 13(k) of the Exchange Act shall be permitted to make payment with respect to any Awards granted under the Plan, or continue any extension of credit with respect to such payment, with a loan from the Company or a loan arranged by the Company in violation of Section 13(k) of the Exchange Act.

10.2 Tax Withholding. The Company or any Subsidiary shall have the authority and the right to deduct or withhold, or require a Holder to remit to the Company, an amount sufficient to satisfy federal, state, local and foreign taxes (including the Holder's FICA, employment tax or other social security contribution obligation) required by law to be withheld with respect to any taxable event concerning a Holder arising as a result of the Plan. The Administrator, in its discretion and in satisfaction of the foregoing requirement, may withhold, or allow a Holder to elect to have the Company withhold, Shares otherwise issuable under an Award (or allow the surrender of Shares). Unless otherwise determined by the Administrator, the number of Shares which may be so withheld or surrendered shall be limited to the number of Shares which have a Fair Market Value on the date of withholding or repurchase equal to the aggregate amount of such liabilities based on the applicable statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such supplemental taxable income. The Administrator shall determine the fair market value of the Shares, consistent with applicable provisions of the Code, for tax withholding obligations due in connection with a broker-assisted cashless Option or Stock Appreciation Right exercise involving the sale of Shares to pay the Option or Stock Appreciation Right exercise price or any tax withholding obligation.

10.3 Transferability of Awards.

(a) Except as otherwise provided in Section 10.3(b):

(i) No Award under the Plan may be sold, pledged, assigned or transferred in any manner other than by will or the laws of descent and distribution or, subject to the consent of the Administrator, pursuant to a DRO, unless and until such Award has been exercised, or the Shares underlying such Award have been issued, and all restrictions applicable to such Shares have lapsed;

(ii) No Award or interest or right therein shall be liable for the debts, contracts or engagements of the Holder or the Holder's successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, hypothecation, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempted disposition thereof shall be null and void and of no effect, except to the extent that such disposition is permitted by Section 10.3(a)(i); and

(iii) During the lifetime of the Holder, only the Holder may exercise an Award (or any portion thereof) granted to such Holder under the Plan, unless it has been disposed of pursuant to a DRO; after the death of the Holder, any exercisable portion of an Award may, prior to the time when such portion becomes unexercisable under the Plan or the Award Agreement, be exercised by the Holder's personal representative or by any person empowered to do so under the deceased Holder's will or under the then-applicable laws of descent and distribution.

(b) Notwithstanding Section 10.3(a), the Administrator, in its discretion, may determine to permit a Holder to transfer an Award to any one or more Permitted Transferees, subject to the following terms and conditions: (i) an Award transferred to a Permitted Transferee shall not be assignable or transferable by the Permitted Transferee other than by will or the laws

of descent and distribution; (ii) an Award transferred to a Permitted Transferee shall continue to be subject to all the terms and conditions of the Award as applicable to the original Holder (other than the ability to further transfer the Award); and (iii) the Holder and the Permitted Transferee shall execute any and all documents requested by the Administrator, including, without limitation documents to (A) confirm the status of the transferee as a Permitted Transferee, (B) satisfy any requirements for an exemption for the transfer under Applicable Law and (C) evidence the transfer.

(c) Notwithstanding Section 10.3(a), a Holder may, in the manner determined by the Administrator, designate a beneficiary to exercise the rights of the Holder and to receive any distribution with respect to any Award upon the Holder's death. A beneficiary, legal guardian, legal representative, or other person claiming any rights pursuant to the Plan is subject to all terms and conditions of the Plan and any Award Agreement applicable to the Holder, except to the extent the Plan and Award Agreement otherwise provide, and to any additional restrictions deemed necessary or appropriate by the Administrator. If the Holder is married or a domestic partner in a domestic partnership qualified under Applicable Law and resides in a community property state, a designation of a person other than the Holder's spouse or domestic partner, as applicable, as the Holder's beneficiary with respect to more than 50% of the Holder's interest in the Award shall not be effective without the prior written or electronic consent of the Holder's spouse or domestic partner. If no beneficiary has been designated or survives the Holder, payment shall be made to the person entitled thereto pursuant to the Holder's will or the laws of descent and distribution. Subject to the foregoing, a beneficiary designation may be changed or revoked by a Holder at any time; provided that the change or revocation is filed with the Administrator prior to the Holder's death.

10.4 Conditions to Issuance of Shares.

(a) Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any certificates or make any book entries evidencing Shares issuable pursuant to any Award, unless and until the Board or the Committee has determined, with advice of counsel, that the issuance of such Shares is in compliance with Applicable Law and the Shares are covered by an effective registration statement or applicable exemption from registration. In addition to the terms and conditions provided herein, the Board or the Committee may require that a Holder make such reasonable covenants, agreements and representations as the Board or the Committee, in its discretion, deems advisable in order to comply with Applicable Law.

(b) All Share certificates delivered pursuant to the Plan and all Shares issued pursuant to book entry procedures are subject to any stop-transfer orders and other restrictions as the Administrator deems necessary or advisable to comply with Applicable Law. The Administrator may place legends on any Share certificate or book entry to reference restrictions applicable to the Shares.

(c) The Administrator shall have the right to require any Holder to comply with any timing or other restrictions with respect to the settlement, distribution or exercise of any Award, including a window-period limitation, as may be imposed in the discretion of the Administrator.

(d) No fractional Shares shall be issued and the Administrator, in its discretion, shall determine whether cash shall be given in lieu of fractional Shares or whether such fractional Shares shall be eliminated by rounding down.

(e) Notwithstanding any other provision of the Plan, unless otherwise determined by the Administrator or required by Applicable Law, the Company shall not deliver to any Holder certificates evidencing Shares issued in connection with any Award and instead such Shares shall be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator).

10.5 Forfeiture and Claw-Back Provisions. Pursuant to its general authority to determine the terms and conditions applicable to Awards under the Plan, the Administrator shall have the right to provide, in an Award Agreement or otherwise, or to require a Holder to agree by separate written or electronic instrument, that:

(a) (i) Any proceeds, gains or other economic benefit actually or constructively received by the Holder upon any receipt or exercise of the Award, or upon the receipt or resale of any Shares underlying the Award, shall be paid to the Company, and (ii) the Award shall terminate and any unexercised portion of the Award (whether or not vested) shall be forfeited, if (x) a Termination of Service occurs prior to a specified date, or within a specified time period following receipt or exercise of the Award, or (y) the Holder at any time, or during a specified time period, engages in any activity in competition with the Company, or which is inimical, contrary or harmful to the interests of the Company, as further defined by the Administrator or (z) the Holder incurs a Termination of Service for "cause" (as such term is defined in the discretion of the Administrator, or as set forth in a written agreement relating to such Award between the Company and the Holder); and

(b) All Awards (including any proceeds, gains or other economic benefit actually or constructively received by the Holder upon any receipt or exercise of any Award or upon the receipt or resale of any Shares underlying the Award) shall be subject to the provisions of any claw-back policy implemented by the Company, including, without limitation, any claw-back policy adopted to comply with the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder, to the extent set forth in such claw-back policy and/or in the applicable Award Agreement.

10.6 Repricing. Subject to Section 11.2, the Administrator shall have the authority, without the approval of the stockholders of the Company, to amend any outstanding Option or Stock Appreciation Right to reduce its price per share or cancel any Option or Stock Appreciation Right in exchange for cash or another Award when the Option or Stock Appreciation Right price per share exceeds the Fair Market Value of the underlying Shares.

10.7 Action Required Upon Grant of Award. The Company shall, in accordance with NASDAQ Rule 5635(c), (a) issue a press release disclosing the material terms of the Award, including the recipient(s) of the Award and the number of Shares involved and (b) provide written notice to the NASDAQ of the grant.

ARTICLE 11.

ADMINISTRATION

11.1 Administrator. The Committee (or another committee or a subcommittee of the Board assuming the functions of the Committee under the Plan) shall administer the Plan (except as otherwise permitted herein) and, unless otherwise determined by the Board, shall consist solely of two or more Non-Employee Directors, each of whom is intended to qualify as both a "non-employee director" as defined by Rule 16b-3 of the Exchange Act or any successor rule and an "independent director" under the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded. Notwithstanding the foregoing, any action taken by the Committee shall be valid and effective, whether or not members of the Committee at the time of such action are later determined not to have satisfied the requirements for membership set forth in this Section 11.1 or otherwise provided in any charter of the Committee. Except as may otherwise be provided in any charter of the Committee, appointment of Committee members shall be effective upon acceptance of appointment. Committee members may resign at any time by delivering written or electronic notice to the Board. Vacancies in the Committee may only be filled by the Board. Notwithstanding the foregoing, (a) the full Board, acting by a majority of its members in office, shall conduct the general administration of the Plan with respect to Awards granted to Non-Employee Directors and, with respect to such Awards, the terms "Administrator" and "Committee" as used in the Plan shall be deemed to refer to the Board and (b) the Board or Committee may delegate its authority hereunder to the extent permitted by Section 11.6. The Administrator may adopt procedures from time to time that are intended to ensure that an individual is an Eligible Individual prior to the granting of any Awards to such individual (including without limitation a requirement that each such individual certify to the Company prior to the receipt of an Award that he or she is not currently employed by the Company or a Subsidiary and, if previously so employed, has had a bona fide period of interruption of employment, and that the grant of Awards is an inducement material to his or her agreement to enter into employment with the Company or a Subsidiary).

11.2 Duties and Powers of Committee. It shall be the duty of the Committee to conduct the general administration of the Plan in accordance with its provisions. The Committee shall have the power to interpret the Plan and Award Agreements, and to adopt such rules for the administration, interpretation and application of the Plan as are not inconsistent therewith, to interpret, amend or revoke any such rules and to amend any Award Agreement; provided that the rights or obligations of the Holder of the Award that is the subject of any such Award Agreement are not affected adversely by such amendment, unless the consent of the Holder is obtained or such amendment is otherwise permitted under Section 10.5 or Section 12.10. Any such grant or award under the Plan need not be the same with respect to each Holder. In its discretion, the Board may at any time and from time to time exercise any and all rights and duties of the Committee under the Plan except with respect to matters which under Rule 16b-3 under the Exchange Act or any successor rule, or any regulations or rules issued thereunder, or the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded are required to be determined in the discretion of the Committee.

11.3 Action by the Committee. Unless otherwise established by the Board or in any charter of the Committee, a majority of the Committee shall constitute a quorum and the acts of a

majority of the members present at any meeting at which a quorum is present, and acts approved in writing by all members of the Committee in lieu of a meeting, shall be deemed the acts of the Committee. Each member of the Committee is entitled to, in good faith, rely or act upon any report or other information furnished to that member by any officer or other employee of the Company or any Subsidiary, the Company's independent certified public accountants, or any executive compensation consultant or other professional retained by the Company to assist in the administration of the Plan.

11.4 Authority of Administrator. Subject to the Company's Bylaws, the Committee's Charter and any specific designation in the Plan, the Administrator has the exclusive power, authority and sole discretion to:

(a) Designate Eligible Individuals to receive Awards;

(b) Determine the type or types of Awards to be granted to Eligible Individuals;

(c) Determine the number of Awards to be granted and the number of Shares to which an Award will relate;

(d) Determine the terms and conditions of any Award granted pursuant to the Plan, including, but not limited to, the exercise price, grant price, purchase price, any Performance Goals or Performance Criteria, any reload provision, any restrictions or limitations on the Award, any schedule for vesting, lapse of forfeiture restrictions or restrictions on the exercisability of an Award, and accelerations or waivers thereof, and any provisions related to non-competition and recapture of gain on an Award, based in each case on such considerations as the Administrator in its sole discretion determines;

(e) Determine whether, to what extent, and pursuant to what circumstances an Award may be settled in, or the exercise price of an Award may be paid in cash, Shares, other Awards, or other property, or an Award may be canceled, forfeited, or surrendered;

(f) Prescribe the form of each Award Agreement, which need not be identical for each Holder;

(g) Decide all other matters that must be determined in connection with an Award;

(h) Establish, adopt or revise any rules and regulations as it may deem necessary or advisable to administer the Plan;

(i) Interpret the terms of, and any matter arising pursuant to, the Plan or any Award Agreement;

(j) Make all other decisions and determinations that may be required pursuant to the Plan or as the Administrator deems necessary or advisable to administer the Plan; and

(k) Accelerate wholly or partially the vesting or lapse of restrictions of any Award or portion thereof at any time after the grant of an Award, subject to whatever terms and conditions it selects.

11.5 Decisions Binding. The Administrator's interpretation of the Plan, any Awards granted pursuant to the Plan, and any Award Agreement and all decisions and determinations by the Administrator with respect to the Plan are final, binding and conclusive on all parties.

11.6 Delegation of Authority. To the extent permitted by Applicable Law, the Board or Committee may from time to time delegate to a committee of one or more members of the Board or one or more officers of the Company the authority to grant or amend Awards or to take other administrative actions pursuant to this Article 11. Any delegation hereunder shall be subject to the restrictions and limits that the Board or Committee specifies at the time of such delegation, and the Board may at any time rescind the authority so delegated or appoint a new delegatee. At all times, the delegatee appointed under this Section 11.6 shall serve in such capacity at the pleasure of the Board and the Committee.

ARTICLE 12.

MISCELLANEOUS PROVISIONS

12.1 Amendment, Suspension or Termination of the Plan. Except as otherwise provided in this Section 12.1, the Plan may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Board or the Committee. However, to the extent required by Applicable Law, without approval of the Company's stockholders given within twelve (12) months before or after the action by the Administrator, no action of the Administrator may, except as provided in Section 12.2, increase the limits imposed in Section 3.1 on the maximum number of Shares which may be issued under the Plan. Except as provided in Section 12.10, no amendment, suspension or termination of the Plan shall, without the consent of the Holder, impair any rights or obligations under any Award theretofore granted or awarded, unless the Award itself otherwise expressly so provides. No Awards may be granted or awarded during any period of suspension or after termination of the Plan, and in no event may any Award be granted under the Plan after the tenth anniversary of the Effective Date (the "Expiration Date"). Any Awards that are outstanding on the Expiration Date shall remain in force according to the terms of the Plan and the applicable Award Agreement.

12.2 Changes in Common Stock or Assets of the Company, Acquisition or Liquidation of the Company and Other Corporate Events.

(a) In connection with the occurrence of any Equity Restructuring, and notwithstanding anything to the contrary in this Section 12.2, the Administrator shall equitably adjust each outstanding Award, which adjustments may include adjustments to the number and type of securities subject to each outstanding Award and/or the exercise price or grant price thereof, if applicable, the grant of new Awards (subject to the requirements of NASDAQ Rule 5635(c)(4) and other Applicable Laws), and/or the making of a cash payment, as the Administrator deems appropriate to reflect such Equity Restructuring. The adjustments provided under this Section 12.2(a) shall be nondiscretionary and shall be final and binding on the affected Holder and the

Company; provided that whether an adjustment is equitable shall be determined in the discretion of the Administrator.

(b) In the event that the Administrator determines that any dividend or other distribution (whether in the form of cash, Common Stock, other securities, or other property), Change in Control, reorganization, merger, amalgamation, consolidation, combination, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or sale or exchange of Common Stock or other securities of the Company, issuance of warrants or other rights to purchase Common Stock or other securities of the Company, or other similar corporate transaction or event, as determined by the Administrator, affects the Common Stock such that an adjustment is determined by the Administrator to be appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award, the Administrator may make equitable adjustments, if any, to reflect such change with respect to: (i) the aggregate number and kind of shares that may be issued under the Plan (including, but not limited to, adjustments of the limitations in Sections 3.1) on the maximum number and kind of shares which may be issued under the Plan); (ii) the number and kind of Shares (or other securities or property) subject to outstanding Awards; (iii) the terms and conditions of any outstanding Awards (including, without limitation, any applicable performance targets or criteria with respect thereto); and (iv) the grant or exercise price per share for any outstanding Awards under the Plan.

(c) In the event of any transaction or event described in Section 12.2(b) or any unusual or nonrecurring transactions or events affecting the Company, any Subsidiary of the Company, or the financial statements of the Company or any Subsidiary, or of changes in Applicable Law or accounting principles, the Administrator, in its discretion, and on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event and either automatically or upon the Holder's request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan or with respect to any Award under the Plan, to facilitate such transactions or events or to give effect to such changes in laws, regulations or principles:

(i) To provide for either (A) termination of any such Award in exchange for an amount of cash, if any, equal to the amount that would have been attained upon the exercise of such Award or realization of the Holder's rights (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction or event described in this Section 12.2 the Administrator determines in good faith that no amount would have been attained upon the exercise of such Award or realization of the Holder's rights, then such Award may be terminated by the Company without payment) or (B) the replacement of such Award with other rights or property selected by the Administrator, in its discretion, having an aggregate value not exceeding the amount that could have been attained upon the exercise of such Award or realization of the Holder's rights had such Award been currently exercisable or payable or fully vested;

(ii) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by similar options, rights

or awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices;

(iii) To make adjustments in the number and type of shares of the Company's stock (or other securities or property) subject to outstanding Awards, and in the number and kind of outstanding Restricted Stock and/or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding Awards and Awards which may be granted in the future;

(iv) To provide that such Award shall be exercisable or payable or fully vested with respect to all shares covered thereby, notwithstanding anything to the contrary in the Plan or the applicable Award Agreement; and

(v) To provide that the Award will terminate and cannot vest, be exercised or become payable after such event.

(d) The Administrator, in its discretion, may include such further provisions and limitations in any Award, agreement or certificate, as it may deem equitable and in the best interests of the Company that are not inconsistent with the provisions of the Plan.

(e) Unless otherwise determined by the Administrator, no adjustment or action described in this Section 12.2 or in any other provision of the Plan shall be authorized to the extent that such adjustment would cause the Plan or an Award to violate NASDAQ Rule 5635(c)(4) or other Applicable Law. Furthermore, no such adjustment or action shall be authorized to the extent such adjustment or action would result in short-swing profits liability under Section 16 of the Exchange Act or violate the exemptive conditions of Rule 16b-3 of the Exchange Act unless the Administrator determines that the Award is not to comply with such exemptive conditions.

(f) The existence of the Plan, the Award Agreement and the Awards granted hereunder shall not affect or restrict in any way the right or power of the Company or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, any merger or consolidation of the Company, any issue of stock or of options, warrants or rights to purchase stock or of bonds, debentures, preferred or prior preference stocks whose rights are superior to or affect the Common Stock or the rights thereof or which are convertible into or exchangeable for Common Stock, or the dissolution or liquidation of the Company, or any sale or transfer of all or any part of its assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise.

(g) No action shall be taken under this Section 12.2 which shall cause an Award to fail to comply with Section 409A of the Code, to the extent applicable.

(h) In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the Shares or the share price of the Common Stock including any Equity Restructuring, for reasons of administrative convenience, the Company, in its discretion, may refuse to permit the exercise of any Award during a period of up to thirty (30) days prior to the consummation of any such transaction.

12.3 Approval of Plan by Stockholders Not Required. It is expressly intended that approval of the Company's stockholders not be required as a condition of the effectiveness of the Plan, and the Plan's provisions shall be interpreted in a manner consistent with such intent for all purposes. Specifically, NASDAQ Rule 5635(c) generally requires stockholder approval for equity-compensation plans adopted by companies whose securities are listed on the NASDAQ Stock Market that provide for the delivery of equity securities to any employees, directors or other service providers of such companies as compensation for services. NASDAQ Rule 5635(c)(4) provides an exemption in certain circumstances for employment inducement awards. Notwithstanding anything to the contrary herein, in accordance with NASDAQ Rule 5635(c)(4), Awards may only be granted as material inducements to Eligible Individuals being hired or rehired as Employees, as applicable, and must be approved by (a) the Board, acting through a majority of the Company's Independent Directors or (b) the independent Compensation Committee of the Board. Accordingly, pursuant to NASDAQ Rule 5635(c)(4), the issuance of Awards and the Shares issuable upon exercise or vesting of such Awards pursuant to the Plan is not subject to the approval of the Company's stockholders.

12.4 No Stockholders Rights. Except as otherwise provided herein, a Holder shall have none of the rights of a stockholder with respect to Shares covered by any Award until the Holder becomes the record owner of such Shares.

12.5 Paperless Administration. In the event that the Company establishes, for itself or using the services of a third party, an automated system for the documentation, granting or exercise of Awards, such as a system using an internet website or interactive voice response, then the paperless documentation, granting or exercise of Awards by a Holder may be permitted through the use of such an automated system.

12.6 Effect of Plan upon Other Compensation Plans. The adoption of the Plan shall not affect any other compensation or incentive plans in effect for the Company or any Subsidiary. Nothing in the Plan shall be construed to limit the right of the Company or any Subsidiary: (a) to establish any other forms of incentives or compensation for Employees, Directors or Consultants of the Company or any Subsidiary, or (b) except as otherwise provided in the penultimate sentence of Section 3.1(a), to grant or assume options or other rights or awards otherwise than under the Plan in connection with any proper corporate purpose including without limitation, the grant or assumption of options in connection with the acquisition by purchase, lease, merger, consolidation or otherwise, of the business, stock or assets of any corporation, partnership, limited liability company, firm or association.

12.7 Compliance with Laws. The Plan, the granting and vesting of Awards under the Plan and the issuance and delivery of Shares and the payment of money under the Plan or under Awards granted or awarded hereunder are subject to compliance with all Applicable Law (including but not limited to state, federal and foreign securities law and margin requirements), and to such approvals by any listing, regulatory or governmental authority as may, in the opinion of counsel for the Company, be necessary or advisable in connection therewith. Any securities delivered under the Plan shall be subject to such restrictions, and the person acquiring such securities shall, if requested by the Company, provide such assurances and representations to the Company as the Company may deem necessary or desirable to assure compliance with all Applicable Law. To the extent permitted by Applicable Law, the Plan and Awards granted or

awarded hereunder shall be deemed amended to the extent necessary to conform to Applicable Law.

12.8 Titles and Headings, References to Sections of the Code or Exchange Act. The titles and headings of the Sections in the Plan are for convenience of reference only and, in the event of any conflict, the text of the Plan, rather than such titles or headings, shall control. References to sections of the Code or the Exchange Act shall include any amendment or successor thereto.

12.9 Governing Law. The Plan and any agreements hereunder shall be administered, interpreted and enforced under the internal laws of the State of Delaware without regard to conflicts of laws thereof or of any other jurisdiction.

12.10 Section 409A. To the extent that the Administrator determines that any Award granted under the Plan is subject to Section 409A of the Code, the Award Agreement evidencing such Award shall incorporate the terms and conditions required by Section 409A of the Code. To the extent applicable, the Plan and any Award Agreements shall be interpreted in accordance with Section 409A of the Code, including without limitation any such regulations or other guidance that may be issued after the Effective Date. Notwithstanding any provision of the Plan to the contrary, in the event that following the Effective Date the Administrator determines that any Award may be subject to Section 409A of the Code (including Department of Treasury guidance as may be issued after the Effective Date), the Administrator may adopt such amendments to the Plan and the applicable Award Agreement or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Administrator determines are necessary or appropriate to (a) exempt the Award from Section 409A of the Code and/or preserve the intended tax treatment of the benefits provided with respect to the Award, or (b) comply with the requirements of Section 409A of the Code and thereby avoid the application of any penalty taxes under such Section.

12.11 No Rights to Awards. No Eligible Individual or other person shall have any claim to be granted any Award pursuant to the Plan, and neither the Company nor the Administrator is obligated to treat Eligible Individuals, Holders or any other persons or Awards (or portions thereof) uniformly.

12.12 Unfunded Status of Awards. The Plan is intended to be an “unfunded” plan for incentive compensation. With respect to any payments not yet made to a Holder pursuant to an Award, nothing contained in the Plan or any Award Agreement shall give the Holder any rights that are greater than those of a general creditor of the Company or any Subsidiary.

12.13 Indemnification. To the extent allowable pursuant to Applicable Law, each member of the Committee or of the Board shall be indemnified and held harmless by the Company from any loss, cost, liability, or expense that may be imposed upon or reasonably incurred by such member in connection with or resulting from any claim, action, suit, or proceeding to which he or she may be a party or in which he or she may be involved by reason of any action or failure to act pursuant to the Plan and against and from any and all amounts paid by him or her in satisfaction of judgment in such action, suit, or proceeding against him or her; provided he or she gives the Company an opportunity, at its own expense, to handle and defend the same before he or she

undertakes to handle and defend it on his or her own behalf. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such persons may be entitled pursuant to the Company's Certificate of Incorporation or Bylaws, as a matter of law, or otherwise, or any power that the Company may have to indemnify them or hold them harmless.

12.14 Relationship to other Benefits. No payment pursuant to the Plan shall be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Subsidiary except to the extent otherwise expressly provided in writing in such other plan or an agreement thereunder.

12.15 Expenses. The expenses of administering the Plan shall be borne by the Company and its Subsidiaries.

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T2 BIOSYSTEMS, INC.
INDUCEMENT AWARD PLAN

STOCK OPTION GRANT NOTICE

T2 Biosystems, Inc., a Delaware corporation, (the "Company"), pursuant to its Inducement Award Plan, as amended from time to time (the "Plan"), hereby grants to the holder listed below ("Participant"), an option to purchase the number of shares of Common Stock ("Stock") set forth below (the "Option"). The Option is subject to the terms and conditions set forth in this Stock Option Grant Notice (the "Grant Notice") and the Stock Option Agreement attached hereto as Exhibit A (the "Agreement") and the Plan, which are incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in the Grant Notice and the Agreement.

Participant:	
Grant Date:	
Exercise Price per Share:	$
Total Exercise Price:	$
Total Number of Shares Subject to the Option:	shares
Expiration Date:	
Vesting Commencement Date:	
Vesting Schedule:	[To be specified in individual agreements]
Type of Option:	Non-Qualified Stock Option

By Participant's signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and the Grant Notice. Participant has reviewed the Agreement, the Plan and the Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing the Grant Notice and fully understands all provisions of the Grant Notice, the Agreement and the Plan. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, the Grant Notice or the Agreement.

T2 BIOSYSTEMS, INC.	**PARTICIPANT**
By:	By:
Print Name:	Print Name:
Title:	

EXHIBIT A
TO STOCK OPTION GRANT NOTICE

STOCK OPTION AGREEMENT

Pursuant to the Grant Notice to which this Agreement is attached, the Company has granted to Participant an Option under the Plan to purchase the number of shares of Stock set forth in the Grant Notice.

ARTICLE 13.
GENERAL

13.1 Defined Terms. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan or the Grant Notice.

13.2 Incorporation of Terms of Plan. The Option is subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

13.3 Employment Inducement Award. The Option is intended to constitute an employment inducement award under NASDAQ Rule 5635(c)(4) that is exempt from the requirements of shareholder approval of equity-compensation plans under NASDAQ Rule 5635(c)(4). This Agreement and the terms and conditions of the Option will be interpreted consistent with such intent.

ARTICLE 14.
GRANT OF OPTION

14.1 Grant of Option. In consideration of Participant's past and/or continued employment with or service to the Company or a Subsidiary and for other good and valuable consideration, effective as of the grant date set forth in the Grant Notice (the "Grant Date"), the Company has granted to Participant the Option to purchase any part or all of an aggregate of the number of shares of Stock set forth in the Grant Notice, upon the terms and conditions set forth in the Grant Notice, the Plan and this Agreement, subject to adjustments as provided in Section 12.2 of the Plan.

14.2 Exercise Price. The exercise price per share of the shares of Stock subject to the Option (the "Exercise Price") shall be as set forth in the Grant Notice.

14.3 Consideration to the Company. In consideration of the grant of the Option by the Company, Participant agrees to render faithful and efficient services to the Company or any Subsidiary. Nothing in the Plan, the Grant Notice or this Agreement shall confer upon Participant any right to continue in the employ or service of the Company or any Subsidiary or shall interfere with or restrict in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason

whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

ARTICLE 15.
PERIOD OF EXERCISABILITY

15.1 Commencement of Exercisability.

(a) Subject to Sections 3.2, 3.3, 5.9 and 5.14 hereof, the Option shall become vested and exercisable in such amounts and at such times as are set forth in the Grant Notice.

(b) Unless otherwise determined by the Administrator, any portion of the Option that has not become vested and exercisable on or prior to the date of the Participant's Termination of Service shall be forfeited on the date of the Participant's Termination of Service and shall not thereafter become vested or exercisable.

15.2 Duration of Exercisability. The installments provided for in the vesting schedule set forth in the Grant Notice are cumulative. Each such installment which becomes vested and exercisable pursuant to the vesting schedule set forth in the Grant Notice shall remain vested and exercisable until it becomes unexercisable under Section 3.3 hereof. Once the Option becomes unexercisable, it shall be forfeited immediately.

15.3 Expiration of Option. The Option may not be exercised to any extent by anyone after the first to occur of the following events:

(a) The expiration date set forth in the Grant Notice;

(b) Except as the Administrator may otherwise approve, in the event of Participant's Termination of Service other than for Cause or by reason of Participant's death or disability, the expiration of three (3) months from the date of Participant's Termination of Service;

(c) Except as the Administrator may otherwise approve, the expiration of one (1) year from the date of Participant's Termination of Service by reason of Participant's death or disability; or

(d) Except as the Administrator may otherwise approve, upon Participant's Termination of Service for Cause.

As used in this Agreement, "Cause" shall mean (a) the Board's determination that Participant failed to substantially perform Participant's duties (other than any such failure resulting from Participant's disability); (b) the Board's determination that Participant failed to carry out, or comply with any lawful and reasonable directive of the Board or Participant's immediate supervisor; (c) Participant's conviction, plea of no contest, plea of nolo contendere, or imposition of unadjudicated probation for any felony, indictable offense or crime involving moral turpitude; (d) Participant's unlawful use (including being under the influence) or possession of illegal drugs on the premises of the Company or any of its Subsidiaries or while performing Participant's duties and responsibilities; or (e) Participant's commission of an act of fraud, embezzlement,

misappropriation, misconduct, or breach of fiduciary duty against the Company of any of its Subsidiaries. Notwithstanding the foregoing, if Participant is a party to a written employment or consulting agreement with the Company (or its Subsidiary) in which the term "cause" is defined, then "Cause" shall be as such term is defined in the applicable written employment or consulting agreement.

15.4 Tax Withholding. Notwithstanding any other provision of this Agreement:

(a) The Company and its Subsidiaries have the authority to deduct or withhold, or require Participant to remit to the Company or the applicable Subsidiary, an amount sufficient to satisfy applicable federal, state, local and foreign taxes (including the employee portion of any FICA obligation) required by law to be withheld with respect to any taxable event arising pursuant to this Agreement. The Company and its Subsidiaries may withhold or Participant may make such payment in one or more of the forms specified below:

(i) by cash or check made payable to the Company or the Subsidiary with respect to which the withholding obligation arises;

(ii) by the deduction of such amount from other compensation payable to Participant;

(iii) with respect to any withholding taxes arising in connection with the exercise of the Option, with the consent of the Administrator, by requesting that the Company withhold a net number of shares of Stock issuable upon the exercise of the Option having a then current Fair Market Value not exceeding the amount necessary to satisfy the withholding obligation of the Company and its Subsidiaries based on the applicable statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes;

(iv) with respect to any withholding taxes arising in connection with the exercise of the Option, with the consent of the Administrator, by tendering to the Company shares of Stock having a then current Fair Market Value not exceeding the amount necessary to satisfy the withholding obligation of the Company and its Subsidiaries based on the applicable statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes;

(v) with respect to any withholding taxes arising in connection with the exercise of the Option, through the delivery of a notice that Participant has placed a market sell order with a broker acceptable to the Company with respect to shares of Stock then issuable upon exercise of the Option, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company or the Subsidiary with respect to which the withholding obligation arises in satisfaction of such withholding taxes; *provided* that payment of such proceeds is then made to the Company or the applicable Subsidiary at such time as may be required by the Administrator, but in any event not later than the settlement of such sale; or

(vi) in any combination of the foregoing.

(b) With respect to any withholding taxes arising in connection with the Option, in the event Participant fails to provide timely payment of all sums required pursuant to Section 3.4(a), the Company shall have the right and option, but not the obligation, to treat such failure as

an election by Participant to satisfy all or any portion of Participant's required payment obligation pursuant to Section 3.4(a)(ii) or Section 3.4(a)(iii) above, or any combination of the foregoing as the Company may determine to be appropriate. The Company shall not be obligated to deliver any certificate representing shares of Stock issuable with respect to the exercise of the Option to Participant or his or her legal representative unless and until Participant or his or her legal representative shall have paid or otherwise satisfied in full the amount of all federal, state, local and foreign taxes applicable with respect to the taxable income of Participant resulting from the exercise of the Option or any other taxable event related to the Option.

(c) In the event any tax withholding obligation arising in connection with the Option will be satisfied under Section 3.4(a)(iii) above, then the Company may elect to instruct any brokerage firm determined acceptable to the Company for such purpose to sell on Participant's behalf a whole number of shares from those shares of Stock that are issuable upon exercise of the Option as the Company determines to be appropriate to generate cash proceeds sufficient to satisfy the tax withholding obligation and to remit the proceeds of such sale to the Company or the Subsidiary with respect to which the withholding obligation arises. Participant's acceptance of this Award constitutes Participant's instruction and authorization to the Company and such brokerage firm to complete the transactions described in this Section 3.4(c), including the transactions described in the previous sentence, as applicable. The Company may refuse to issue any shares of Stock to Participant until the foregoing tax withholding obligations are satisfied.

(d) Participant is ultimately liable and responsible for all taxes owed in connection with the Option, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the Option. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or exercise of the Option or the subsequent sale of Stock. The Company and the Subsidiaries do not commit and are under no obligation to structure the Option to reduce or eliminate Participant's tax liability.

ARTICLE 16.
EXERCISE OF OPTION

16.1 Person Eligible to Exercise. During the lifetime of Participant, only Participant may exercise the Option or any portion thereof. After the death of Participant, any exercisable portion of the Option may, prior to the time when the Option becomes unexercisable under Section 3.3 hereof, be exercised by Participant's personal representative or by any person empowered to do so under the deceased Participant's will or under the then applicable laws of descent and distribution.

16.2 Partial Exercise. Subject to Section 5.2, any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised in whole or in part at any time prior to the time when the Option or portion thereof becomes unexercisable under Section 3.3 hereof.

16.3 Manner of Exercise. The Option, or any exercisable portion thereof, may be exercised solely by delivery to the Secretary of the Company (or any third party administrator or other person or entity designated by the Company), during regular business hours, of all of the

following prior to the time when the Option or such portion thereof becomes unexercisable under Section 3.3 hereof.

(a) An exercise notice in a form specified by the Administrator, stating that the Option or portion thereof is thereby exercised, such notice complying with all applicable rules established by the Administrator;

(b) The receipt by the Company of full payment for the shares of Stock with respect to which the Option or portion thereof is exercised, in such form of consideration permitted under Section 4.4 hereof that is acceptable to the Administrator;

(c) The payment of any applicable withholding tax in accordance with Section 3.4;

(d) Any other written representations or documents as may be required in the Administrator's sole discretion to effect compliance with Applicable Law; and

(e) In the event the Option or portion thereof shall be exercised pursuant to Section 4.1 hereof by any person or persons other than Participant, appropriate proof of the right of such person or persons to exercise the Option.

Notwithstanding any of the foregoing, the Administrator shall have the right to specify all conditions of the manner of exercise, which conditions may vary by country and which may be subject to change from time to time.

16.4 Method of Payment. Payment of the exercise price shall be by any of the following, or a combination thereof, at the election of Participant:

(a) Cash or check;

(b) With the consent of the Administrator, surrender of shares of Stock (including, without limitation, shares of Stock otherwise issuable upon exercise of the Option) held for such period of time as may be required by the Administrator in order to avoid adverse accounting consequences and having a Fair Market Value on the date of delivery equal to the aggregate exercise price of the Option or exercised portion thereof;

(c) Through the delivery of a notice that Participant has placed a market sell order with a broker acceptable to the Company with respect to shares of Stock then issuable upon exercise of the Option, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the Option exercise price; *provided* that payment of such proceeds is then made to the Company at such time as may be required by the Administrator, but in any event not later than the settlement of such sale; or

(d) Any other form of legal consideration acceptable to the Administrator.

16.5 Conditions to Issuance of Stock. The Company shall not be required to issue or deliver any shares of Stock purchased upon the exercise of the Option or portion thereof prior to fulfillment of all of the following conditions: (A) the admission of such shares of Stock to listing

on all stock exchanges on which such Stock is then listed, (B) the completion of any registration or other qualification of such shares of Stock under any state or federal law or under rulings or regulations of the Securities and Exchange Commission or other governmental regulatory body, which the Administrator shall, in its absolute discretion, deem necessary or advisable, (C) the obtaining of any approval or other clearance from any state or federal governmental agency which the Administrator shall, in its absolute discretion, determine to be necessary or advisable, (D) the receipt by the Company of full payment for such shares of Stock, which may be in one or more of the forms of consideration permitted under Section 4.4 hereof, and (E) the receipt of full payment of any applicable withholding tax in accordance with Section 3.4 by the Company or its Subsidiary with respect to which the applicable withholding obligation arises.

16.6 Rights as Stockholder. Neither Participant nor any person claiming under or through Participant will have any of the rights or privileges of a stockholder of the Company in respect of any shares of Stock purchasable upon the exercise of any part of the Option unless and until certificates representing such shares of Stock (which may be in book-entry form) will have been issued and recorded on the records of the Company or its transfer agents or registrars and delivered to Participant (including through electronic delivery to a brokerage account). No adjustment will be made for a dividend or other right for which the record date is prior to the date of such issuance, recordation and delivery, except as provided in Section 12.2 of the Plan. Except as otherwise provided herein, after such issuance, recordation and delivery, Participant will have all the rights of a stockholder of the Company with respect to such shares of Stock, including, without limitation, the right to receipt of dividends and distributions on such shares.

ARTICLE 17.
OTHER PROVISIONS

17.1 Administration. The Administrator shall have the power to interpret the Plan, the Grant Notice and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan, the Grant Notice and this Agreement as are consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator will be final and binding upon Participant, the Company and all other interested persons. To the extent allowable pursuant to Applicable Law, no member of the Committee or the Board will be personally liable for any action, determination or interpretation made with respect to the Plan, the Grant Notice or this Agreement.

17.2 Whole Shares. The Option may only be exercised for whole shares of Stock.

17.3 Option Not Transferable. Subject to Section 4.1 hereof, the Option may not be sold, pledged, assigned or transferred in any manner other than by will or the laws of descent and distribution, unless and until the shares of Stock underlying the Option have been issued, and all restrictions applicable to such shares of Stock have lapsed. Neither the Option nor any interest or right therein or part thereof shall be liable for the debts, contracts or engagements of Participant or his or her successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempted disposition thereof

shall be null and void and of no effect, except to the extent that such disposition is permitted by the preceding sentence.

17.4 Adjustments. The Administrator may accelerate the vesting of all or a portion of the Option in such circumstances as it, in its sole discretion, may determine. In addition, upon the occurrence of certain events relating to the Stock contemplated by Section 12.2 of the Plan (including, without limitation, an extraordinary cash dividend on such Stock), the Administrator may make such adjustments as the Administrator deems appropriate in the number of shares of Stock subject to the Option, the exercise price of the Option and the kind of securities that may be issued upon exercise of the Option. Participant acknowledges that the Option is subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan, including Section 12.2 of the Plan.

17.5 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to Participant shall be addressed to Participant (or, if Participant is then deceased, to the person entitled to exercise the Option pursuant to Section 4.1) at Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 5.5, either party may hereafter designate a different address for notices to be given to that party. Any notice shall be deemed duly given when sent via email (if to Participant) or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

17.6 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

17.7 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

17.8 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws, including, without limitation, the provisions of the Securities Act and the Exchange Act and any and all regulations and rules promulgated thereunder by the Securities and Exchange Commission and state securities laws and regulations. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the Option is granted and may be exercised, only in such a manner as to conform to Applicable Law. To the extent permitted by Applicable Law, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to Applicable Law.

17.9 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board, *provided* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the Option in any material way without the prior written consent of Participant.

17.10 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in Section 5.3 and the Plan, this Agreement shall be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

17.11 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Option, the Grant Notice and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

17.12 Not a Contract of Employment. Nothing in this Agreement or in the Plan shall confer upon Participant any right to continue to serve as an employee or other service provider of the Company or any Subsidiary or shall interfere with or restrict in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

17.13 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

17.14 Section 409A. This Award is not intended to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date hereof, "Section 409A"). However, notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that this Award (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate for this Award either to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

17.15 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held invalid or unenforceable, such provision will be severable from, and such invalidity or unenforceability will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

17.16 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant shall have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Option, and rights no greater than the right to receive the Stock as a general unsecured creditor with respect to options, as and when exercised pursuant to the terms hereof.

17.17 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which shall be deemed an original and all of which together shall constitute one instrument.

17.18 Broker-Assisted Sales. In the event of any broker-assisted sale of shares of Stock in connection with the payment of withholding taxes as provided in Section 3.4(a)(v) or Section 3.4(c) or the payment of the exercise price as provided in Section 4.4(c): (A) any shares of Stock to be sold through a broker-assisted sale will be sold on the day the tax withholding obligation or exercise of the Option, as applicable, occurs or arises, or as soon thereafter as practicable; (B) such shares of Stock may be sold as part of a block trade with other participants in the Plan in which all participants receive an average price; (C) Participant will be responsible for all broker's fees and other costs of sale, and Participant agrees to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale; (D) to the extent the proceeds of such sale exceed the applicable tax withholding obligation or exercise price, the Company agrees to pay such excess in cash to Participant as soon as reasonably practicable; (E) Participant acknowledges that the Company or its designee is under no obligation to arrange for such sale at any particular price, and that the proceeds of any such sale may not be sufficient to satisfy the applicable tax withholding obligation or exercise price; and (F) in the event the proceeds of such sale are insufficient to satisfy the applicable tax withholding obligation, Participant agrees to pay immediately upon demand to the Company or its Subsidiary with respect to which the withholding obligation arises, an amount sufficient to satisfy any remaining portion of the Company's or the applicable Subsidiary's withholding obligation.

* * * * *

T2 BIOSYSTEMS, INC.
INDUCEMENT AWARD PLAN

RESTRICTED STOCK GRANT NOTICE

T2 Biosystems, Inc., a Delaware corporation (the "Company"), pursuant to its Inducement Award Plan, as amended from time to time (the "Plan"), hereby grants to the holder listed below ("Participant") the number of shares of Restricted Stock (the "Shares") set forth below. The Shares are subject to the terms and conditions set forth in this Restricted Stock Grant Notice (the "Grant Notice") and the Restricted Stock Agreement attached hereto as Exhibit A (the "Agreement") and the Plan, which are incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in the Grant Notice and the Agreement.

Participant:

Grant Date:

Total Number of Shares of Restricted Stock:

Vesting Schedule: [To be specified in individual agreements]

By Participant's signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and the Grant Notice. Participant has reviewed the Agreement, the Plan and the Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing the Grant Notice and fully understands all provisions of the Grant Notice, the Agreement and the Plan. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, the Grant Notice or the Agreement.

T2 BIOSYSTEMS, INC. HOLDER:	**PARTICIPANT**
By:	By:
Print Name:	Print Name:
Title:	

EXHIBIT A
TO RESTRICTED STOCK GRANT NOTICE

RESTRICTED STOCK AGREEMENT

Pursuant to the Grant Notice to which this Agreement is attached, the Company has granted to Participant the number of Shares set forth in the Grant Notice.

ARTICLE I.

GENERAL

1.1 Defined Terms. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan or the Grant Notice.

1.2 Incorporation of Terms of Plan. The Shares issued to Participant pursuant to the Grant Notice are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

1.3 Employment Inducement Award. The Shares are intended to constitute an employment inducement award under NASDAQ Rule 5635(c)(4) that is exempt from the requirements of shareholder approval of equity-compensation plans under NASDAQ Rule 5635(c)(4). This Agreement and the terms and conditions of the Shares will be interpreted consistent with such intent.

ARTICLE II.

ISSUANCE OF SHARES

2.1 Issuance of Shares. In consideration of Participant's past and/or continued employment with or service to the Company or a Subsidiary and for other good and valuable consideration, effective as of the grant date set forth in the Grant Notice (the "Grant Date"), the Company has granted to Participant the number of Shares set forth in the Grant Notice, upon the terms and conditions set forth in the Grant Notice, this Agreement and the Plan.

2.2 Issuance Mechanics. As of the Grant Date, the Company shall issue the Shares in the form of Common Stock ("Stock") to Participant and shall (a) cause a stock certificate or certificates representing such shares of Stock to be registered in the name of Participant, or (b) cause such shares of Stock to be held in book-entry form. If a stock certificate is issued, it shall be delivered to and held in custody by the Company and shall bear the restrictive legends required by Section 5.1. If the shares of Stock are held in book-entry form, then such entry will reflect that the shares are subject to the restrictions of this Agreement.

ARTICLE III.

FORFEITURE AND TRANSFER RESTRICTIONS

3.1 Forfeiture Restriction. Subject to the provisions of Section 3.2 below, in the event of Participant's Termination of Service for any reason, including as a result of Participant's death or disability, all of the Unreleased Shares (as defined below) shall thereupon be forfeited immediately and without any further action by the Company (the "Forfeiture Restriction"), except as otherwise provided in a written agreement between Participant and the Company. Upon the occurrence of such forfeiture, the Company shall become the legal and beneficial owner of the Unreleased Shares and all rights and interests therein or

relating thereto, and the Company shall have the right to retain and transfer to its own name the number of Unreleased Shares being forfeited by Participant. The Unreleased Shares shall be held by the Company in accordance with Section 3.3 until the Shares are forfeited as provided in this Section 3.1, until such Unreleased Shares are fully released from the Forfeiture Restriction as provided in Section 3.2 or until such time as this Agreement is no longer in effect. Participant hereby authorizes and directs the Secretary of the Company, or such other person designated by the Administrator, to transfer any Unreleased Shares that are forfeited pursuant to this Section 3.1 from Participant to the Company.

3.2 Release of Shares from Forfeiture Restriction. The Shares shall be released from the Forfeiture Restriction in accordance with the vesting schedule set forth in the Grant Notice. Any of the Shares which, from time to time, have not yet been released from the Forfeiture Restriction are referred to herein as "Unreleased Shares." In the event any of the Unreleased Shares are released from the Forfeiture Restriction, any Retained Distributions (as defined below) paid on such Unreleased Shares shall be promptly paid by the Company to Participant. As soon as administratively practicable following the release of any Shares from the Forfeiture Restriction, the Company shall, as applicable, either deliver to Participant the certificate or certificates representing such Shares in the Company's possession belonging to Participant, or, if the Shares are held in book-entry form, then the Company shall remove the notations indicating that the shares are subject to the restrictions of this Agreement. Participant (or the beneficiary or personal representative of Participant in the event of Participant's death or incapacity, as the case may be) shall deliver to the Company any representations or other documents or assurances as the Company or its representatives deem necessary or advisable in connection with any such delivery.

3.3 Escrow.

The Unreleased Shares shall be held by the Company until such Unreleased Shares are forfeited as provided in Section 3.1, until such Unreleased Shares are fully released from the Forfeiture Restriction as provided in Section 3.2 or until such time as this Agreement is no longer in effect. Participant shall not retain physical custody of any certificates representing Unreleased Shares issued to Participant. Participant, by acceptance of this Award, shall be deemed to appoint, and does so appoint, the Company and each of its authorized representatives as Participant's attorney(s)-in-fact to effect any transfer of forfeited Unreleased Shares (and Retained Distributions, if any, paid on such forfeited Unreleased Shares) to the Company as may be required pursuant to the Plan or this Agreement, and to execute such representations or other documents or assurances as the Company or such representatives deem necessary or advisable in connection with any such transfer. To the extent allowable by Applicable Law, the Company, or its designee, shall not be liable for any act it may do or omit to do with respect to holding the Shares in escrow and while acting in good faith and in the exercise of its judgment.

The Company will retain custody of all cash dividends and other distributions ("Retained Distributions") made or declared with respect to Unreleased Shares (and such Retained Distributions will be subject to the Forfeiture Restriction and the other terms and conditions under this Agreement that are applicable to the Shares) until such time, if ever, as the Unreleased Shares with respect to which such Retained Distributions shall have been made, paid or declared shall have become vested pursuant to the Grant Notice. Retained Distributions that were made or declared in cash will be retained by the Company in a bookkeeping account until the Unreleased Shares with respect to which such Retained Distributions relate shall have become vested pursuant to the Grant Notice, at which time the Company shall release to Participant the amount retained in the Participant's bookkeeping account, without interest, as cash; provided that, at the Company's option, Retained Distributions may be deemed reinvested in notional shares of Stock such that upon release and distribution of such Retained Distributions to Participant, Participant shall be entitled to receive on the date of such distribution or release an amount of cash or the number of whole shares of Stock or a combination thereof, as determined by the Administrator, the aggregate fair value of

which shall be equal to the Fair Market Value of the notional shares of Stock to which such released Retained Distributions relate. Any Retained Distributions with respect to Unreleased Shares shall be forfeited in the event such Unreleased Shares are forfeited.

3.4 Rights as Stockholder. Except as otherwise provided herein, upon issuance of the Shares by the Company, Participant shall have all the rights of a stockholder with respect to said Shares, subject to the restrictions herein, including the right to vote the Shares and to receive all dividends or other distributions paid or made with respect to the Shares.

ARTICLE IV.

TAXATION AND TAX WITHHOLDING

4.1 Representation. Participant represents to the Company that Participant has reviewed with his or her own tax advisors the federal, state, local and foreign tax consequences of this investment and the transactions contemplated by this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

4.2 Section 83(b) Election. If Participant makes an election under Section 83(b) of the Internal Revenue Code of 1986, as amended (the "Code"), to be taxed with respect to the Shares as of the date of transfer of the Shares rather than as of the date or dates upon which Participant would otherwise be taxable under Section 83(a) of the Code, Participant shall deliver a copy of such election to the Company promptly upon filing such election with the Internal Revenue Service.

4.3 Tax Withholding. Notwithstanding any other provision of this Agreement:

The Company and its Subsidiaries have the authority to deduct or withhold, or require Participant to remit to the Company or the applicable Subsidiary, an amount sufficient to satisfy applicable federal, state, local and foreign taxes (including the employee portion of any FICA obligation) required by law to be withheld with respect to any taxable event arising pursuant to this Agreement. The Company and its Subsidiaries may withhold or Participant may make such payment in one or more of the forms specified below:

(i) by cash or check made payable to the Company or the Subsidiary with respect to which the withholding obligation arises;

(ii) by the deduction of such amount from other compensation payable to Participant;

(iii) with respect to any withholding taxes arising in connection with the vesting of the Shares, with the consent of the Administrator, by requesting that the Company and its Subsidiaries withhold a net number of vested Shares having a then current Fair Market Value not exceeding the amount necessary to satisfy the withholding obligation of the Company and its Subsidiaries based on the applicable statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes;

(iv) with respect to any withholding taxes arising in connection with the vesting of the Shares, with the consent of the Administrator, by tendering to the Company vested shares of Stock having a then current Fair Market Value not exceeding the amount necessary to satisfy the withholding obligation of the Company and its Subsidiaries based on the applicable statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes;

(v) with respect to any withholding taxes arising in connection with the vesting of the Shares, through the delivery of a notice that Participant has placed a market sell order with a broker acceptable to the Company with respect to those Shares that are then becoming vested and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company or the Subsidiary with respect to which the withholding obligation arises in satisfaction of such withholding taxes; *provided* that payment of such proceeds is then made to the Company or the applicable Subsidiary at such time as may be required by the Administrator, but in any event not later the settlement of such sale; or

(vi) in any combination of the foregoing.

With respect to any withholding taxes arising in connection with the Shares, in the event Participant fails to provide timely payment of all sums required pursuant to Section 4.3(a), the Company shall have the right and option, but not the obligation, to treat such failure as an election by Participant to satisfy all or any portion of Participant's required payment obligation pursuant to Section 4.3(a)(ii) or Section 4.3(a)(iii) above, or any combination of the foregoing as the Company may determine to be appropriate. The Company shall not be obligated to deliver any certificate representing the Shares to Participant or his or her legal representative unless and until Participant or his or her legal representative shall have paid or otherwise satisfied in full the amount of all federal, state, local and foreign taxes applicable with respect to the taxable income of Participant resulting from the vesting of the Shares or any other taxable event related to the Shares.

In the event any tax withholding obligation arising in connection with the Shares will be satisfied under Section 4.3(a)(iii), then the Company may elect to instruct any brokerage firm determined acceptable to the Company for such purpose to sell on Participant's behalf a whole number of shares of Stock from those Shares that are then becoming vested as the Company determines to be appropriate to generate cash proceeds sufficient to satisfy the tax withholding obligation and to remit the proceeds of such sale to the Company or the Subsidiary with respect to which the withholding obligation arises. Participant's acceptance of this Award constitutes Participant's instruction and authorization to the Company and such brokerage firm to complete the transactions described in this Section 4.3(c), including the transactions described in the previous sentence, as applicable. The Company may refuse to deliver any certificate representing the Shares to Participant or his or her legal representative until the foregoing tax withholding obligations are satisfied.

Participant is ultimately liable and responsible for all taxes owed in connection with the Shares, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the Shares. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the Shares or the subsequent sale of the Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure this Award to reduce or eliminate Participant's tax liability.

ARTICLE V.

RESTRICTIVE LEGENDS AND STOP-TRANSFER ORDERS

5.1 Legends. The certificate or certificates representing the Shares, if any, shall bear the following legend (as well as any legends required by the Company's charter and Applicable Law):

THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO FORFEITURE IN FAVOR OF THE COMPANY AND MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE

TERMS OF A RESTRICTED STOCK AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

5.2 Refusal to Transfer; Stop-Transfer Notices. The Company shall not be required (a) to transfer on its books any Shares that have been sold or otherwise transferred in violation of any of the provisions of this Agreement or (b) to treat as owner of such Shares or to accord the right to vote or pay dividends to any purchaser or other transferee to whom such Shares shall have been so transferred. Participant agrees that, in order to ensure compliance with the restrictions referred to herein, the Company may issue appropriate "stop transfer" instructions to its transfer agent, if any, and that, if the Company transfers its own securities, it may make appropriate notations to the same effect in its own records.

5.3 Removal of Legend. After such time as the Forfeiture Restriction shall have lapsed with respect to the Shares, and upon Participant's request, a new certificate or certificates representing such Shares shall be issued without the legend referred to in Section 5.1 and delivered to Participant. If the Shares are held in book entry form, the Company shall cause any restrictions noted on the book form to be removed.

ARTICLE VI.

OTHER PROVISIONS

6.1 Administration. The Administrator shall have the power to interpret the Plan, the Grant Notice and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan, the Grant Notice and this Agreement as are consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator will be final and binding upon Participant, the Company and all other interested persons. To the extent allowable pursuant to Applicable Law, no member of the Committee or the Board will be personally liable for any action, determination or interpretation made with respect to the Plan, the Grant Notice or this Agreement.

6.2 Shares Not Transferable. The Shares and Retained Distributions may not be sold, pledged, assigned or transferred in any manner unless and until the Forfeiture Restrictions have lapsed. No Unreleased Shares or Retained Distributions or any interest or right therein or part thereof shall be liable for the debts, contracts or engagements of Participant or his or her successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempted disposition thereof shall be null and void and of no effect.

6.3 Adjustments. The Administrator may accelerate the vesting of all or a portion of the Unreleased Shares in such circumstances as it, in its sole discretion, may determine. Participant acknowledges that the Shares are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan, including Section 12.2 of the Plan.

6.4 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to Participant shall be addressed to Participant at Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 6.4, either party may hereafter designate a different address for notices to be given to that party. Any notice shall be deemed duly given when sent via email (if to Participant) or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the

United States Postal Service.

6.5 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

6.6 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

6.7 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Law, including, without limitation, the provisions of the Securities Act and the Exchange Act, and any and all regulations and rules promulgated thereunder by the Securities and Exchange Commission, and state securities laws and regulations. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the Shares are granted, only in such a manner as to conform to Applicable Law. To the extent permitted by Applicable Law, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to Applicable Law.

6.8 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board, *provided* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the Shares in any material way without the prior written consent of Participant.

6.9 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in Section 6.2 and the Plan, this Agreement shall be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

6.10 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Shares, the Grant Notice and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

6.11 Not a Contract of Employment. Nothing in this Agreement or in the Plan shall confer upon Participant any right to continue to serve as an employee or other service provider of the Company or any Subsidiary or shall interfere with or restrict in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

6.12 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

6.13 Section 409A. This Award is not intended to constitute “nonqualified deferred

compensation" within the meaning of Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date hereof, "Section 409A"). However, notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that this Award (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate for this Award either to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

6.14 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held invalid or unenforceable, such provision will be severable from, and such invalidity or unenforceability will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

6.15 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant shall have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Award.

6.16 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which shall be deemed an original and all of which together shall constitute one instrument.

6.17 Broker-Assisted Sales. In the event of any broker-assisted sale of shares of Stock in connection with the payment of withholding taxes as provided in Section 4.3(a)(iii) or Section 4.3(a)(v): (A) any shares of Stock to be sold through a broker-assisted sale will be sold on the day the tax withholding obligation arises or as soon thereafter as practicable; (B) such shares of Stock may be sold as part of a block trade with other participants in the Plan in which all participants receive an average price; (C) Participant will be responsible for all broker's fees and other costs of sale, and Participant agrees to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale; (D) to the extent the proceeds of such sale exceed the applicable tax withholding obligation, the Company agrees to pay such excess in cash to Participant as soon as reasonably practicable; (E) Participant acknowledges that the Company or its designee is under no obligation to arrange for such sale at any particular price, and that the proceeds of any such sale may not be sufficient to satisfy the applicable tax withholding obligation; and (F) in the event the proceeds of such sale are insufficient to satisfy the applicable tax withholding obligation, Participant agrees to pay immediately upon demand to the Company or its Subsidiary with respect to which the withholding obligation arises an amount in cash sufficient to satisfy any remaining portion of the Company's or the applicable Subsidiary's withholding obligation.

* * * * *

T2 BIOSYSTEMS, INC.
INDUCEMENT AWARD PLAN

RESTRICTED STOCK UNIT GRANT NOTICE

T2 Biosystems, Inc., a Delaware corporation (the "Company"), pursuant to its Inducement Award Plan, as amended from time to time (the "Plan"), hereby grants to the holder listed below ("Participant") the number of Restricted Stock Units (the "RSUs") set forth below. The RSUs are subject to the terms and conditions set forth in this Restricted Stock Unit Grant Notice (the "Grant Notice") and the Restricted Stock Unit Agreement attached hereto as Exhibit A (the "Agreement") and the Plan, which are incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in the Grant Notice and the Agreement.

Participant:

Grant Date:

Number of RSUs:

Type of Shares Issuable: Common Stock

Vesting Schedule: [To be specified in individual agreements]

By Participant's signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and the Grant Notice. Participant has reviewed the Agreement, the Plan and the Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing the Grant Notice and fully understands all provisions of the Grant Notice, the Agreement and the Plan. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, the Grant Notice or the Agreement.

T2 BIOSYSTEMS, INC. HOLDER:	**PARTICIPANT**
By:	By:
Print Name:	Print Name:
Title:	

EXHIBIT A
TO RESTRICTED STOCK UNIT GRANT NOTICE

RESTRICTED STOCK UNIT AGREEMENT

Pursuant to the Grant Notice to which this Agreement is attached, the Company has granted to Participant the number of RSUs set forth in the Grant Notice.

ARTICLE 18.
GENERAL

18.1 Defined Terms. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan or the Grant Notice.

18.2 Incorporation of Terms of Plan. The RSUs and the shares of Common Stock ("Stock") issued to Participant hereunder ("Shares") are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

18.3 Employment Inducement Award

18.4 . The RSUs are intended to constitute an employment inducement award under NASDAQ Rule 5635(c)(4) that is exempt from the requirements of shareholder approval of equity-compensation plans under NASDAQ Rule 5635(c)(4). This Agreement and the terms and conditions of the RSUs will be interpreted consistent with such intent.

ARTICLE 19.
AWARD OF RESTRICTED STOCK UNITS AND DIVIDEND EQUIVALENTS

19.1 Award of RSUs and Dividend Equivalents.

(a) In consideration of Participant's past and/or continued employment with or service to the Company or a Subsidiary and for other good and valuable consideration, effective as of the grant date set forth in the Grant Notice (the "Grant Date"), the Company has granted to Participant the number of RSUs set forth in the Grant Notice, upon the terms and conditions set forth in the Grant Notice, the Plan and this Agreement, subject to adjustment as provided in Section 12.2 of the Plan. Each RSU represents the right to receive one Share or, at the option of the Company, an amount of cash as set forth in Section 2.3(b), in either case, at the times and subject to the conditions set forth herein. However, unless and until the RSUs have vested, Participant will have no right to the payment of any Shares subject thereto. Prior to the actual delivery of any Shares, the RSUs will represent an unsecured obligation of the Company, payable only from the general assets of the Company.

(b) The Company hereby grants to Participant an Award of Dividend Equivalents with respect to each RSU granted pursuant to the Grant Notice for all ordinary cash dividends which are paid to all or substantially all holders of the outstanding shares of Stock between the Grant Date and the date when the applicable RSU is distributed or paid to Participant or is forfeited or expires. The Dividend Equivalents for each RSU shall be equal to the amount of cash which is paid as a dividend on one share of Stock. All

such Dividend Equivalents shall be credited to Participant and retained by the Company (without interest) or, at the Company's option, may be deemed to be reinvested in additional RSUs as of the date of payment of any such dividend based on the Fair Market Value of a share of Stock on such date. Each Dividend Equivalent (including and any additional RSU which results from the deemed reinvestment of Dividend Equivalents granted hereunder, if applicable) shall be subject to the same vesting, distribution or payment, adjustment and other provisions which apply to the underlying RSU to which such Dividend Equivalent relates.

19.2 Vesting of RSUs and Dividend Equivalents.

(a) Subject to Participant's continued employment with or service to the Company or a Subsidiary on each applicable vesting date and subject to the terms of this Agreement, the RSUs shall vest in such amounts and at such times as are set forth in the Grant Notice. Each Dividend Equivalent (including any additional RSU which results from deemed reinvestments of Dividend Equivalents pursuant to Section 2.1(b) hereof, if applicable) shall vest whenever the underlying RSU to which such Dividend Equivalent relates vests.

(b) In the event Participant incurs a Termination of Service, except as may be otherwise provided by the Administrator or as set forth in a written agreement between Participant and the Company, Participant shall immediately forfeit any and all RSUs and Dividend Equivalents (including any additional RSU which results from deemed reinvestments of Dividend Equivalents pursuant to Section 2.1(b) hereof, if applicable) granted under this Agreement which have not vested or do not vest on or prior to the date on which such Termination of Service occurs, and Participant's rights in any such RSUs and Dividend Equivalents which are not so vested shall lapse and expire.

19.3 Distribution or Payment of RSUs.

(a) Participant's RSUs shall be distributed in Shares (either in book-entry form or otherwise) or, at the option of the Company, paid in an amount of cash as set forth in Section 2.3(b), in either case, as soon as administratively practicable following the vesting of the applicable RSU pursuant to Section 2.2, and, in any event, within sixty (60) days following such vesting. Notwithstanding the foregoing, the Company may delay a distribution or payment in settlement of RSUs if it reasonably determines that such payment or distribution will violate Federal securities laws or any other Applicable Law, *provided* that such distribution or payment shall be made at the earliest date at which the Company reasonably determines that the making of such distribution or payment will not cause such violation, as required by Treasury Regulation Section 1.409A-2(b)(7)(ii), and *provided further* that no payment or distribution shall be delayed under this Section 2.3(a) if such delay will result in a violation of Section 409A of the Code.

(b) In the event that the Company elects to make payment of Participant's RSUs in cash, the amount of cash payable with respect to each RSU shall be equal to the Fair Market Value of a Share on the day immediately preceding the applicable distribution or payment date set forth in Section 2.3(a). All distributions made in Shares shall be made by the Company in the form of whole Shares, and any fractional share shall be distributed in cash in an amount equal to the value of such fractional share determined based on the Fair Market Value as of the date immediately preceding the date of such distribution.

19.4 Conditions to Issuance of Certificates. The Company shall not be required to issue or deliver any certificate or certificates for any Shares prior to the fulfillment of all of the following conditions: (A) the admission of the Shares to listing on all stock exchanges on which such Shares are then listed, (B) the completion of any registration or other qualification of the Shares under any state or federal law or under rulings or regulations of the Securities and Exchange Commission or other governmental regulatory

body, which the Administrator shall, in its absolute discretion, deem necessary or advisable, and (C) the obtaining of any approval or other clearance from any state or federal governmental agency that the Administrator shall, in its absolute discretion, determine to be necessary or advisable.

19.5 Tax Withholding. Notwithstanding any other provision of this Agreement:

(a) The Company and its Subsidiaries have the authority to deduct or withhold, or require Participant to remit to the Company or the applicable Subsidiary, an amount sufficient to satisfy applicable federal, state, local and foreign taxes (including the employee portion of any FICA obligation) required by law to be withheld with respect to any taxable event arising pursuant to this Agreement. The Company and its Subsidiaries may withhold or Participant may make such payment in one or more of the forms specified below:

(i) by cash or check made payable to the Company or the Subsidiary with respect to which the withholding obligation arises;

(ii) by the deduction of such amount from other compensation payable to Participant;

(iii) with respect to any withholding taxes arising in connection with the distribution of the RSUs, with the consent of the Administrator, by requesting that the Company and its Subsidiaries withhold a net number of vested shares of Stock otherwise issuable pursuant to the RSUs having a then current Fair Market Value not exceeding the amount necessary to satisfy the withholding obligation of the Company and its Subsidiaries based on the applicable statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes;

(iv) with respect to any withholding taxes arising in connection with the distribution of the RSUs, with the consent of the Administrator, by tendering to the Company vested shares of Stock having a then current Fair Market Value not exceeding the amount necessary to satisfy the withholding obligation of the Company and its Subsidiaries based on the applicable statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes;

(v) with respect to any withholding taxes arising in connection with the distribution of the RSUs, through the delivery of a notice that Participant has placed a market sell order with a broker acceptable to the Company with respect to shares of Stock then issuable to Participant pursuant to the RSUs, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company or the Subsidiary with respect to which the withholding obligation arises in satisfaction of such withholding taxes; *provided* that payment of such proceeds is then made to the Company or the applicable Subsidiary at such time as may be required by the Administrator, but in any event not later than the settlement of such sale; or

(vi) in any combination of the foregoing.

(b) With respect to any withholding taxes arising in connection with the RSUs, in the event Participant fails to provide timely payment of all sums required pursuant to Section 2.5(a), the Company shall have the right and option, but not the obligation, to treat such failure as an election by Participant to satisfy all or any portion of Participant's required payment obligation pursuant to Section 2.5(a)(ii) or Section 2.5(a)(iii) above, or any combination of the foregoing as the Company may determine to be appropriate. The Company shall not be obligated to deliver any certificate representing shares of Stock issuable with respect to the RSUs to Participant or his or her legal representative unless and until Participant or his or her legal representative shall have paid or otherwise satisfied in full the amount of all federal, state,

local and foreign taxes applicable with respect to the taxable income of Participant resulting from the vesting or settlement of the RSUs or any other taxable event related to the RSUs.

(c) In the event any tax withholding obligation arising in connection with the RSUs will be satisfied under Section 2.5(a)(iii), then the Company may elect to instruct any brokerage firm determined acceptable to the Company for such purpose to sell on Participant's behalf a whole number of shares from those shares of Stock then issuable to Participant pursuant to the RSUs as the Company determines to be appropriate to generate cash proceeds sufficient to satisfy the tax withholding obligation and to remit the proceeds of such sale to the Company or the Subsidiary with respect to which the withholding obligation arises. Participant's acceptance of this Award constitutes Participant's instruction and authorization to the Company and such brokerage firm to complete the transactions described in this Section 2.5(c), including the transactions described in the previous sentence, as applicable. The Company may refuse to issue any shares of Stock in settlement of the RSUs to Participant until the foregoing tax withholding obligations are satisfied, *provided* that no payment shall be delayed under this Section 2.5(c) if such delay will result in a violation of Section 409A of the Code.

(d) Participant is ultimately liable and responsible for all taxes owed in connection with the RSUs, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the RSUs. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the RSUs or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the RSUs to reduce or eliminate Participant's tax liability.

19.6 Rights as Stockholder. Neither Participant nor any person claiming under or through Participant will have any of the rights or privileges of a stockholder of the Company in respect of any Shares deliverable hereunder unless and until certificates representing such Shares (which may be in book-entry form) will have been issued and recorded on the records of the Company or its transfer agents or registrars, and delivered to Participant (including through electronic delivery to a brokerage account). Except as otherwise provided herein, after such issuance, recordation and delivery, Participant will have all the rights of a stockholder of the Company with respect to such Shares, including, without limitation, the right to receipt of dividends and distributions on such Shares.

ARTICLE 20.
OTHER PROVISIONS

20.1 Administration. The Administrator shall have the power to interpret the Plan, the Grant Notice and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan, the Grant Notice and this Agreement as are consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator will be final and binding upon Participant, the Company and all other interested persons. To the extent allowable pursuant to Applicable Law, no member of the Committee or the Board will be personally liable for any action, determination or interpretation made with respect to the Plan, the Grant Notice or this Agreement.

20.2 RSUs Not Transferable. The RSUs may not be sold, pledged, assigned or transferred in any manner other than by will or the laws of descent and distribution, unless and until the Shares underlying the RSUs have been issued, and all restrictions applicable to such Shares have lapsed. No RSUs or any interest or right therein or part thereof shall be liable for the debts, contracts or engagements of Participant or his or her successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary

or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempted disposition thereof shall be null and void and of no effect, except to the extent that such disposition is permitted by the preceding sentence.

20.3 Adjustments. The Administrator may accelerate the vesting of all or a portion of the RSUs in such circumstances as it, in its sole discretion, may determine. Participant acknowledges that the RSUs and the Shares subject to the RSUs are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan, including Section 12.2 of the Plan.

20.4 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to Participant shall be addressed to Participant at Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 3.4, either party may hereafter designate a different address for notices to be given to that party. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

20.5 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

20.6 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

20.7 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws, including, without limitation, the provisions of the Securities Act and the Exchange Act, and any and all regulations and rules promulgated thereunder by the Securities and Exchange Commission, and state securities laws and regulations. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the RSUs are granted, only in such a manner as to conform to Applicable Law. To the extent permitted by Applicable Law, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to Applicable Law.

20.8 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board, *provided* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the RSUs in any material way without the prior written consent of Participant.

20.9 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in Section 3.2 and the Plan, this Agreement shall be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

20.10 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the RSUs, the Dividend Equivalents (including RSUs which result from deemed reinvestments of Dividend Equivalents pursuant to Section 2.1(b) hereof, if applicable), the Grant Notice and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act

(including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

20.11 Not a Contract of Employment. Nothing in this Agreement or in the Plan shall confer upon Participant any right to continue to serve as an employee or other service provider of the Company or any Subsidiary or shall interfere with or restrict in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

20.12 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

20.13 Section 409A. This Award is not intended to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date hereof, "Section 409A"). However, notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that this Award (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate for this Award either to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

20.14 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held invalid or unenforceable, such provision will be severable from, and such invalidity or unenforceability will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

20.15 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant shall have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the RSUs and Dividend Equivalents.

20.16 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which shall be deemed an original and all of which together shall constitute one instrument.

20.17 Broker-Assisted Sales. In the event of any broker-assisted sale of shares of Stock in connection with the payment of withholding taxes as provided in Section 2.5(a)(iii) or Section 2.5(a)(v): (A) any shares of Stock to be sold through a broker-assisted sale will be sold on the day the tax withholding obligation arises or as soon thereafter as practicable; (B) such shares of Stock may be sold as part of a block trade with other participants in the Plan in which all participants receive an average price; (C) Participant will be responsible for all broker's fees and other costs of sale, and Participant agrees to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale; (D) to the

extent the proceeds of such sale exceed the applicable tax withholding obligation, the Company agrees to pay such excess in cash to Participant as soon as reasonably practicable; (E) Participant acknowledges that the Company or its designee is under no obligation to arrange for such sale at any particular price, and that the proceeds of any such sale may not be sufficient to satisfy the applicable tax withholding obligation; and (F) in the event the proceeds of such sale are insufficient to satisfy the applicable tax withholding obligation, Participant agrees to pay immediately upon demand to the Company or its Subsidiary with respect to which the withholding obligation arises an amount in cash sufficient to satisfy any remaining portion of the Company's or the applicable Subsidiary's withholding obligation.

* * * * *

Exhibit 10.52

November 2, 2021

Brett Giffin
[*******]
[*******]

Dear Brett:

On behalf of T2 Biosystems, Inc., (the "Company") I am delighted to make this offer of employment to you to join us in the role of Chief Commercial Officer for the Company beginning on November 8, 2021.

At T2 Biosystems, a leader in the detection of sepsis causing pathogens, our mission is to save lives and improve healthcare by empowering clinicians to get patients on the right therapy faster than ever. We have developed game-changing detection technology, T2 Magnetic Resonance (T2MR®), that enables the rapid detection of clinically relevant targets and helps clinicians to optimize outcomes for their patients. We come to work every day to solve critical and unmet needs in healthcare diagnostics that make a significant impact on patient care.

We are positively impacting the lives of patients and saving hospitals millions of dollars each year. Our products are being used in more than 180 hospitals around the world. We have a strong pipeline of products in development, including a next-generation, high-throughput instrument to further round out our sepsis portfolio, as well as products for the detection of viruses such as SARS-CoV-2 which is responsible for COVID-19 infections, in addition to a panel for the detection of biothreat pathogens. There is a lot of growth ahead and you are joining us at a very exciting time!

Brett, we are thrilled to extend this offer of employment to you. We think you can help us fulfill our mission and we believe you'd be a great fit for our team. To kick things off, you will find all of the pertinent information related to our offer of employment in the attached pages. Please read the offer carefully and, if it is acceptable, sign and return one copy to my attention (PDF copy is fine).

If you have any questions, please do not hesitate to contact me at (781) 457-1283 or email at kmorgan@t2biosystems.com. We are looking forward to having you on our team!

Sincerely,

Kelley Morgan
Chief People Officer

OFFER OF EMPLOYMENT

Date of employment: Should you accept the terms of this offer, your employment with the Company will commence on November 8, 2021 (the “Start Date”).

Background check: Your employment is contingent upon your successful completion of a background check, which is required for all employees of the Company. The Company will forward you the appropriate documents, and such documents shall be required to be submitted to the Company by no later than one week prior to the Start Date.

Position: You have been offered the position of Chief Commercial Officer. In this capacity, you will report to John Sperzel, Chief Executive Officer. Your duties and responsibilities will include all those customarily attendant to such a position, and any other such duties or responsibilities that John Sperzel or the Company may, from time to time, assign to you. You agree that you shall not enter into any employment endeavors which may conflict with your ability to devote the necessary time and energies to the Company’s business interest while engaged by the Company. You further agree to comply with all applicable laws and with all Company rules and policies established by the Company from time to time.

Compensation and Tax Matters: Your salary shall be $15,000.00 (the equivalent of $360,000 when annualized), payable semi-monthly and subject to pro-ration for any partial initial or terminal week during which you are employed, in accordance with normal payroll practices and schedule of the Company.

You will be eligible to receive an annual bonus (the "Annual Bonus") based upon the achievement of specific company and individual milestones as determined by the Board of Directors (the “Board”). The target amount of your Annual Bonus will be 60% of your Base Salary, subject to adjustment by the Board. Payment of the Annual Bonus will be subject to your continued employment with the Company through the date of payment, and pro-rated for 2021 based on your Start Date.

All compensation amounts stated are before any deductions for FICA taxes, state and federal withholding taxes and other payroll deductions required to be made by the Company under applicable law.

Restricted Stock: Subject to your execution of the enclosed Non Competition/Non-Disclosure/Invention Assignment Agreement and the execution of a Restricted Stock Award Agreement, you will receive a grant of 500,000 restricted shares (“RSUs”) of T2 Biosystems common stock under the Company’s Inducement Award Plan (the “Inducement Plan”). The RSUs will have a 3-year vesting schedule with 1/3 of the shares vesting annually in equal installments on the anniversary of the Start Date. The terms and conditions of the restricted stock award will be more fully described in the Company’s Inducement Plan document and the applicable Restricted Stock Award Agreement.

Severance Compensation: Also subject to your execution of the enclosed Non Competition/Non-Disclosure/Invention Assignment Agreement and Change of Control Severance Agreement (the “Change in Control Agreement”), you will receive certain benefits in the event of a change in control of the Company, as set forth in more detail and defined in the Change in Control Agreement, including severance compensation and the acceleration of certain equity awards, each such benefit to be subject to the terms of the Change in Control Agreement.

Fringe Benefits: You will have the opportunity to participate in the Company’s fringe benefits program. Currently, these fringe benefits are as follows:

- The Company currently provides contributions toward a medical and dental plan for yourself and immediate family members

Active: 2021

- Three (3) weeks paid vacation, Company designated holidays, personal holidays and sick days (see Benefits Summary for more information).

- The Company provides 100% contribution towards Term Life Insurance, Accidental Death and Dismemberment Insurance, and Short and Long-Term Disability Insurance;

- The opportunity to enroll in the Company's 401(k) Investment and Section 125 Plans based on plan eligibility requirements; and

- Pay or reimburse you in accordance with the Company's reimbursement policies from time to time in connection with the performance of your duties for the Company subject to your submission of satisfactory documentation with respect thereto.

The Company reserves the right to amend, delete or change any of its employment policies and/or benefits at any time in its sole discretion.

Non-Competition/Non-Disclosure/Invention Assignment Agreement: No later than on the first day of your employment with the Company you will be required to sign the enclosed Non-Competition/Non-Disclosure/Inventions Assignment Agreement ("Obligations Agreement") which includes non-competition, nondisclosure, inventions ownership, and other provisions that are necessary to protect the Company's confidential information, intellectual; property, trade secrets, and customer relationships. As you may be given access to such protectable interests, your employment is contingent upon your signing the Obligations Agreement. The terms of the Obligations Agreement will survive termination, for whatever reason, of the employment relationship.

Prior Agreements: You acknowledge and confirm that you have provided/disclosed to the Company all restrictive covenants and agreements, including nondisclosure and confidentiality agreements, to which you are a party. You agree that you shall not disclose to the Company or use while an employee of the Company any confidential or trade secret information obtained by you from other persons or employers and shall not bring any property upon the Company premises which has been misappropriated by others. You also acknowledge that the Company expects you to honor any prior obligations to former employers to which you remain bound.

Employment At Will: Although you are being hired as an employee commencing on November 8, 2021, your employment with the Company shall be at will. This means that your employment is not guaranteed for any definite period of time, and you or the Company may terminate your employment relationship with or without notice at any time and for any or no reason or cause. The Company is not bound to follow any policy, procedure, or process in connection with employee discipline, employment termination or otherwise.

Entire Agreement: This letter (together with the attached Obligations Agreement and Change in Control Agreement) sets forth the entire understanding between the Company and yourself with respect to your employment by the Company. All prior discussions, negotiations, correspondence and other understandings between you and the Company are superseded, and there are no representations, warranties or undertakings by the Company or you with respect to your employment by the Company, which are not set forth in this letter.

If you agree with the terms of this offer, please acknowledge your understanding and acceptance of this offer by signing where indicated below and return to me by 5:00pm ET on November 4, 2021. We look forward to working with you.

Sincerely,
Active: 2021

T2 Biosystems, Inc.

By: _____
Kelley Morgan Date
Chief People Officer

I have read agree with and accept the items contained in this letter.

By: _____
Brett Giffin Date

The Immigration Control and Reform Act of 1986 requires that all new employees complete the I-9 form and submit proof of employment eligibility to work in the United States within the first three days of their start date. If accepting employment the Company will provide you the I-9 form and requests that you present appropriate documents when you report to the Company and a representative of the Company will complete the I-9 form with you. Accordingly, you will have three days from your start date to submit proof of your eligibility to work in the United States.

Active: 2021

Exhibit 10.53

March 21, 2022

John Sprague
[*******]
[*******]

Dear John,

This letter sets forth the agreement between you and T2 Biosystems, Inc. (the "Company") regarding certain terms and conditions of your employment. This replaces any prior agreement between yourself and the Company with respect to the subject matter contained herein. You are entitled to receive the following:

1. Severance Compensation (Unrelated to a Change of Control). If your employment is terminated either by you with Good Reason, or by the Company without Cause, in either case, other than in the circumstances described in Section 2 of this letter, subject to your executing and delivering to the Company, and not revoking, a release of claims in a form acceptable to the Company (the "Release") within the 30-day period following your termination of employment:

(a) the Company will pay you severance in an amount equal to 9 months of your then current annual base salary, payable in equal installments over a period of 9 months (the "Non-COC Severance Period") in accordance with the Company's payroll practices, commencing on your termination of employment;

(b) If you timely elect continued group medical insurance coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company will reimburse you for a portion of the applicable premiums, based on the then-current cost-sharing rates for active employees, for you and your eligible dependents during the period commencing on the date of your termination of employment and ending on the earliest to occur of (a) the final day of the Non-COC Severance Period, (b) the date you and/or your eligible dependents are no longer eligible for COBRA, and (c) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines that it cannot provide such reimbursement of premiums to you without potentially violating applicable law, the Company shall in lieu thereof provide to you a taxable monthly payment in an amount equal to a portion of the applicable premiums, based on then-current cost-sharing rates for active employees, which payment will be made regardless of whether you elect COBRA continuation coverage and will commence in the month following the month in which your termination of employment occurs and end on the earliest to occur of (x) the final day of the Non-COC Severance Period, (y) the date you and/or your eligible dependents are no longer eligible for COBRA, and (z) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility).

2. Severance Compensation (In Connection with a Change of Control). If your employment is terminated either by you with Good Reason within 12 months following a Change of Control, or by the

Company without Cause within 3 months preceding or within 12 months following a Change of Control, subject to your executing and delivering to the Company, and not revoking, a Release within the 30-day period following your termination of employment, you will be entitled to the following payments and benefits, which shall be in lieu of any payments or benefits under Section 1 of this letter:

(a) the Company will pay you severance in an amount equal to 12 months of your then current annual base salary, payable in equal installments over a period of 12 months (the "COC Severance Period") in accordance with the Company's payroll practices, commencing on your termination of employment;

(b) an amount in cash equal to the annual incentive compensation you would have otherwise been entitled to under an annual incentive program established by the Company's Board of Directors for the year in which the termination occurs (based on actual achievement of performance goals determined by the Board), which amount, if any, shall be prorated based on the number of days elapsed from the commencement of such fiscal year through and including the date of such termination and paid at such time as such year's annual bonus would have been paid had your employment not terminated, but in no event later than the date that is 2½ months following the last day of the fiscal year in which the termination occurred;

(c) if you have been continuously employed by the Company for at least one year as of the date your employment terminates, all of the outstanding unvested equity awards of the Company held by you shall become fully vested and, if applicable, exercisable as of the date of your termination, provided that with respect to any such awards intended to constitute "qualified performance based compensation" under Section 162(m) of the Code, whether a Change of Control has occurred shall be determined without regard to clause (iv) of the definition of Change of Control below; and

(d) If you timely elect continued group medical insurance coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company will reimburse you for a portion of the applicable premiums, based on the then-current cost-sharing rates for active employees, for you and your eligible dependents during the period commencing on the date of your termination of employment and ending on the earliest to occur of (a) the final day of the COC Severance Period, (b) the date you and/or your eligible dependents are no longer eligible for COBRA, and (c) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines that it cannot provide such reimbursement of premiums to you without potentially violating applicable law, the Company shall in lieu thereof provide to you a taxable monthly payment in an amount equal to a portion of the applicable premiums, based on then-current cost-sharing rates for active employees, which payment will be made regardless of whether you elect COBRA continuation coverage and will commence in the month following the month in which your termination of employment occurs and end on the earliest to occur of (x) the final day of the COC Severance Period, (y) the date you and/or your eligible dependents are no longer eligible for COBRA, and (z) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility).

Notwithstanding anything herein to the contrary, in the event that any compensation or benefit that constitutes "nonqualified deferred compensation" within the meaning of Section 409A (as defined below) becomes payable upon the occurrence of a Change of Control, such compensation or benefit shall not be paid unless such Change of Control constitutes a "change in control event" within the meaning of Section 409A.

3. Definitions. For purposes of this letter, the terms "Change of Control," "Cause," and "Good Reason" shall have the following meanings.

(a) "Change of Control" means that any of the following events has occurred:

(i)Any person (as such term is used in Section 13(d) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company, any employee benefit plan of the Company, or any entity organized, appointed, or established by the Company for or pursuant to the terms of any such plan, together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Exchange Act) becomes the beneficial owner or owners (as defined in Rule 13d-3 and 13d-5 promulgated under the Exchange Act), directly or indirectly (the "Control Group"), of more than 50% of the outstanding equity securities of the Company, or otherwise becomes entitled, directly or indirectly, to vote more than 50% of the voting power entitled to be cast at elections for directors ("Voting Power") of the Company, provided that a Change of Control will not have occurred if such Control Group acquired securities or Voting Power solely by purchasing securities from the Company, including, without limitation, acquisition of securities by one or more third party investors;

(ii)A consolidation or merger (in one transaction or a series of related transactions) of the Company pursuant to which the holders of the Company's equity securities immediately prior to such transaction or series of related transactions cease to be the holders, directly or indirectly, immediately after such transaction or series of related transactions of more than 50% of the Voting Power of the entity surviving such transaction or series of related transactions;

(iii)The sale, lease, exchange, or other transfer (in one transaction or series of related transactions) of all or substantially all of the assets of the Company; or

(iv)The liquidation or dissolution of the Company or the Company ceasing to do business.

(b) "Cause" means:

(i) Your conviction of a felony, either in connection with the performance of your obligations to the Company or which otherwise materially and adversely affects your ability to perform such obligations;

(ii) Your willful disloyalty to the Company or deliberate material dishonesty to the Company;

(iii) The commission by you of an act of fraud or embezzlement against the Company;

(iv) Your willful, substantial failure to perform any of your duties hereunder or your deliberate failure to follow reasonable, lawful directions of the Company's Board of Directors or your direct supervisor, which failure, if capable of being cured, is not cured within 30 days after delivery to you by the Company of written notice of such failure; or

(v) A material breach by you of any material provision of this letter which breach is not cured within 30 days after delivery to you by the Company of written notice of such breach.

(c) "Good Reason" means one or more of the following:

(i) A material change in the principal location at which you provide services to the Company, without your prior written consent;

(ii) A material and continuing diminution by the Company in the duties, authority or responsibilities of your position which causes such position to become of less responsibility or authority than immediately prior to such material and continuing diminution, provided that such change is not in connection with a termination of your employment hereunder by the Company;

(iii) A material reduction in your base salary or other benefits except if such a reduction is in connection with a general reduction in compensation or other benefits of all similarly situated employees of the Company;

(iv) Failure by the Company to obtain the assumption of this Agreement by any successor to the Company.

Notwithstanding the foregoing, Good Reason shall only exist if you have given written notice to the Company within 90 days of the initial existence of the Good Reason condition(s), the Company has failed to cure such event(s) within 30 days of its receipt of said notice and you terminate employment within 90 days following expiration of such cure period.

4. Section 409A.

(a) *Separation from Service*. Notwithstanding anything in this letter to the contrary, any compensation or benefit payable under this letter that is designated as payable upon your termination of employment shall be payable only upon your "separation from service" with the Company (a "Separation from Service") within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (collectively, "Section 409A"), and except as provided below, any such compensation or benefits shall not be paid, or, in the case of installments, shall not commence payment, until the 30th day following your Separation from Service. Any installment payments that would have been made to you during the 30 day period immediately following your Separation from Service but for the preceding sentence shall be paid to you on the 30th day following your Separation from Service and the remaining payments shall be made as provided in this letter.

(b) *Specified Employee*. Notwithstanding anything in this letter to the contrary, if you are deemed by the Company at the time of your Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which you are entitled under this letter is required in order to avoid a prohibited distribution under Section 409A, such portion of your benefits shall not be provided to you prior to the earlier of (i) the expiration of the six-month period measured from the date of your Separation from Service with the Company or (ii) the date of your death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump-sum to you (or your estate or beneficiaries), and any remaining payments due to you under this letter shall be paid as otherwise provided herein.

(c) *Installments*. Your right to receive any installment payments under this letter shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

5. General

(a) No provision of this letter shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by you and by an authorized officer of the Company (other than you). No waiver by either party of any breach of, or of compliance with, any condition or provision of this letter by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time. The validity, interpretation, construction and performance of this letter shall be governed by the laws of the Commonwealth of Massachusetts without regard to conflicts of law. The invalidity or unenforceability of any provision or provisions of this letter shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect. This letter may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

(b) This letter contains the entire and exclusive agreement between the parties with respect to the subject matter hereof and is intended to supersede and replace all previous agreements, negotiations, and representations between the parties, whether written or oral, including any provision of the employment offer letter agreement between you and the Company, dated as of January 29, 2018, to the extent such letter addresses the subject matter hereof.

Sincerely,

T2 BIOSYSTEMS, INC.

By: /s/ John Sperzel
Name: John Sperzel
Title: Chairman, President & CEO

Acknowledged and Agreed

/s/ John Sprague
Name: John Sprague

Exhibit 10.54

March 21, 2022

Michael Gibbs
[*******]
[*******]

Dear Michael,

This letter sets forth the agreement between you and T2 Biosystems, Inc. (the "Company") regarding certain terms and conditions of your employment. This replaces any prior agreement between yourself and the Company with respect to the subject matter contained herein. You are entitled to receive the following:

1. Severance Compensation (Unrelated to a Change of Control). If your employment is terminated either by you with Good Reason, or by the Company without Cause, in either case, other than in the circumstances described in Section 2 of this letter, subject to your executing and delivering to the Company, and not revoking, a release of claims in a form acceptable to the Company (the "Release") within the 30-day period following your termination of employment:

(a) the Company will pay you severance in an amount equal to 9 months of your then current annual base salary, payable in equal installments over a period of 9 months (the "Non-COC Severance Period") in accordance with the Company's payroll practices, commencing on your termination of employment;

(b) If you timely elect continued group medical insurance coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company will reimburse you for a portion of the applicable premiums, based on the then-current cost-sharing rates for active employees, for you and your eligible dependents during the period commencing on the date of your termination of employment and ending on the earliest to occur of (a) the final day of the Non-COC Severance Period, (b) the date you and/or your eligible dependents are no longer eligible for COBRA, and (c) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines that it cannot provide such reimbursement of premiums to you without potentially violating applicable law, the Company shall in lieu thereof provide to you a taxable monthly payment in an amount equal to a portion of the applicable premiums, based on then-current cost-sharing rates for active employees, which payment will be made regardless of whether you elect COBRA continuation coverage and will commence in the month following the month in which your termination of employment occurs and end on the earliest to occur of (x) the final day of the Non-COC Severance Period, (y) the date you and/or your eligible dependents are no longer eligible for COBRA, and (z) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility).

2. Severance Compensation (In Connection with a Change of Control). If your employment is terminated either by you with Good Reason within 12 months following a Change of Control, or by the

Company without Cause within 3 months preceding or within 12 months following a Change of Control, subject to your executing and delivering to the Company, and not revoking, a Release within the 30-day period following your termination of employment, you will be entitled to the following payments and benefits, which shall be in lieu of any payments or benefits under Section 1 of this letter:

(a) the Company will pay you severance in an amount equal to 12 months of your then current annual base salary, payable in equal installments over a period of 12 months (the "COC Severance Period") in accordance with the Company's payroll practices, commencing on your termination of employment;

(b) an amount in cash equal to the annual incentive compensation you would have otherwise been entitled to under an annual incentive program established by the Company's Board of Directors for the year in which the termination occurs (based on actual achievement of performance goals determined by the Board), which amount, if any, shall be prorated based on the number of days elapsed from the commencement of such fiscal year through and including the date of such termination and paid at such time as such year's annual bonus would have been paid had your employment not terminated, but in no event later than the date that is 2½ months following the last day of the fiscal year in which the termination occurred;

(c) if you have been continuously employed by the Company for at least one year as of the date your employment terminates, all of the outstanding unvested equity awards of the Company held by you shall become fully vested and, if applicable, exercisable as of the date of your termination, provided that with respect to any such awards intended to constitute "qualified performance based compensation" under Section 162(m) of the Code, whether a Change of Control has occurred shall be determined without regard to clause (iv) of the definition of Change of Control below; and

(d) If you timely elect continued group medical insurance coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company will reimburse you for a portion of the applicable premiums, based on the then-current cost-sharing rates for active employees, for you and your eligible dependents during the period commencing on the date of your termination of employment and ending on the earliest to occur of (a) the final day of the COC Severance Period, (b) the date you and/or your eligible dependents are no longer eligible for COBRA, and (c) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines that it cannot provide such reimbursement of premiums to you without potentially violating applicable law, the Company shall in lieu thereof provide to you a taxable monthly payment in an amount equal to a portion of the applicable premiums, based on then-current cost-sharing rates for active employees, which payment will be made regardless of whether you elect COBRA continuation coverage and will commence in the month following the month in which your termination of employment occurs and end on the earliest to occur of (x) the final day of the COC Severance Period, (y) the date you and/or your eligible dependents are no longer eligible for COBRA, and (z) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility).

Notwithstanding anything herein to the contrary, in the event that any compensation or benefit that constitutes "nonqualified deferred compensation" within the meaning of Section 409A (as defined below) becomes payable upon the occurrence of a Change of Control, such compensation or benefit shall not be paid unless such Change of Control constitutes a "change in control event" within the meaning of Section 409A.

3. Definitions. For purposes of this letter, the terms "Change of Control," "Cause," and "Good Reason" shall have the following meanings.

(a) "Change of Control" means that any of the following events has occurred:

(i)Any person (as such term is used in Section 13(d) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company, any employee benefit plan of the Company, or any entity organized, appointed, or established by the Company for or pursuant to the terms of any such plan, together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Exchange Act) becomes the beneficial owner or owners (as defined in Rule 13d-3 and 13d-5 promulgated under the Exchange Act), directly or indirectly (the "Control Group"), of more than 50% of the outstanding equity securities of the Company, or otherwise becomes entitled, directly or indirectly, to vote more than 50% of the voting power entitled to be cast at elections for directors ("Voting Power") of the Company, provided that a Change of Control will not have occurred if such Control Group acquired securities or Voting Power solely by purchasing securities from the Company, including, without limitation, acquisition of securities by one or more third party investors;

(ii)A consolidation or merger (in one transaction or a series of related transactions) of the Company pursuant to which the holders of the Company's equity securities immediately prior to such transaction or series of related transactions cease to be the holders, directly or indirectly, immediately after such transaction or series of related transactions of more than 50% of the Voting Power of the entity surviving such transaction or series of related transactions;

(iii)The sale, lease, exchange, or other transfer (in one transaction or series of related transactions) of all or substantially all of the assets of the Company; or

(iv)The liquidation or dissolution of the Company or the Company ceasing to do business.

(b) "Cause" means:

(i) Your conviction of a felony, either in connection with the performance of your obligations to the Company or which otherwise materially and adversely affects your ability to perform such obligations;

(ii) Your willful disloyalty to the Company or deliberate material dishonesty to the Company;

(iii) The commission by you of an act of fraud or embezzlement against the Company;

(iv) Your willful, substantial failure to perform any of your duties hereunder or your deliberate failure to follow reasonable, lawful directions of the Company's Board of Directors or your direct supervisor, which failure, if capable of being cured, is not cured within 30 days after delivery to you by the Company of written notice of such failure; or

(v) A material breach by you of any material provision of this letter which breach is not cured within 30 days after delivery to you by the Company of written notice of such breach.

(c) "Good Reason" means one or more of the following:

(i) A material change in the principal location at which you provide services to the Company, without your prior written consent;

(ii) A material and continuing diminution by the Company in the duties, authority or responsibilities of your position which causes such position to become of less responsibility or authority than immediately prior to such material and continuing diminution, provided that such change is not in connection with a termination of your employment hereunder by the Company;

(iii) A material reduction in your base salary or other benefits except if such a reduction is in connection with a general reduction in compensation or other benefits of all similarly situated employees of the Company;

(iv) Failure by the Company to obtain the assumption of this Agreement by any successor to the Company.

Notwithstanding the foregoing, Good Reason shall only exist if you have given written notice to the Company within 90 days of the initial existence of the Good Reason condition(s), the Company has failed to cure such event(s) within 30 days of its receipt of said notice and you terminate employment within 90 days following expiration of such cure period.

4. Section 409A.

(a) *Separation from Service*. Notwithstanding anything in this letter to the contrary, any compensation or benefit payable under this letter that is designated as payable upon your termination of employment shall be payable only upon your "separation from service" with the Company (a "Separation from Service") within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (collectively, "Section 409A"), and except as provided below, any such compensation or benefits shall not be paid, or, in the case of installments, shall not commence payment, until the 30th day following your Separation from Service. Any installment payments that would have been made to you during the 30 day period immediately following your Separation from Service but for the preceding sentence shall be paid to you on the 30th day following your Separation from Service and the remaining payments shall be made as provided in this letter.

(b) *Specified Employee*. Notwithstanding anything in this letter to the contrary, if you are deemed by the Company at the time of your Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which you are entitled under this letter is required in order to avoid a prohibited distribution under Section 409A, such portion of your benefits shall not be provided to you prior to the earlier of (i) the expiration of the six-month period measured from the date of your Separation from Service with the Company or (ii) the date of your death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump-sum to you (or your estate or beneficiaries), and any remaining payments due to you under this letter shall be paid as otherwise provided herein.

(c) *Installments*. Your right to receive any installment payments under this letter shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

5. General

(a) No provision of this letter shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by you and by an authorized officer of the Company (other than you). No waiver by either party of any breach of, or of compliance with, any condition or provision of this letter by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time. The validity, interpretation, construction and performance of this letter shall be governed by the laws of the Commonwealth of Massachusetts without regard to conflicts of law. The invalidity or unenforceability of any provision or provisions of this letter shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect. This letter may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

(b) This letter contains the entire and exclusive agreement between the parties with respect to the subject matter hereof and is intended to supersede and replace all previous agreements, negotiations, and representations between the parties, whether written or oral, including any provision of the employment offer letter agreement between you and the Company, dated as of October 29, 2014, to the extent such letter addresses the subject matter hereof.

Sincerely,

T2 BIOSYSTEMS, INC.

By: /s/ John Sperzel
Name: John Sperzel
Title: Chairman, CEO & President

Acknowledged and Agreed

/s/ Michael Gibbs
Name: Michael Gibbs

Exhibit 10.55

March 21, 2022

Brett Giffin
[*******]
[*******]

Dear Brett,

This letter sets forth the agreement between you and T2 Biosystems, Inc. (the "Company") regarding certain terms and conditions of your employment. This replaces any prior agreement between yourself and the Company with respect to the subject matter contained herein. You are entitled to receive the following:

1. Severance Compensation (Unrelated to a Change of Control). If your employment is terminated either by you with Good Reason, or by the Company without Cause, in either case, other than in the circumstances described in Section 2 of this letter, subject to your executing and delivering to the Company, and not revoking, a release of claims in a form acceptable to the Company (the "Release") within the 30-day period following your termination of employment:

(a) the Company will pay you severance in an amount equal to 9 months of your then current annual base salary, payable in equal installments over a period of 9 months (the "Non-COC Severance Period") in accordance with the Company's payroll practices, commencing on your termination of employment;

(b) If you timely elect continued group medical insurance coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company will reimburse you for a portion of the applicable premiums, based on the then-current cost-sharing rates for active employees, for you and your eligible dependents during the period commencing on the date of your termination of employment and ending on the earliest to occur of (a) the final day of the Non-COC Severance Period, (b) the date you and/or your eligible dependents are no longer eligible for COBRA, and (c) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines that it cannot provide such reimbursement of premiums to you without potentially violating applicable law, the Company shall in lieu thereof provide to you a taxable monthly payment in an amount equal to a portion of the applicable premiums, based on then-current cost-sharing rates for active employees, which payment will be made regardless of whether you elect COBRA continuation coverage and will commence in the month following the month in which your termination of employment occurs and end on the earliest to occur of (x) the final day of the Non-COC Severance Period, (y) the date you and/or your eligible dependents are no longer eligible for COBRA, and (z) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility).

2. Severance Compensation (In Connection with a Change of Control). If your employment is terminated either by you with Good Reason within 12 months following a Change of Control, or by the

Company without Cause within 3 months preceding or within 12 months following a Change of Control, subject to your executing and delivering to the Company, and not revoking, a Release within the 30-day period following your termination of employment, you will be entitled to the following payments and benefits, which shall be in lieu of any payments or benefits under Section 1 of this letter:

(a) the Company will pay you severance in an amount equal to 12 months of your then current annual base salary, payable in equal installments over a period of 12 months (the "COC Severance Period") in accordance with the Company's payroll practices, commencing on your termination of employment;

(b) an amount in cash equal to the annual incentive compensation you would have otherwise been entitled to under an annual incentive program established by the Company's Board of Directors for the year in which the termination occurs (based on actual achievement of performance goals determined by the Board), which amount, if any, shall be prorated based on the number of days elapsed from the commencement of such fiscal year through and including the date of such termination and paid at such time as such year's annual bonus would have been paid had your employment not terminated, but in no event later than the date that is 2½ months following the last day of the fiscal year in which the termination occurred;

(c) if you have been continuously employed by the Company for at least one year as of the date your employment terminates, all of the outstanding unvested equity awards of the Company held by you shall become fully vested and, if applicable, exercisable as of the date of your termination, provided that with respect to any such awards intended to constitute "qualified performance based compensation" under Section 162(m) of the Code, whether a Change of Control has occurred shall be determined without regard to clause (iv) of the definition of Change of Control below; and

(d) If you timely elect continued group medical insurance coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company will reimburse you for a portion of the applicable premiums, based on the then-current cost-sharing rates for active employees, for you and your eligible dependents during the period commencing on the date of your termination of employment and ending on the earliest to occur of (a) the final day of the COC Severance Period, (b) the date you and/or your eligible dependents are no longer eligible for COBRA, and (c) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines that it cannot provide such reimbursement of premiums to you without potentially violating applicable law, the Company shall in lieu thereof provide to you a taxable monthly payment in an amount equal to a portion of the applicable premiums, based on then-current cost-sharing rates for active employees, which payment will be made regardless of whether you elect COBRA continuation coverage and will commence in the month following the month in which your termination of employment occurs and end on the earliest to occur of (x) the final day of the COC Severance Period, (y) the date you and/or your eligible dependents are no longer eligible for COBRA, and (z) the date you become eligible to receive medical insurance coverage from a subsequent employer (and you agree to notify the Company of such eligibility).

Notwithstanding anything herein to the contrary, in the event that any compensation or benefit that constitutes "nonqualified deferred compensation" within the meaning of Section 409A (as defined below) becomes payable upon the occurrence of a Change of Control, such compensation or benefit shall not be paid unless such Change of Control constitutes a "change in control event" within the meaning of Section 409A.

3. Definitions. For purposes of this letter, the terms "Change of Control," "Cause," and "Good Reason" shall have the following meanings.

(a) "Change of Control" means that any of the following events has occurred:

(i)Any person (as such term is used in Section 13(d) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company, any employee benefit plan of the Company, or any entity organized, appointed, or established by the Company for or pursuant to the terms of any such plan, together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Exchange Act) becomes the beneficial owner or owners (as defined in Rule 13d-3 and 13d-5 promulgated under the Exchange Act), directly or indirectly (the "Control Group"), of more than 50% of the outstanding equity securities of the Company, or otherwise becomes entitled, directly or indirectly, to vote more than 50% of the voting power entitled to be cast at elections for directors ("Voting Power") of the Company, provided that a Change of Control will not have occurred if such Control Group acquired securities or Voting Power solely by purchasing securities from the Company, including, without limitation, acquisition of securities by one or more third party investors;

(ii)A consolidation or merger (in one transaction or a series of related transactions) of the Company pursuant to which the holders of the Company's equity securities immediately prior to such transaction or series of related transactions cease to be the holders, directly or indirectly, immediately after such transaction or series of related transactions of more than 50% of the Voting Power of the entity surviving such transaction or series of related transactions;

(iii)The sale, lease, exchange, or other transfer (in one transaction or series of related transactions) of all or substantially all of the assets of the Company; or

(iv)The liquidation or dissolution of the Company or the Company ceasing to do business.

(b) "Cause" means:

(i) Your conviction of a felony, either in connection with the performance of your obligations to the Company or which otherwise materially and adversely affects your ability to perform such obligations;

(ii) Your willful disloyalty to the Company or deliberate material dishonesty to the Company;

(iii) The commission by you of an act of fraud or embezzlement against the Company;

(iv) Your willful, substantial failure to perform any of your duties hereunder or your deliberate failure to follow reasonable, lawful directions of the Company's Board of Directors or your direct supervisor, which failure, if capable of being cured, is not cured within 30 days after delivery to you by the Company of written notice of such failure; or

(v) A material breach by you of any material provision of this letter which breach is not cured within 30 days after delivery to you by the Company of written notice of such breach.

(c) "Good Reason" means one or more of the following:

(i) A material change in the principal location at which you provide services to the Company, without your prior written consent;

(ii) A material and continuing diminution by the Company in the duties, authority or responsibilities of your position which causes such position to become of less responsibility or authority than immediately prior to such material and continuing diminution, provided that such change is not in connection with a termination of your employment hereunder by the Company;

(iii) A material reduction in your base salary or other benefits except if such a reduction is in connection with a general reduction in compensation or other benefits of all similarly situated employees of the Company;

(iv) Failure by the Company to obtain the assumption of this Agreement by any successor to the Company.

Notwithstanding the foregoing, Good Reason shall only exist if you have given written notice to the Company within 90 days of the initial existence of the Good Reason condition(s), the Company has failed to cure such event(s) within 30 days of its receipt of said notice and you terminate employment within 90 days following expiration of such cure period.

4. Section 409A.

(a) *Separation from Service*. Notwithstanding anything in this letter to the contrary, any compensation or benefit payable under this letter that is designated as payable upon your termination of employment shall be payable only upon your "separation from service" with the Company (a "Separation from Service") within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (collectively, "Section 409A"), and except as provided below, any such compensation or benefits shall not be paid, or, in the case of installments, shall not commence payment, until the 30th day following your Separation from Service. Any installment payments that would have been made to you during the 30 day period immediately following your Separation from Service but for the preceding sentence shall be paid to you on the 30th day following your Separation from Service and the remaining payments shall be made as provided in this letter.

(b) *Specified Employee*. Notwithstanding anything in this letter to the contrary, if you are deemed by the Company at the time of your Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which you are entitled under this letter is required in order to avoid a prohibited distribution under Section 409A, such portion of your benefits shall not be provided to you prior to the earlier of (i) the expiration of the six-month period measured from the date of your Separation from Service with the Company or (ii) the date of your death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump-sum to you (or your estate or beneficiaries), and any remaining payments due to you under this letter shall be paid as otherwise provided herein.

(c) *Installments*. Your right to receive any installment payments under this letter shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

5. General

(a) No provision of this letter shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by you and by an authorized officer of the Company (other than you). No waiver by either party of any breach of, or of compliance with, any condition or provision of this letter by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time. The validity, interpretation, construction and performance of this letter shall be governed by the laws of the Commonwealth of Massachusetts without regard to conflicts of law. The invalidity or unenforceability of any provision or provisions of this letter shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect. This letter may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

(b) This letter contains the entire and exclusive agreement between the parties with respect to the subject matter hereof and is intended to supersede and replace all previous agreements, negotiations, and representations between the parties, whether written or oral, including any provision of the employment offer letter agreement between you and the Company, dated as of November 2, 2021, to the extent such letter addresses the subject matter hereof.

Sincerely,

T2 BIOSYSTEMS, INC.

By: /s/ John Sperzel
Name: John Sperzel
Title: Chairman, CEO & President

Acknowledged and Agreed

/s/ Brett Giffin
Name: Brett Giffin

Exhibit 10.56
Execution Version

AMENDMENT NO. 7 TO TERM LOAN AGREEMENT

THIS AMENDMENT NO. 7 TO TERM LOAN AGREEMENT, dated as of February 15, 2022 (this "***Amendment***") is made among T2 BIOSYSTEMS, INC., a Delaware corporation ("***Borrower***"), the other Obligors party hereto, CRG SERVICING LLC, as administrative agent and collateral agent (in such capacities, "***Administrative Agent***") and the lenders listed on the signature pages hereof under the heading "LENDERS" (each, a "***Lender***" and, collectively, the "***Lenders***"), with respect to the Loan Agreement described below.

RECITALS

WHEREAS, Borrower, Administrative Agent and the Lenders are parties to the Term Loan Agreement, dated as of December 30, 2016, with the Subsidiary Guarantors from time to time party thereto (as amended by Amendment No. 1 to Term Loan Agreement, dated as of March 1, 2017, as further amended by Amendment No. 2 to Term Loan Agreement, dated as of December 18, 2017, as further amended by Amendment No. 3 to Term Loan Agreement, dated as of March 16, 2018, as further amended by Amendment No. 4 to Term Loan Agreement, dated as of March 13, 2019, as further amended by Amendment No. 5 to Term Loan Agreement, dated as of September 10, 2019, and as further amended by Amendment No. 6, dated as of January 25, 2021, in each case, by and among Borrower, Administrative Agent and the lenders party thereto, and as further amended, supplemented or modified to date, the "***Loan Agreement***"); and

WHEREAS, Borrower has requested that Administrative Agent and the Lenders, and Administrative Agent and the Lenders have agreed to, amend the Minimum Required Revenue covenant in **Section 10.02(e)** of the Loan Agreement and make certain other changes as more fully set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements, provisions and covenants contained herein, the parties agree as follows:

SECTION 1.Definitions; Interpretation.

(a) **Terms Defined in Loan Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement.

(b) **Interpretation**. The rules of interpretation set forth in **Section 1.03** of the Loan Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2.Amendments to Loan Agreement. Subject to **Section 3** of this Amendment, the following definitions in **Section 1.01** of the Loan Agreement are hereby amended and restated in their entirety:

> "***Interest-Only Period***" means the period from and including the first Borrowing Date and through but excluding the twenty-eighth (28th) Payment Date following the first Borrowing Date.

"***Stated Maturity Date***" means the twenty-eighth (28th) Payment Date following the first Borrowing Date.

SECTION 3.Conditions of Effectiveness. The effectiveness of **Section 2** of this Amendment shall be subject to the following conditions precedent:

(a) Borrower, Administrative Agent and each of the Lenders shall have duly executed and delivered this Amendment pursuant to **Section 13.04(a)(i)** of the Loan Agreement; *provided*, *however*, that this Amendment shall have no binding force or effect unless all conditions set forth in this **Section 3** have been satisfied;

(b) no Default or Event of Default (in each case subject to any cure period provided under the Loan Agreement) under the Loan Agreement shall have occurred and be continuing; and

(c) Borrower shall have paid or reimbursed Administrative Agent and the Lenders for their reasonable out of pocket costs and expenses (including the reasonable fees and expenses of Administrative Agent's and the Lenders' legal counsel) incurred in connection with this Amendment pursuant to **Section 13.03(a)(i)(z)** of the Loan Agreement.

SECTION 4.Representations and Warranties; Reaffirmation.

(a) Borrower hereby represents and warrants to each Lender as follows:

(i) Borrower has full power, authority and legal right to make and perform this Amendment. This Amendment is within Borrower's corporate powers and has been duly authorized by all necessary corporate action and, if required, by all necessary shareholder action. This Amendment has been duly executed and delivered by Borrower and constitutes a legal, valid and binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by (a) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights and (b) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law). This Amendment (x) does not require any consent or approval of, registration or filing with, or any other action by, any Governmental Authority or any third party, except for such as have been obtained or made and are in full force and effect, (y) will not violate (i) the charter, bylaws or other organizational documents of Borrower and its Subsidiaries or (ii) any applicable law or regulation or any order of any Governmental Authority, other than any such violations in the case of this clause (ii) that, individually or in the aggregate, could not reasonably be expected to have a Material Adverse Effect and (z) will not violate or result in a default under any Material Agreement or agreement creating or evidencing any Material Indebtedness, or give rise to a right thereunder to require any payment to be made by any such Person.

(ii) No Default has occurred or is continuing or will result after giving effect to this Amendment.

(iii) The representations and warranties in **Section 7** of the Loan Agreement are true and correct in all material respects (taking into account any changes made to schedules updated in

accordance with **Section 7.20** of the Loan Agreement) (unless qualified by materiality or Material Adverse Effect, in which case they are true in all respects (taking into account any changes made to schedules updated in accordance with **Section 7.20** of the Loan Agreement)) on and as of the date hereof, with the same force as if made on and as of the date hereof (except that the representation regarding representations and warranties that refer to a specific earlier date is that they were true and correct in all material respects (taking into account any changes made to schedules updated in accordance with **Section 7.20** of the Loan Agreement) (unless qualified by materiality or Material Adverse Effect, in which case they are true in and correct in all respects (taking into account any changes made to schedules updated in accordance with **Section 7.20** of the Loan Agreement)) on such earlier date).

(iv) There has been no Material Adverse Effect since the date of the Loan Agreement.

(b) Each Obligor hereby ratifies, confirms, reaffirms, and acknowledges its obligations under the Loan Documents to which it is a party and agrees that the Loan Documents remain in full force and effect, undiminished by this Amendment, except as expressly provided herein. By executing this Amendment, Borrower acknowledges that it has read, consulted with its attorneys regarding, and understands, this Amendment.

SECTION 5.Release. In consideration of the agreements of Administrative Agent and the Lenders contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Administrative Agent and each Lender, and their respective successors and assigns, and their respective present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Administrative Agent, each Lender and all such other persons being hereinafter referred to collectively as the "***Releasees***" and individually as a "***Releasee***"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower or any of its successors, assigns or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, including, without limitation, for or on account of, or in relation to, or in any way in connection with the Loan Agreement or any of the other Loan Documents or transactions thereunder or related thereto (collectively, the "***Released Claims***"). Borrower understands, acknowledges and agrees that the release set forth above (the "***Release***") may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of the Release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the Release. Borrower acknowledges that the Release constitutes a material inducement to Administrative Agent and the Lenders to enter into this Amendment and that Administrative Agent and the Lenders would not have done so but

for Administrative Agent's and each Lender's expectation that the Release is valid and enforceable in all events.

SECTION 6.Governing Law; Submission to Jurisdiction; WAIVER OF JURY TRIAL.

(a) **Governing Law**. This Amendment and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction; *provided that* Section 5-1401 of the New York General Obligations Law shall apply.

(b) **Submission to Jurisdiction**. Borrower agrees that any suit, action or proceeding with respect to this Amendment or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in Houston, Texas or in the courts of its own corporate domicile and irrevocably submits to the non-exclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This **Section 6** is for the benefit of Administrative Agent and the Lenders only and, as a result, none of Administrative Agent or any Lender shall be prevented from taking proceedings in any other courts with jurisdiction. To the extent allowed by applicable Laws, Administrative Agent and the Lenders may take concurrent proceedings in any number of jurisdictions.

(c) **WAIVER OF JURY TRIAL**. BORROWER, ADMINISTRATIVE AGENT AND EACH LENDER HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AMENDMENT.

SECTION 7.Miscellaneous.

(a) **No Waiver**. Except as expressly stated herein, nothing contained herein shall be deemed to constitute a waiver of compliance with any term or condition contained in the Loan Agreement or any of the other Loan Documents or constitute a course of conduct or dealing among the parties. Except as expressly stated herein, Administrative Agent and the Lenders reserve all rights, privileges and remedies under the Loan Documents. Except as amended hereby, the Loan Agreement and other Loan Documents remain unmodified and in full force and effect. All references in the Loan Documents to the Loan Agreement shall be deemed to be references to the Loan Agreement as amended hereby.

(b) **Severability**. In case any provision of or obligation under this Amendment shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

(c) **Headings**. Headings and captions used in this Amendment (including the Exhibits, Schedules and Annexes hereto, if any) are included for convenience of reference only and shall not be given any substantive effect.

(d) **Integration**. This Amendment constitutes a Loan Document and, together with the other Loan Documents, incorporates all negotiations of the parties hereto with respect to the subject matter hereof and is the final expression and agreement of the parties hereto with respect to the subject matter hereof.

(e) **Counterparts**. This Amendment may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Amendment by signing any such counterpart. Executed counterparts delivered by facsimile or other electronic transmission (e.g., "PDF" or "TIF") shall be effective as delivery of a manually executed counterpart.

(f) **Controlling Provisions**. In the event of any inconsistencies between the provisions of this Amendment and the provisions of any other Loan Document, the provisions of this Amendment shall govern and prevail. Except as expressly modified by this Amendment, the Loan Documents shall not be modified and shall remain in full force and effect.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment as of the date first above written.

BORROWER:

T2 BIOSYSTEMS, INC.

By _____/s/ John Sprague_____
Name: John Sprague
Title: CFO

[Signature Page to Amendment No. 7 to Term Loan Agreement]

ADMINISTRATIVE AGENT:

CRG SERVICING LLC

By /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

LENDERS:

CRG PARTNERS III L.P.
By CRG PARTNERS III GP L.P., its General Partner
By CRG PARTNERS III GP LLC, its General Partner

By /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

CRG PARTNERS III – PARALLEL FUND "A" L.P.
By CRG PARTNERS III – PARALLEL FUND "A" GP L.P., its General Partner
By CRG PARTNERS III – PARALLEL FUND "A" GP LLC, its General Partner

By /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

CRG PARTNERS III (CAYMAN) UNLEV AIV I L.P.

By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By By /s/ Nathan Hull
Name: Nathan Hukill
Title: Authorized Signatory

Witness: _____
Name: _____

CRG PARTNERS III (CAYMAN) LEV AIV L.P.
By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By /s/ Nathan Hull_____
Name: Nathan Hukill
Title: Authorized Signatory

Witness: /s/ Ben Wessner_____
Name: Ben Wessner_____

CRG PARTNERS III PARALLEL FUND "B" (CAYMAN) L.P.
By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By /s/ Nathan Hull_____
Name: Nathan Hukill
Title: Authorized Signatory

Witness: /s/ Ben Wessner_____
Name: Ben Wessner_____

AMENDMENT NO. 6 TO COMMERCIAL LEASE BETWEEN
COLUMBUS DAY REALTY, INC. AND T2 BIOSYSTEMS, INC.

This Amendment No. 6 is to a Commercial Lease dated May 6, 2013, by and between Columbus Day Realty, Inc. (LESSOR), and T2 Biosystems, Inc. (LESSEE), which lease relates to the premises at 231 Andover Street, Wilmington, Massachusetts.

WHEREAS, the Commercial Lease is dated May 6, 2013;

WHEREAS, the parties signed Amendment No. 1 to the Commercial Lease on September 24, 2103;

WHEREAS, the parties signed Amendment No. 2 to the Commercial Lease on September 21, 2015;

WHEREAS, the parties signed Amendment No. 3 to the Commercial Lease on August 10, 2017;

WHEREAS, the parties signed Amendment No. 4 to the Commercial Lease on August 31, 2018;

WHEREAS, the parties signed Amendment No. 5 to the Commercial Lease on October 20, 2020;

WHEREAS, the parties are desirous of amending the Commercial Lease for the purpose of extending the term of the Lease to December 31, 2024;

NOW, THEREFORE, in accordance with the covenants, considerations and conditions contained herein, the parties agree to further amend the Commercial Lease as follows:

3. TERM

This paragraph of the Commercial Lease is hereby amended by extending the expiration date to December 31, 2024.

4. RENT

The base rent for the period of January 1, 2023 to December 31, 2023 shall be at the rate of Fifteen Dollars ($15.00) per square foot. The base rent for the period of January 1, 2024 shall be at the rate of Seventeen Dollars ($17.00) per square foot.

Except as modified by this Amendment, all other terms of the Commercial Lease and Amendments No. 1, No.2, No. 3, No. 4, and No. 5 shall remain in full force and effect for the remaining term of the Lease.

IN WITNESS WHEREOF, the LESSOR and LESSEE have set their hands and seals this 26th day of September 2022.

COLUMBUS DAY REALITY, INC.

By: /s/ [Illegible Signature]
Its President

By: /s/ Susan Johnson
Its Treasure

T2 BIOSYSTEMS, INC.

By: /s/ John Sperzel
Its Chairman & CEO

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 of 7

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00012	See Block 16C		

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
ASPR-BARDA	ASPR-BARDA	ASPR-BARDA	ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

ASPR-BARDA
US DEPT OF HEALTH & HUMAN SERVICES
BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT
200 INDEPENDENCE AVE, S.W.
Washington DC 20201

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

T2 BIOSYSTEMS, INC. 1512719
Attn : MICHAEL GIBBS
T2 BIOSYSTEMS, INC. 101 HARTWE
101 HARTWELL AVE
LEXINGTON MA 02421

CODE	FACILITY CODE
1512719	

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

X 10A. MODIFICATION OF CONTRACT/ORDER NO.
75A50119C00053

10B. DATED *(SEE ITEM 13)*
09/30/2019

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended , by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted ; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted , such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
2022.1992022.25106

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR Part 43.103(a) - Bilateral Modification
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor is not ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Tax ID Number: 20-4827488
DUNS Number: 803126320
UEI: QVYNQM9WLJG3

The purpose of this no-cost modification is to extend the period of performance for CLIN Option Period 3, from 09/30/2022 - 03/31/2023 to 09/30/2022 - 08/31/2023. See Block 14 Continuation Sheet.

OTA: N
Appr. Yr.: 2022 CAN: 1992022 Object Class: 25106
Period of Performance: 04/01/2022 to 03/31/2025

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect .

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*
Roger Smith SVP Science R&D	RICHARD A. HALL

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Roger Smith Digitally signed *(Signature of person authorized to sign)* Date: 2023.03.16	by Roger Smith 08:35:36 -04'00'	Richard A. Hall -S Digitally signed Date: 2023.03.20 *(Signature of Contracting Officer)*	by Richard A. Hall -S 10:20:21 -04'00'

Previous edition unusable

STANDARD FORM 30 (REV. 11/2016)
Prescribed by GSA FAR (48 CFR) 53.243

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED	PAGE	OF
	75A50119C00053/P00012	2	7

NAME OF OFFEROR OR CONTRACTOR
T2 BIOSYSTEMS, INC. 1512719

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Change Item 11 to read as follows (amount shown is the obligated amount):				
11	ASPR-22-02198- Option 3 funds to T2 Biosystems under Contract Number 75A50119C00053 Obligated Amount: $0.00				0.00

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Contract No. 75A50119C00053 Modification No. P00012	Continuation Sheet Block 14	

****Yellow Highlights denotes applicable changes**

Beginning with the effective date of this modification, the Government and the Contractor mutually agree as follows:

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS,

ARTICLE B.3 OPTION PERIODS - the table included in this Article is hereby modified to reflect the following:

B.3. COST REIMBURSEMENT OPTIONS

I. The contract includes optional, cost reimbursement CLINs 0002 through 0007. The Government may exercise Option Periods in accordance with FAR 52.217-9 Option to Extend the Term of the Contract (March 2000), as set forth in Section I of the contract.

II. The contract includes optional services, cost reimbursement CLIN 0008. The Government may exercise Option Services in accordance with FAR 52.217-8 Option to Extend Services, as set forth in Section I of the contract.

III. Unless the government exercises its option pursuant to the option clause contained in ARTICLE 1.2, the contract consists only of the Base Work segment specified in the Statement of Work as defined in SECTION C and F, for the price set forth in ARTICLE B.2 of the contract.

IV. The Government may modify the contract unilaterally and require the contractor to provide supplies and services for Option Periods listed below, in accordance with FAR 52.217-9.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

V. If the Government decides to exercise an option(s), the Government will provide the Contractor a preliminary written notice of its intent as referenced in the clause. Specific information regarding the time frame for this notice is set forth in the OPTION CLAUSE Article in SECTION G of this contract. The estimated cost of the contract will be increased as set forth below:

Option	CLIN	Period of Performance	Supplies/Services	BARDA Estimated Not to Exceed	T2 Estimated Not to Exceed	Overall Total Estimated Not to Exceed
1	0002	09/14/2020 - 10/15/2021	Option 1 Period: Optimize the T2 Biothreat Panel to meet requirements on the T2Dx device. Design, build, and optimize T2Nxt subsystems, and integrate those subsystems into	$10,495,783	$3,925,669	$14,421,452
			a working device. Optimize the T2AMR Panel to detect targets			
2A	0003	09/30/2021-03/31/2022	Option 2A Continue T2Biothreat verification testing and initiate validation testing. Produce a functioning Beta instrument. Complete initial optimization studies and demonstrate required sensitivity with a manual process. Initiate T2Resistance Panel verification and clinical validation studies	$6,357,371	$2,087,418	$8,444,789
2B	0004	04/01/2022-09/30/2022	Option 2B Continue T2Biothreat verification testing and initiate validation testing. Produce a functioning Beta instrument. Complete initial optimization studies and demonstrate required sensitivity with a manual process.	$4,389,160	$2,960,502	$7,349,662

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

3	0005	**09/30/2022 - 08/31/2023**	**Option 3 Period:** Complete validation testing of the T2Biothreat panel on the T2Dx instrument under BSL-3 and prepare and submit a 510(k) application to the FDA for the T2Biothreat panel for use on the T2Dx instrument. The contractor will also complete verification and validation testing and prepare and submit a 510(k) application to the FDA for the T2Resistance Panel for use on the T2Dx instrument. In AIM 1, the contractor will complete contrived sample verification studies of the T2Biothreat panel, prepare a 510(k) application and submit to FDA for clearance. In AIM 6, the contractor will complete verification and validation testing of the T2Resistance panel and prepare a 510(k) application and submit to FDA for clearance.	$3,690,810	$3,332,064	$7,022,874

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

4	0006	[***]- [***]	Option 4 Period: [***]	$[***]	$[***]	$[***]
5	0007	[***]- [***]	Option 5 Period: [***]	$[***]	$[***]	$[***]
6	0008	[***]- [***]	Option 6 Period: [***]	$[***]	$[***]	$[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Optional Services	0009	TBD-TBD as Exercised	Option 7 Period: [***]	$[***]	$[***]	$[***]
		TOTALS	Only option years	**$**[***]	**$**[***]	**$**[***]
		TOTALS	Base+ options	**$62,024,574**	**$**[***]	**$**[***]

End of Changes for Modification P00012.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Execution Version

WAIVER

THIS WAIVER, dated as of January 23, 2023 (this "***Waiver***") is made among T2 BIOSYSTEMS, INC., a Delaware corporation ("***Borrower***"), CRG SERVICING LLC, as administrative agent and collateral agent (in such capacities, "***Administrative Agent***") and the lenders listed on the signature pages hereof under the heading "LENDERS" (each, a "***Lender***" and, collectively, the "***Lenders***"), with respect to the Loan Agreement described below.

RECITALS

WHEREAS, Borrower, Administrative Agent and the Lenders are parties to the Term Loan Agreement, dated as of December 30, 2016, with the Subsidiary Guarantors from time to time party thereto (as amended by Amendment No. 1 to Term Loan Agreement, dated as of March 1, 2017, as further amended by Amendment No. 2 to Term Loan Agreement, dated as of December 18, 2017, as further amended by Amendment No. 3 to Term Loan Agreement, dated as of March 16, 2018, as further amended by Amendment No. 4 to Term Loan Agreement, dated as of March 13, 2019, as further amended by Amendment No. 5 to Term Loan Agreement, dated as of September 10, 2019, as further amended by Amendment No. 6, dated as of January 25, 2021, as further amended by Amendment No. 7, dated as of February 15, 2022, and as further amended by Amendment No. 8, dated as of November 10, 2022, in each case, by and among Borrower, Administrative Agent and the lenders party thereto, and as further amended, supplemented or modified to date, the "***Loan Agreement***");

WHEREAS, Borrower (i) issued shares of Series A convertible preferred stock, par value $0.001 per share (the "***Series A Preferred Stock***"), which constituted Indebtedness of the Borrower, in violation of Section 9.01 of the Loan Agreement, (ii) on October 26, 2022, paid $330,000 in connection with the redemption of the Series A Preferred Stock, in violation of Sections 9.06 and 9.07 of the Loan Agreement, and (iii) failed to deliver notice of the occurrence of Events of Default as a result of the actions described in the foregoing clauses (i) and (ii), in violation of Section 8.02(a) of the Loan Agreement (the actions described in the foregoing clauses (i) through (iii), collectively, the "***Specified Events of Default***"); and

WHEREAS, Borrower has requested that Administrative Agent and the Lenders (which Lenders constitute the Majority Lenders pursuant to **Section 13.04** of the Loan Agreement), and Administrative Agent and such Lenders have agreed to waive the Specified Events of Default.

NOW, THEREFORE, in consideration of the mutual agreements, provisions and covenants contained herein, the parties agree as follows:

SECTION 1. Definitions; Interpretation.

(a) **Terms Defined in Loan Agreement**. All capitalized terms used in this Waiver (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement.

(b) **Interpretation**. The rules of interpretation set forth in **Section 1.03** of the Loan Agreement shall be applicable to this Waiver and are incorporated herein by this reference.

SECTION 2. Waiver. Subject to **Section 4** of this Waiver, Administrative Agent and the Lenders, which constitute the Majority Lenders as required by **Section 13.04** of the Loan Agreement, hereby waive the Specified Events of Default.

SECTION 3. Representations and Warranties; Reaffirmation.

(a) On and as of the date hereof, immediately after giving effect to this Waiver, Borrower hereby represents and warrants to each Lender as follows:

(i) Borrower has full power, authority and legal right to make and perform this Waiver. This Waiver is within Borrower's corporate powers and has been duly authorized by all necessary corporate board of directors (or the equivalent thereof) and, if required, by all necessary shareholder (or the equivalent thereof) action. This Waiver has been duly executed and delivered by Borrower and constitutes a legal, valid and binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by (a) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights and (b) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law). This Waiver (x) does not require any consent or approval of, registration or filing with, or any other action by, any Governmental Authority or any third party, except for such as have been obtained or made and are in full force and effect, (y) will not violate (i) the charter, bylaws or other organizational documents of Borrower and its Subsidiaries or (ii) any applicable law or regulation or any order of any Governmental Authority, other than any such violations in the case of this clause (ii) that, individually or in the aggregate, could not reasonably be expected to have a Material Adverse Effect and (z) will not violate or result in a default under any Material Agreement or agreement creating or evidencing any Material Indebtedness, or give rise to a right thereunder to require any payment to be made by any such Person.

(ii) The representations and warranties in **Section 7** of the Loan Agreement are true and correct in all material respects (taking in to account any changes made to schedules updated in accordance with **Section 7.20** of the Loan Agreement) (unless qualified by materiality or Material Adverse Effect, in which case they are true in all respects (taking into account any changes made to schedules updated in accordance with **Section 7.20** of the Loan Agreement)), in each case on and as of the date hereof, with the same force and effect as if made on and as of the date hereof (except that the representation regarding representations and warranties that refer to a specific earlier date is that they were true and correct in all material respects on such earlier date (taking into account any changes made to schedules updated in accordance with Section 7.20 of the Loan Agreement) (unless qualified).

(iii) No Default or Event of Default under the Loan Agreement shall have occurred and be continuing.

(b) Each Obligor hereby ratifies, confirms, reaffirms, and acknowledges its obligations under the Loan Documents to which it is a party and agrees that the Loan Documents remain in full force and effect, undiminished by this Waiver, except as expressly provided herein. By executing this Waiver, each Obligor acknowledges that it has read, consulted with its attorneys regarding, and understands, this Waiver.

SECTION 4. Conditions of Effectiveness. The effectiveness of **Section 2** of this Waiver shall be subject to the following conditions precedent:

(a) Borrower, Administrative Agent and the Majority Lenders shall have duly executed and delivered this Waiver pursuant to **Section 13.04** of the Loan Agreement;

(b) The representations and warranties contained in **Section 3(a)** of this Waiver shall be true and correct; and

(c) Borrower shall have paid or reimbursed Administrative Agent and the Lenders for their reasonable and documented out of pocket costs and expenses (including the reasonable and documented fees and expenses of Administrative Agent's and the Lenders' legal counsel) incurred in connection with this Waiver pursuant to **Section 13.03(a)(i)(z)** of the Loan Agreement.

SECTION 5. Governing Law; Submission to Jurisdiction; Waiver of Jury Trial.

(a) **Governing Law**. This Waiver and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction; *provided* that Section 5-1401 of the New York General Obligations Law shall apply.

(b) **Submission to Jurisdiction**. Borrower agrees that any suit, action or proceeding with respect to this Waiver or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in Houston, Texas or in the courts of its own corporate domicile and irrevocably submits to the non-exclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This **Section 5** is for the benefit of Administrative Agent and the Lenders only and, as a result, none of Administrative Agent or any Lender shall be prevented from taking proceedings in any other courts with jurisdiction. To the extent allowed by applicable Laws, Administrative Agent and the Lenders may take concurrent proceedings in any number of jurisdictions.

(c) **WAIVER OF JURY TRIAL**. BORROWER, ADMINISTRATIVE AGENT AND EACH LENDER HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS WAIVER.

SECTION 6. Release of Claims. Each Obligor hereby absolutely and unconditionally releases and forever discharges Administrative Agent and each Lender, and any and all parent corporations, subsidiary corporations, affiliated corporations, insurers, indemnitors, successors and assigns thereof, together with all of the present and former directors, officers, agents, attorneys and employees of any of the foregoing (each, a "***Releasee***" and collectively, the "***Releasees***"), from any and all claims, demands or causes of action of any kind, nature or description, whether arising in law or equity or upon contract or tort or under any state or federal law or otherwise (each, a "***Claim***" and collectively, the "***Claims***"), which such Obligor has had, now has or has made claim to have against any such person for or by reason of any act, omission, matter, cause or thing whatsoever arising from the beginning of time to and including the date of this Waiver, whether such claims, demands and causes of action are matured or unmatured or known or unknown. Each

Obligor understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense to any Claim and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Each Obligor agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered will affect in any manner the final, absolute and unconditional nature of the release set forth above.

SECTION 7. Miscellaneous.

(a) **No Waiver**. Except as expressly set forth in **Section 2**, nothing contained herein shall be deemed to constitute a waiver of compliance with any term or condition contained in the Loan Agreement or any of the other Loan Documents or constitute a course of conduct or dealing among the parties. Except as expressly stated herein, Administrative Agent and the Lenders reserve all rights, privileges and remedies under the Loan Documents. Except as amended hereby, the Loan Agreement and other Loan Documents remain unmodified and in full force and effect. All references in the Loan Documents to the Loan Agreement shall be deemed to be references to the Loan Agreement as amended hereby.

(b) **Severability**. In case any provision of or obligation under this Waiver shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

(c) **Headings**. Headings and captions used in this Waiver (including the Exhibits, Schedules and Annexes hereto, if any) are included for convenience of reference only and shall not be given any substantive effect.

(d) **Integration**. This Waiver constitutes a Loan Document and, together with the other Loan Documents, incorporates all negotiations of the parties hereto with respect to the subject matter hereof and is the final expression and agreement of the parties hereto with respect to the subject matter hereof.

(e) **Counterparts**. This Waiver may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Waiver by signing any such counterpart. Executed counterparts delivered by facsimile or other electronic transmission (e.g., “PDF” or “TIF”) shall be effective as delivery of a manually executed counterpart.

(f) **Controlling Provisions**. In the event of any inconsistencies between the provisions of this Waiver and the provisions of any other Loan Document, the provisions of this Waiver shall govern and prevail. Except as expressly modified by this Waiver, the Loan Documents shall not be modified and shall remain in full force and effect.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have duly executed this Waiver, as of the date first above written.

BORROWER:

T2 BIOSYSTEMS, INC.

By_____ Name: John M. Sprague
Title: Chief Financial Officer

ADMINISTRATIVE AGENT:

CRG SERVICING LLC

By: _____
Name: Nathan Hukill
Title: Authorized Signatory

LENDERS:

CRG PARTNERS III L.P.
By CRG PARTNERS III GP L.P., its General Partner
By CRG PARTNERS III GP LLC, its General Partner

By_____ Name: Nathan Hukill
Title: Authorized Signatory

CRG PARTNERS III – PARALLEL FUND "A" L.P.
By CRG PARTNERS III – PARALLEL FUND "A" GP L.P., its General Partner
By CRG PARTNERS III – PARALLEL FUND "A" GP LLC, its General Partner

By_____ Name: Nathan Hukill
Title: Authorized Signatory

CRG PARTNERS III (CAYMAN) UNLEV AIV I L.P.
By CRG PARTNERS III (CAYMAN) GP L.P., its General Partner
By CRG PARTNERS III (CAYMAN) GP LLC, its General Partner

By_____ Name: Nathan Hukill

_____
Erica PalestriniTitle: Authorized Signatory

Witness: Name:

CRG PARTNERS III (CAYMAN) LEV AIV I L.P.
By CRG PARTNERS III (CAYMAN) GP L.P.,
its General Partner
By CRG PARTNERS III (CAYMAN) GP LLC,
its General Partner

By_____ Name: Nathan Hukill
Title: Authorized Signatory

Witness: ____

[Signature Page to Waiver]

Name:

[Signature Page to Waiver]

Erica Palestrini

[Signature Page to Waiver]

CRG PARTNERS III PARALLEL FUND "B" (CAYMAN) L.P.
By CRG PARTNERS III (CAYMAN) GP L.P.,
its General Partner
By CRG PARTNERS III (CAYMAN) GP LLC,
its General Partner

By_____ Name: Nathan Hukill
Title: Authorized Signatory

Witness: ____
Name: ____Erica Palestrini____

[Signature Page to Waiver]

March 30, 2023

John Sprague

Re: *Retention Bonus*

Dear John,

T2 Biosystems, Inc. (the “Company” or “T2”) is pleased to inform you that you are eligible to earn a special, one-time retention bonus (the “Retention Bonus”) in the total aggregate amount of $80,000, to be paid in two installments of $40,000, pursuant to the terms and conditions set forth in this letter agreement.

Subject to the terms of this letter agreement, including continued employment through the applicable date set forth below, the Retention Bonus will be paid to you by the Company in two installments. Within five (5) business days following June 30, 2023 (the “Initial Retention Date”) the Company shall pay you the amount of $40,000 and within five (5) business days following November 15, 2023 (the “Second Retention Date”) the Company shall pay you the amount of $40,000.

Notwithstanding any other provision of this letter agreement, payment of the applicable installment of the Retention Bonus shall be subject to your continued employment with the Company through the Initial Retention Date or the Second Retention Date, as applicable.

The Retention Bonus will be in addition to, and not in lieu of, any other bonus or compensation that you are entitled to with respect to your employment with the Company.

For the avoidance of doubt, if your employment with the Company terminates for any reason prior to the Initial Retention Date or the Second Retention Date, as applicable, you will forfeit any right to receive any unpaid installment of the Retention Bonus.

Payment of the Retention Bonus will be subject to all applicable tax and other withholdings. This letter agreement may be amended only by an instrument in writing signed by both you and an authorized officer of the Company, and any provision hereof may be waived only by an instrument in writing signed by the party against whom or which enforcement of such waiver is sought. This letter agreement does not confer upon you any right to continued employment with the Company or any of its subsidiaries or interfere in any way with the rights of the Company and its subsidiaries to terminate your employment at any time. This letter agreement is binding on and is for the benefit of the parties hereto and their respective successors, assigns, heirs, executors, administrators and other legal representatives. You may not assign, transfer, alienate, sell, pledge or encumber, whether voluntarily, involuntarily or by operation of law your rights under this letter agreement. This letter agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to conflict of law principles that would result in the application of any law other than the law of the Commonwealth of Massachusetts. This letter agreement constitutes the entire agreement among the parties hereto with respect to the subject matter hereof, and supersedes any prior understandings or agreements with respect thereto. This letter agreement may be executed in several counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same instrument. A facsimile, email, .pdf

or other electronic transmission of a signature shall be deemed to be and have the effect of an original signature.

Please indicate your acceptance of and agreement to the terms and conditions of this letter agreement by signing and returning a copy of this letter to the undersigned. If you have any questions or concerns about this letter, please contact John Sperzel, Chairman and Chief Executive Officer.

Thank you for your hard work and commitment to the Company.

Sincerely,

T2 BIOSYSTEMS, INC.

By: /s/ John Sperzel

Name: John Sperzel
Title: Chairman and Chief Executive Officer

Acknowledged and agreed:

/s/ John Sprague

John Sprague

March 30, 2023

Michael Gibbs

Re: *Retention Bonus*

Dear Michael,

T2 Biosystems, Inc. (the “Company” or “T2”) is pleased to inform you that you are eligible to earn a special, one-time retention bonus (the “Retention Bonus”) in the total aggregate amount of $80,000, to be paid in two installments of $40,000, pursuant to the terms and conditions set forth in this letter agreement.

Subject to the terms of this letter agreement, including continued employment through the applicable date set forth below, the Retention Bonus will be paid to you by the Company in two installments. Within five (5) business days following June 30, 2023 (the “Initial Retention Date”) the Company shall pay you the amount of $40,000 and within five (5) business days following November 15, 2023 (the “Second Retention Date”) the Company shall pay you the amount of $40,000.

Notwithstanding any other provision of this letter agreement, payment of the applicable installment of the Retention Bonus shall be subject to your continued employment with the Company through the Initial Retention Date or the Second Retention Date, as applicable.

The Retention Bonus will be in addition to, and not in lieu of, any other bonus or compensation that you are entitled to with respect to your employment with the Company.

For the avoidance of doubt, if your employment with the Company terminates for any reason prior to the Initial Retention Date or the Second Retention Date, as applicable, you will forfeit any right to receive any unpaid installment of the Retention Bonus.

Payment of the Retention Bonus will be subject to all applicable tax and other withholdings. This letter agreement may be amended only by an instrument in writing signed by both you and an authorized officer of the Company, and any provision hereof may be waived only by an instrument in writing signed by the party against whom or which enforcement of such waiver is sought. This letter agreement does not confer upon you any right to continued employment with the Company or any of its subsidiaries or interfere in any way with the rights of the Company and its subsidiaries to terminate your employment at any time. This letter agreement is binding on and is for the benefit of the parties hereto and their respective successors, assigns, heirs, executors, administrators and other legal representatives. You may not assign, transfer, alienate, sell, pledge or encumber, whether voluntarily, involuntarily or by operation of law your rights under this letter agreement. This letter agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to conflict of law principles that would result in the application of any law other than the law of the Commonwealth of Massachusetts. This letter agreement constitutes the entire agreement among the parties hereto with respect to the subject matter hereof, and supersedes any prior understandings or agreements with respect thereto. This letter agreement may be executed in several counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same instrument. A facsimile, email, .pdf

or other electronic transmission of a signature shall be deemed to be and have the effect of an original signature.

Please indicate your acceptance of and agreement to the terms and conditions of this letter agreement by signing and returning a copy of this letter to the undersigned. If you have any questions or concerns about this letter, please contact John Sperzel, Chairman and Chief Executive Officer.

Thank you for your hard work and commitment to the Company.

Sincerely,

T2 BIOSYSTEMS, INC.

By: /s/ John Sperzel

Name: John Sperzel
Title: Chairman and Chief Executive Officer

Acknowledged and agreed:

/s/ Michael Gibbs

Michael Gibbs

Exhibit 10.69

March 30, 2023

Brett Giffin

Re: *Retention Bonus*

Dear Brett,

T2 Biosystems, Inc. (the “Company” or “T2”) is pleased to inform you that you are eligible to earn a special, one-time retention bonus (the “Retention Bonus”) in the total aggregate amount of $80,000, to be paid in two installments of $40,000, pursuant to the terms and conditions set forth in this letter agreement.

Subject to the terms of this letter agreement, including continued employment through the applicable date set forth below, the Retention Bonus will be paid to you by the Company in two installments. Within five (5) business days following June 30, 2023 (the “Initial Retention Date”) the Company shall pay you the amount of $40,000 and within five (5) business days following November 15, 2023 (the “Second Retention Date”) the Company shall pay you the amount of $40,000.

Notwithstanding any other provision of this letter agreement, payment of the applicable installment of the Retention Bonus shall be subject to your continued employment with the Company through the Initial Retention Date or the Second Retention Date, as applicable.

The Retention Bonus will be in addition to, and not in lieu of, any other bonus or compensation that you are entitled to with respect to your employment with the Company.

For the avoidance of doubt, if your employment with the Company terminates for any reason prior to the Initial Retention Date or the Second Retention Date, as applicable, you will forfeit any right to receive any unpaid installment of the Retention Bonus.

Payment of the Retention Bonus will be subject to all applicable tax and other withholdings. This letter agreement may be amended only by an instrument in writing signed by both you and an authorized officer of the Company, and any provision hereof may be waived only by an instrument in writing signed by the party against whom or which enforcement of such waiver is sought. This letter agreement does not confer upon you any right to continued employment with the Company or any of its subsidiaries or interfere in any way with the rights of the Company and its subsidiaries to terminate your employment at any time. This letter agreement is binding on and is for the benefit of the parties hereto and their respective successors, assigns, heirs, executors, administrators and other legal representatives. You may not assign, transfer, alienate, sell, pledge or encumber, whether voluntarily, involuntarily or by operation of law your rights under this letter agreement. This letter agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to conflict of law principles that would result in the application of any law other than the law of the Commonwealth of Massachusetts. This letter agreement constitutes the entire agreement among the parties hereto with respect to the subject matter hereof, and supersedes any prior understandings or agreements with respect thereto. This letter agreement may be executed in several counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same instrument. A facsimile, email, .pdf

or other electronic transmission of a signature shall be deemed to be and have the effect of an original signature.

Please indicate your acceptance of and agreement to the terms and conditions of this letter agreement by signing and returning a copy of this letter to the undersigned. If you have any questions or concerns about this letter, please contact John Sperzel, Chairman and Chief Executive Officer.

Thank you for your hard work and commitment to the Company.

Sincerely,

T2 BIOSYSTEMS, INC.

By: /s/ John Sperzel

Name: John Sperzel
Title: Chairman and Chief Executive Officer

Acknowledged and agreed:

/s/ Brett Giffin

Brett Giffin

Exhibit 21.1

Subsidiaries of T2 Biosystems, Inc.:

Name	Jurisdiction of Organization
T2 Biosystems Securities Corporation	Massachusetts

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

T2 Biosystems, Inc.
Lexington, Massachusetts

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-254918, No. 333-206707, No. 333-216833, No. 333-225275, and No. 333-227847) and Form S-8 (No. 333-197946, No. 333-227850, and No. 333-238727) of T2 Biosystems, Inc. of our report dated March 31, 2023, relating to the consolidated financial statements, which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP
Boston, Massachusetts

March 31, 2023

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John Sperzel, certify that:

1. I have reviewed this Annual Report on Form 10-K of T2 Biosystems, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 31, 2023

By: /s/ John Sperzel
John Sperzel
President, Chief Executive Officer and Chairman of the Board of Directors

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John Sprague, certify that:

1. I have reviewed this Annual Report on Form 10-K of T2 Biosystems, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 31, 2023

By: /s/ John M. Sprague
John M. Sprague
Principal Financial Officer

Exhibit 32.1

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

In connection with the Annual Report of T2 Biosystems, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2022 (the "Report"), as filed with the Securities and Exchange Commission on or about the date hereof, I, John Sperzel, President, Chief Executive Officer and Chairman of the Board of Directors of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(i) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2023

By: /s/ John Sperzel
John Sperzel
President, Chief Executive Officer and Chairman of the Board of Directors

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of T2 Biosystems, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

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

In connection with the Annual Report of T2 Biosystems, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2022 (the "Report"), as filed with the Securities and Exchange Commission on or about the date hereof, I, John M. Sprague, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(i) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2023

By: /s/ John M. Sprague
John M. Sprague
Principal Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of T2 Biosystems, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.