UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 3, 2024

T2 BIOSYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-36571	20-4827488
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

101 Hartwell Avenue, Lexington, Massachusetts 02421
(Address of principal executive offices, including Zip Code)

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

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 per share	TTOO	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 1.01 Entrance into Material Definitive Agreement

The Exchange

On May 3, 2024, the Company entered into a Securities Purchase Agreement (the "SPA") with CRG Partners III L.P., CRG Partners III - Parallel Fund "A" L.P., CRG Partners III (Cayman) Unlev AIV I L.P., CRG Partners III (Cayman) Lev AIV I L.P. and CRG Partners III Parallel Fund "B" (Cayman) L.P. (collectively in such capacity, the "Lenders" or the "Purchasers") pursuant to which the Company issued to the Lenders in a private placement offering 4,748,335 shares (the "Shares") of the Company's common stock in exchange for the Lenders surrendering for cancellation $15.0 million of outstanding loans (the "Exchange") under 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, and the lenders named therein (as amended from time to time to date, the "Loan Agreement").

Consent to Term Loan Agreement

On May 3, 2024, the Company entered into the Consent and Amendment No. 11 to Term Loan Agreement ("Consent No. 11") to the Loan Agreement. Consent No. 11 provides for, among other things, (i) the consent of the Administrative Agent and the Lenders (who constitute all of the lenders under the Loan Agreement) to the Exchange and (ii) an amendment to the "Change of Control" definition to allow the Lenders or their affiliates to acquire a majority of shares in the Company without causing a Change of Control under the Loan Agreement.

The foregoing summary of the SPA and Consent do not purport to be complete and are qualified in its entirety by the full text of the SPA and Consent, copies of which is filed as Exhibits 10.1 and 10.2 to this report.

Item 2.02 Results of Operations and Financial Condition

On May 6, 2024, the Company issued a press release announcing its financial results for its fiscal quarter ended March 31, 2024, and held a conference call to discuss those results. A copy of the Company's press release and a copy of the transcript of the conference call are furnished with this report as Exhibits 99.1 and 99.2, respectively.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 and Exhibits 99.1 and 99.2 of this Current Report on Form 8-K are being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. Furthermore, such information, including Exhibits 99.1 and 99.2 attached hereto, shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly stated by specific reference in such a filing.

Item 3.02 Unregistered Sales of Equity Securities

The disclosure included in Item 1.01 of this report is incorporated under this Item by reference.

Each of the Purchasers is an "accredited investor" and the offer and sale of the shares of Common Stock and was exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended.

The Shares have not been registered under the Securities Act of 1933, as amended (the "Securities Act"), or any state securities laws. We relied on exemptions from the registration requirements of the Securities Act by virtue of Section 3(a)(9) and Section 4(a)(2) thereof. Each Purchaser represented that it was acquiring the securities for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof.

Item 8.01 Other Events

On May 6, 2024, the Company reported the following operational and clinical updates:

- Executed contracts for 8 T2Dx® Instruments during the first quarter, including 5 T2Dx Instruments from outside the U.S. and 3 T2Dx Instruments from the U.S.
- Extended multi-year capital equipment supplier agreement with Vizient, Inc., the largest member-driven health care performance improvement company in the U.S., through March 31, 2025.
- Received FDA 510(k) clearance for the expanded T2Bacteria Panel to include the detection of *Acinetobacter baumannii.*
- Advanced discussions with potential LDT partners to initiate commercialization the T2Lyme Panel in the third quarter of 2024 as a laboratory developed test (LDT).
- Submitted a 510(k) premarket notification to the U.S. FDA to expand the use of the T2Candida Panel to include pediatric testing.
- Advanced the T2Resistance Panel toward U.S. FDA 510(k) submission, expected to occur during the third quarter of 2024.
- Engaged Dr. Robin Robinson, former Director of BARDA and former Deputy Assistant Secretary for ASPR, as a strategic advisor to aid in commercialization of the T2Biothreat Panel.
- Prospective two-center clinical trial data comparing theReal-world use of the T2Resistnace Panel in the EU T2Resistance Panel to blood culture and conventional microbiological methods was published in the *Journal of Clinical Microbiology*, demonstrated the T2Resistance Panel's high sensitivity and specificity, reductions in the time to detection of resistance by approximately 90% compared to standard methodology and positive impacts to clinical decisions for antimicrobial therapy.
- New data presented at the ECCMID 2024 conference found improved patient outcomes with T2Candida compared to conventional blood culture testing and the ability for T2Bacteria to detect persistent *S. aureus* infections better than blood culture.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
10.1	Securities Purchase Agreement, dated May 3, 2024 by and between the Company and the Lenders party thereto
10.2	Consent and Amendment No. 11 to Term Loan Agreement, dated May 3, 2024 by and between the Company and the Lenders party thereto
99.1	Press Release issued May 6, 2024
99.2	Transcript of conference call held on May 6, 2024
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

Pursuant to the requirements 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 hereunto duly authorized.

Date: May 6, 2024

T2 BIOSYSTEMS, INC.

By: /s/ John Sprague
John Sprague
Chief Financial Officer

Exhibit 10.1

Execution Version

SECURITIES PURCHASE AGREEMENT

This Securities Purchase Agreement (this "**Agreement**") is made as of May 3, 2024, by and among CRG Partners III L.P., CRG Partners III—Parallel Fund "A" L.P., CRG Partners III (Cayman) Unlev AIV I L.P., CRG Partners III (Cayman) Lev AIV I L.P. and CRG Partners III Parallel Fund "B" (Cayman) L.P. (together, "**CRG**" or the "**Purchasers**", with each of the purchasing entities, a "**Purchaser**") and T2 Biosystems, Inc., a Delaware corporation (the "**Company**").

WHEREAS, the parties desire for CRG to exchange a portion of its currently outstanding debt (including outstanding principal amounts, but excluding any accrued but unpaid interest thereon, and provided that the prepayment premiums and back-end fees associated with such principal amounts shall be waived upon the Closing (as defined below)) in the amounts set forth on Schedule A hereto into equity securities of the Company (the "**Exchange**," with such exchanged amount, the "**Exchange Amount**");

WHEREAS, the parties intend to execute that certain Consent to Term Loan Agreement relating to the reduction of its currently outstanding debt (the "**Consent to Term Loan Agreement**" and, together with this Agreement, the "**Transaction Documents**") in connection with the Exchange; and

WHEREAS, as consideration for the Exchange, at the Closing (as defined below) the Company shall issue to the Purchasers in a private placement offering (the "**Offering**") a Corresponding Number (defined below) of shares ("**Shares**") of the Company's common stock, par value $0.001 per share (the "**Common Stock**"), upon Exchange of the Exchange Amounts set forth on Schedule A hereto.

NOW THEREFORE, in consideration of the foregoing premises and the respective representations and warranties, covenants and agreements contained herein, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. **Sale and Purchase**. Subject to the terms and conditions of this Agreement, each Purchaser hereby agrees to purchase at the Closing and the Company hereby agrees to sell and issue to each Purchaser at the Closing, a Corresponding Number of Shares in exchange for the outstanding debt set forth opposite such Purchaser's name on Schedule A hereto. The "Corresponding Number" shall be determined by dividing the Exchange Amount by $3.159.

2. **Closing; Delivery**.

(a) Closing. The purchase and sale of the Shares shall take place remotely via the exchange of documents and signatures within two business days following the satisfaction of each of the conditions set forth in Section 7 and Section 8 (to the extent not waived in accordance therewith) (the "**Closing**," and the date on which the Closing occurs hereinafter referred to as the "**Closing Date**").

(b) Exchange; Delivery. Immediately upon the Closing, the Exchange shall be effected. At the Closing, the Company shall deliver to each Purchaser an instruction to the Company's transfer agent to issue evidence of book-entry notation, registered in the name of such Purchaser, representing the Corresponding Number of Shares to be issued and delivered to such Purchaser pursuant to the Exchange.

3. **Representations and Warranties of the Company**. Except as set forth in the SEC Reports, the Company hereby represents and warrants to each Purchaser, as of the Closing Date, the following:

(a) Organization and Qualification. The Company and each of its subsidiaries is a corporation or other business entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its formation, and has the requisite corporate power to own its properties and to carry on its business as now being conducted. The Company and each of its subsidiaries is duly qualified as a foreign corporation to do business and is in good standing in every jurisdiction in which the nature of the business conducted by it makes such qualification necessary, except to the extent that the failure to be so qualified or be in good standing would not have a material adverse effect on the assets, business, conditions (financial or otherwise), results of operations of the Company and its subsidiaries taken as a whole (a "**Material Adverse Effect**").

(b) Authorization, Enforcement, Compliance with Other Instruments.

(i) The Company has the requisite corporate power and authority to enter into and perform its obligations under this Agreement and any other agreements and documents that are exhibits hereto or thereto or are contemplated hereby or thereby or necessary or desirable to effect the transactions contemplated hereby or thereby and to issue the Shares, in accordance with the terms hereof and thereof;

(ii) the execution and delivery by the Company of each of the Transaction Documents and the consummation by it of the transactions contemplated hereby and thereby, including, without limitation, the issuance of the Shares, have been, or will be at the time of execution of such Transaction Document, duly authorized by the Company's Board of Directors, and no further consent or authorization is, or will be at the time of execution of such Transaction Document, required by the Company, its respective Board of Directors or its stockholders;

(iii) each of the Transaction Documents will be duly executed and delivered by the Company; and

(iv) the Transaction Documents when executed will constitute the valid and binding obligations of the Company enforceable against the Company in accordance with their terms, except as such enforceability may be limited by general principles of equity or applicable bankruptcy, insolvency, reorganization, moratorium, liquidation or similar laws relating to, or affecting generally, the enforcement of creditors' rights and remedies.

(c) Capitalization. The authorized capital stock of the Company consists of 400,000,000 shares of Common Stock and 10,000,000 shares of Preferred Stock. All of the outstanding shares of Common Stock and of the stock of each of the Company's subsidiaries have been duly authorized, validly issued and are fully paid and nonassessable, free and clear of all liens. After giving effect to the Closing:

(i) no shares of capital stock of the Company or any of its subsidiaries will be subject to preemptive rights or any other similar rights or any liens or encumbrances suffered or permitted by the Company;

(ii) all of the outstanding shares of capital stock of the Company have the rights, preferences, privileges and restrictions set forth in the Company's Restated Certificate of Incorporation, as in effect as of the date hereof (the "**Certificate of Incorporation**"), and the Company's Amended and Restated Bylaws, as in effect as of the date hereof (the "**Bylaws**").

(iii) there are no agreements or arrangements under which the Company or any of its subsidiaries is obligated to register the sale of any of their securities under the Securities Act;

(iv) except as set forth in the SEC Reports (as defined below), there are no outstanding comment letters from the SEC or any other regulatory agency;

(v) there are no securities or instruments containing anti-dilution or similar provisions, including the right to adjust the exercise, exchange or reset price under such securities, that will be triggered by the issuance of the Shares; and

(vi) no co-sale right, right of first refusal or other similar right will exist with respect to the Shares or the issuance and sale thereof.

(d) Issuance of Shares. The Shares are duly authorized and, upon issuance in accordance with the terms hereof, shall be duly issued, fully paid and nonassessable, and are free and clear from all taxes, liens and charges with respect to the issue thereof.

(e) No Conflicts. The execution, delivery and performance of each of the Transaction Documents by the Company, and the consummation by the Company of the transactions contemplated hereby and thereby will not (i) result in a violation of the Certificate of Incorporation or the Bylaws (or equivalent constitutive document) of the Company or any of its subsidiaries or (ii) violate or conflict with, or result in a breach of any provision of, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, indenture or instrument to which the Company or any subsidiary is a party, except for those which would not reasonably be expected to have a Material Adverse Effect, or (iii) result in a material violation of any law, rule, regulation, order, judgment or decree (including U.S. federal and state securities laws and regulations) applicable to the Company or any subsidiary or by which any property or asset of the Company or any subsidiary is bound or affected. Neither the Company nor any of its subsidiaries is in violation of any term of or in default under its Certificate of Incorporation, Bylaws or any other constitutive documents. Except for those violations or defaults which would not reasonably be expected to have a Material Adverse Effect, neither the Company nor any subsidiary is in violation of any term of or in default under any contract, agreement, mortgage, indebtedness, indenture, instrument, judgment, decree or order or any statute, rule or regulation applicable to the Company or any subsidiary. The business of the Company and its subsidiaries is not being conducted, and shall not be conducted in violation of any law, ordinance or regulation of any governmental entity, except for any violation which would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. Except as specifically contemplated by this Agreement and as required

under the Securities Act and any applicable state securities laws and the rules of the Principal Market, neither the Company nor any of its subsidiaries is required to obtain any consent, authorization or order of, or make any filing or registration with, any court or governmental agency in order for it to execute, deliver or perform any of its obligations under or contemplated by this Agreement or the other Transaction Documents in accordance with the terms hereof or thereof. Neither the execution and delivery by the Company of the Transaction Documents, nor the consummation by the Company of the transactions contemplated hereby or thereby, will require any notice, consent or waiver under any contract or instrument to which the Company or any subsidiary is a party or by which the Company or any subsidiary is bound or to which any of their assets is subject. The Company is unaware of any facts or circumstance, which might give rise to any of the foregoing.

(f) Absence of Litigation. Except as set forth in the SEC Reports, there is no action, suit, claim, inquiry, notice of violation, proceeding (including any partial proceeding such as a deposition) or investigation before or by any court, public board, governmental or administrative agency, self-regulatory organization, arbitrator, regulatory authority, stock market, stock exchange or trading facility (an "**Action**") now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries. For the purpose of this Agreement, the knowledge of the Company means the knowledge of the officers of the Company (both actual or knowledge that they would have had upon reasonable investigation).

(g) Acknowledgment Regarding Purchaser's Purchase of the Shares. The Company acknowledges and agrees that each Purchaser is acting solely in the capacity of an arm's length purchaser with respect to the Transaction Documents and the transactions contemplated hereby and thereby.

(h) No General Solicitation. Neither the Company, nor any of its Affiliates, nor, to the knowledge of the Company, any person acting on its or their behalf, has engaged in any form of general solicitation or general advertising (within the meaning of Regulation D) in connection with the offer or sale of the Shares. With respect to a Purchaser, any investment fund or managed account that is managed on a discretionary basis by the same investment manager as such Purchaser will be deemed to be an Affiliate of such Purchaser. For purposes of this Agreement, "**Affiliate**" means, with respect to any person, any other person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such person, as such terms are used in and construed under Rule 144 under the Securities Act ("**Rule 144**").

(i) No Integrated Offering. Neither the Company, nor any of its Affiliates, nor to the knowledge of the Company, any person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would require registration of the Shares under the Securities Act or cause this offering of the Shares to be integrated with prior offerings by the Company for purposes of the Securities Act.

(j) Employee Relations. Neither Company nor any subsidiary is involved in any labor dispute nor, to the knowledge of the Company, is any such dispute threatened. Neither Company nor any subsidiary is party to any collective bargaining agreement. The Company's and/or its subsidiaries' employees are not members of any union, and the Company believes that its and its subsidiaries' relationship with their respective employees is good.

(k) Intellectual Property Rights. Except as set forth in the SEC Reports, the Company and each of its subsidiaries owns, possesses, or has rights to, all Intellectual Property necessary for the conduct of the Company's and its subsidiaries' business as now conducted, except as such failure to own, possess or have such rights would not reasonably be expected to result in a Material Adverse Effect and (ii) there are no unreleased liens or security interests which have been filed, or which the Company has received notice of, against any of the patents owned or licenses to the Company. Furthermore, (A) to the Company's knowledge, there is no infringement, misappropriation or violation by third parties of any such Intellectual Property, except as such infringement, misappropriation or violation would not result in a Material Adverse Effect; (B) there is no pending or, to the Company's knowledge, threatened, action, suit, proceeding or claim by others challenging the Company's or any of its subsidiaries' rights in or to any such Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such claim; (C) the Intellectual Property owned by the Company and its subsidiaries, and to the Company's knowledge, the Intellectual Property licensed to the Company and its subsidiaries, has not been adjudged invalid or unenforceable, in whole or in part, and there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity, enforceability or scope of any such Intellectual Property, and, to the Company's knowledge, there are no facts which would form a reasonable basis for any such claim, other than any such action, suit, proceeding or claim that would not be reasonably expected to have a Material Adverse Effect; (D) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others that the Company or any of its subsidiaries infringes, misappropriates or otherwise violates any Intellectual Property or other proprietary rights of others, neither the Company nor any of its subsidiaries has received any notice of such claim and, to the Company's knowledge, there are no other facts which would form a reasonable basis for any such claim, except for any action, suit, proceeding or claim as would not be reasonably expected to have a Material Adverse Effect; and (E) to the Company's knowledge, no employee of the Company or any of its subsidiaries is in or has ever been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company or any of its subsidiaries or actions undertaken by the employee while employed with the Company or any of its subsidiaries, except as such violation would not reasonably be expected to have a Material Adverse Effect. Except as would not reasonably be expected to have a Material Adverse Effect and to the Company's knowledge, (A) there are no facts that are reasonably likely to provide a basis for a finding that the Company or any of its subsidiaries does not have clear title or valid license or sublicense rights to the patents or patent applications owned or licensed to the Company or other proprietary information rights as being owned by, or licensed or sublicensed to, as the case may be, the Company or any of its subsidiaries, (B) no valid issued U.S. patent is or would be infringed by the activities of the Company or any of its subsidiaries relating to products currently or proposed to be manufactured, used or sold by the Company or any of its subsidiaries and (C) there are no facts with respect to any issued patent owned or licensed to the Company that would cause any claim of any such patent not to be valid and enforceable in accordance with applicable regulations. "**Intellectual Property**" shall mean all patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, domain names, technology and know-how.

(l) Environmental Laws.

(i) The Company and each subsidiary has complied with all applicable Environmental Laws (as defined below), except for violations of Environmental Laws that, individually or in the aggregate, have not had and would not reasonably be expected to have a Material Adverse Effect. There is no pending or, to the knowledge of the Company, threatened civil or criminal litigation, notice of violation, formal administrative proceeding, or investigation, inquiry or information request, relating to any Environmental Law involving the Company or any subsidiary, except for litigation, notices of violations, formal administrative proceedings or investigations, inquiries or information requests that, individually or in the aggregate, have not had and would not reasonably be expected to have a Material Adverse Effect. For purposes of this Agreement, "**Environmental Law**" means any national, state, provincial or local law, statute, rule or regulation or the common law relating to the environment or occupational health and safety, including without limitation any statute, regulation, administrative decision or order pertaining to (i) treatment, storage, disposal, generation and transportation of industrial, toxic or hazardous materials or substances or solid or hazardous waste; (ii) air, water and noise pollution; (iii) groundwater and soil contamination; (iv) the release or threatened release into the environment of industrial, toxic or hazardous materials or substances, or solid or hazardous waste, including without limitation emissions, discharges, injections, spills, escapes or dumping of pollutants, contaminants or chemicals; (v) the protection of wild life, marine life and wetlands, including without limitation all endangered and threatened species; (vi) storage tanks, vessels, containers, abandoned or discarded barrels, and other closed receptacles; (vii) health and safety of employees and other persons; and (viii) manufacturing, processing, using, distributing, treating, storing, disposing, transporting or handling of materials regulated under any law as pollutants, contaminants, toxic or hazardous materials or substances or oil or petroleum products or solid or hazardous waste. As used above, the terms "release" and "environment" shall have the meaning set forth in the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended.

(ii) To the knowledge of the Company, there is no material environmental liability with respect to any solid or hazardous waste transporter or treatment, storage or disposal facility that has been used by the Company or any subsidiary.

(iii) The Company and its subsidiaries (i) have received all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses except to the extent that the failure to have such permits, licenses or other approvals would not have a Material Adverse Effect, and (ii) are in compliance, in all material respects, with all terms and conditions of any such permit, license or approval.

(m) Authorizations; Regulatory Compliance. The Company and each of its subsidiaries holds, and is operating in compliance with, all authorizations, licenses, permits, approvals, clearances, registrations, exemptions, consents, certificates and orders of any governmental authority and supplements and amendments thereto (collectively, "**Authorizations**") required for the conduct of its business and all such Authorizations are valid and in full force and effect and neither the Company nor any of its subsidiaries is in material violation of any terms of any such

Authorizations, except, in each case, as would not reasonably be expected to have a Material Adverse Effect; and neither the Company nor any of its subsidiaries has received notice of any revocation or modification of any such Authorization, or has reason to believe that any such Authorization will not be renewed in the ordinary course, except to the extent that any such revocation, modification, or non-renewal would not be reasonably expected to have a Material Adverse Effect. The Company and each of its subsidiaries is in compliance with all applicable federal, state, local and foreign laws, regulations, orders and decrees, except as would not reasonably be expected to have a Material Adverse Effect. Neither the Company nor any of its subsidiaries has received any unresolved FDA Form 483, notice of adverse filing, warning letter, untitled letter or other correspondence or notice from the U.S. Food and Drug Administration ("**FDA**"), or any other federal, state, local, or foreign governmental or regulatory authority, alleging or asserting noncompliance with the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.) or comparable applicable law. The Company and each of its subsidiaries, and to the Company's knowledge, each of their respective directors, officers, employees and agents, is and has been in material compliance with applicable health care laws (collectively, "**Health Care Laws**"). Neither the Company nor any of its subsidiaries has received notice of any ongoing claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Authority or third party alleging that any product operation or activity is in material violation of any Health Care Laws or Authorizations and has no knowledge that any such Governmental Authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding. Neither the Company nor any of its subsidiaries has received notice that any governmental authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations and has no knowledge that any such governmental authority is considering such action. The Company and each of its subsidiaries has filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments thereto as required by any Health Care Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete, correct and not misleading on the date filed (or were corrected or supplemented by a subsequent submission). Neither the Company nor any of its subsidiaries has, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post sale warning, "dear doctor" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Company's knowledge, no third party has initiated or conducted any such notice or action. Neither the Company nor any of its subsidiaries is a party to any corporate integrity agreement, deferred prosecution agreement, monitoring agreement, consent decree, settlement order, or similar agreements, or has any reporting obligations pursuant to any such agreement, plan or correction or other remedial measure entered into with any Governmental Authority. Neither the Company, its subsidiaries nor their officers, directors, employees, agents or contractors has been or is currently suspended, disbarred or excluded from participation in the Medicare and Medicaid programs or any other state or federal health care program or in human clinical research.

(n) Title. Neither the Company nor any of its subsidiaries owns any real property. Each of the Company and its subsidiaries has good and marketable title to all of its personal property and assets, free and clear of any restriction, mortgage, deed of trust, pledge, lien, security interest or other charge, claim or encumbrance which would have a Material Adverse Effect. With respect to properties and assets it leases, each of the Company and its subsidiaries is in compliance with such leases and holds a valid leasehold interest free of any liens, claims or encumbrances which would have a Material Adverse Effect.

(o) No Material Restrictions, Breaches, etc. Neither Company nor any subsidiary is subject to any charter, corporate or other legal restriction, or any judgment, decree, order, rule or regulation which in the judgment of the Company's officers has had, or is reasonably expected in the future to have, a Material Adverse Effect. Neither Company nor any subsidiary is in breach of any contract or agreement which breach, in the judgment of the Company's officers, has had, or is reasonably expected to have a Material Adverse Effect.

(p) Tax Status. The Company and each subsidiary has made and filed (taking into account any valid extensions) all federal and state income and all other tax returns, reports and declarations required by any jurisdiction to which it is subject and (unless and only to the extent that the Company or such subsidiary has set aside on its books provisions reasonably adequate for the payment of all unpaid and unreported taxes) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations, except those being contested in good faith and has set aside on its books provision reasonably adequate for the payment of all taxes for periods subsequent to the periods to which such returns, reports or declarations apply. To the knowledge of the Company, there are no unpaid taxes in any material amount claimed to be due from the Company or any subsidiary by the taxing authority of any jurisdiction, and the officers of the Company know of no basis for any such claim.

(q) Certain Transactions. Except for arm's length transactions pursuant to which the Company or any subsidiary makes payments in the ordinary course of business upon terms no less favorable than it could obtain from third parties, none of the officers, directors, or employees of the Company or any subsidiary is a party to any transaction with the Company or any subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any corporation, partnership, trust or other entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee or partner.

(r) Rights of First Refusal. The Company is not obligated to offer the securities offered hereunder on a right of first refusal basis or otherwise to any third parties including, but not limited to, current or former stockholders of the Company, underwriters, brokers, agents or other third parties.

(s) Insurance. The Company has insurance policies of the type and in amounts customarily carried by organizations conducting businesses or owning assets similar to those of the Company and its subsidiaries. There is no material claim pending under any such policy as to which coverage has been questioned, denied or disputed by the underwriter of such policy.

(t) SEC Reports. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), including pursuant to Section 15(d) thereof (or that it would have been required to file by Section 15(d) of the Exchange Act if its duty to file thereunder had not been automatically suspended) (collectively, the "**SEC Reports**") for the two (2) years preceding the date hereof.

(u) Financial Statements. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the SEC with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with GAAP applied on a consistent basis during the periods involved, except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated subsidiaries taken as a whole as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, year-end audit adjustments. The pro forma financial information and the related notes, if any, included in the SEC Reports have been properly compiled and prepared in accordance with the applicable requirements of the Securities Act and the regulations promulgated thereunder and fairly present in all material respects the information shown therein, and the assumptions used in the preparation thereof are reasonable and the adjustments used therein are appropriate to give effect to the transactions and circumstances referred to therein.

(v) Material Changes. Since the respective date of the latest balance sheet of the Company included in the financial statements contained within the SEC Reports, except as specifically disclosed in the SEC Reports, (i) there have been no events, occurrences or developments that have had or would reasonably be expected to have a Material Adverse Effect with respect to the Company, (ii) the Company has not incurred any material liabilities (contingent or otherwise) other than (A) trade payables, accrued expenses and other liabilities incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the financial statements of the Company pursuant to GAAP or to be disclosed in filings made with the SEC, (iii) the Company has not materially altered its method of accounting or the manner in which it keeps its accounting books and records, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock (other than in connection with repurchases of unvested stock issued to employees of the Company), (v) the Company has not issued any equity securities to any officer, director or Affiliate, except Common Stock issued in the ordinary course pursuant to existing Company stock option or stock purchase plans or executive and director corporate arrangements disclosed in the SEC Reports, (vi) there has not been any change or amendment to, or any waiver of any material right under, any material contract under which the Company, or any of its assets are bound or subject, and (vii) except for the issuance of the Shares contemplated by this Agreement, no event, liability or development has occurred or exists with respect to the Company, its businesses, properties, operations or financial condition, as applicable, that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made that has not been publicly disclosed in the SEC Reports.

(w) Transactions With Affiliates and Employees. None of the officers or directors of the Company and, to the Company's knowledge, none of the employees of the Company, is a party to any transaction with the Company or to a transaction contemplated by the Company (other than for services as employees, officers and directors) that would be required to be disclosed by the Company pursuant to Item 404 of Regulation S-K promulgated under the Securities Act, except as set forth in the SEC Reports.

(x) Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has taken no action designed to terminate the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the SEC is contemplating terminating such registration. Except as set forth in the SEC Reports, the Company has not, in the previous twelve (12) months, received (i) written notice from the Nasdaq Capital Market (or such other market or exchange on which the Common Stock is then listed or traded) (the "**Principal Market**") that the Company is not in compliance with the listing or maintenance requirements of Principal Market that would result in immediate delisting or (ii) any notification, Staff Delisting Determination, or Public Reprimand Letter (as such terms are defined in applicable listing rules of the Principal Market) that requires a public announcement by the Company of any noncompliance or deficiency with respect to such listing or maintenance requirements. Except as set forth in the SEC Reports, the Company is in compliance with all listing and maintenance requirements of the Principal Market on the date hereof.

(y) Sarbanes-Oxley. The Company is in compliance in all material respects with all of the provisions of the Sarbanes-Oxley Act of 2002 which are applicable to it.

(z) Disclosure Controls. The Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-14 and 15d-14 under the Exchange Act) and such controls and procedures are effective in ensuring that material information relating to the Company, including its subsidiaries, is made known to the principal executive officer and the principal financial officer.

(aa) Off-Balance Sheet Arrangements. There is no transaction, arrangement, or other relationship between the Company and an unconsolidated or other off-balance sheet entity that is required to be disclosed by the Company in its SEC Reports and is not so disclosed or that otherwise would have a Material Adverse Effect.

(bb) Foreign Corrupt Practices. Neither the Company and its subsidiaries, nor to the Company's knowledge, any agent or other person acting on behalf of the Company and its subsidiaries, has: (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company (or made by any person acting on its behalf of which the Company is aware) which is in violation of law or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended.

(cc) Brokers' Fees. Neither of the Company nor any of its subsidiaries has any liability or obligation to pay any fees or commissions to any broker, finder or agent with respect to the transactions contemplated by this Agreement.

(dd) Disclosure Materials. The SEC Reports and the disclosure materials taken as a whole do not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading.

(ee) Investment Company. The Company is not required to be registered as, and is not an Affiliate of, and immediately following the Closing will not be required to register as, an "investment company" within the meaning of the Investment Company Act of 1940, as amended.

(ff) Reliance. The Company acknowledges that the Purchaser is relying on the representations and warranties made by the Company hereunder and that such representations and warranties are a material inducement to the Purchaser purchasing the Shares. The Company further acknowledges that without such representations and warranties of the Company made hereunder, the Purchasers would not enter into this Agreement.

(gg) U.S. Real Property Holding Corporation. The Company is not now and has never been a "United States real property holding corporation" as defined in the Internal Revenue Code of 1986, as amended (the "**Code**"), and any applicable regulations promulgated thereunder.

4. **Representations, Warranties and Agreements of the Purchasers**. Each Purchaser represents and warrants to, and agrees with, the Company the following:

(a) Organization; Authority. Such Purchaser is an entity duly incorporated or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation or formation with full right, corporate, partnership, limited liability company or similar power and authority to enter into and to consummate the transactions contemplated by this Agreement and otherwise to carry out its obligations hereunder. The execution and delivery of this Agreement performance by such Purchaser of the transactions contemplated hereby have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of such Purchaser. This Agreement has been duly executed by such Purchaser, and when delivered by such Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of such Purchaser, enforceable against it in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) Own Account. Such Purchaser understands that the Shares are "restricted securities" and have not been registered under the Securities Act or any applicable state securities law and is acquiring the Shares as principal for its own account and not with a view to or for distributing or reselling such Shares or any part thereof in violation of the Securities Act or any applicable state securities law, has no present intention of distributing any of such Shares in violation of the Securities Act or any applicable state securities law and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Shares in violation of the Securities Act or any applicable state securities law (this representation and warranty not limiting such Purchaser's right to sell the Shares pursuant to a registration statement or otherwise in compliance with applicable federal and state securities laws).

(c) Purchaser Status. At the time such Purchaser was offered the Shares, it was, and as of the date hereof it is, and on each date on which it converts any Shares, it will be either: (i) an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act or (ii) a "qualified institutional buyer" as defined in Rule 144A(a) under the Securities Act.

(d) Experience of Such Purchaser. Such Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Shares, and has so evaluated the merits and risks of such investment. Such Purchaser is able to bear the economic risk of an investment in the Shares and, at the present time, is able to afford a complete loss of such investment. Such Purchaser and its advisors, if any, have been furnished with all materials relating to the business, financial condition and results of operations of the Company, and materials relating to the offer and sale of the Shares, that have been requested by such Purchaser or its advisors, if any. Such Purchaser acknowledges and understands that its investment in the Shares involves a significant degree of risk.

(e) General Solicitation. Such Purchaser is not purchasing the Shares as a result of any advertisement, article, notice or other communication regarding the Shares published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or, to such Purchaser's knowledge, any other general solicitation or general advertisement.

(f) Access to Information. Such Purchaser acknowledges that it has had the opportunity to review the Transaction Documents (including all exhibits and schedules thereto) and the SEC Reports and has been afforded (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the terms and conditions of the offering of the Shares and the merits and risks of investing in the Shares; (ii) access to information about the Company and its financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment.

(g) No Governmental Review. Such Purchaser understands that no United States federal or state agency or any other government or governmental agency has passed on or made any recommendation or endorsement of the Shares or the fairness or suitability of the investment in the Shares nor have such authorities passed upon or endorsed the merits of the offering of the Shares.

(h) No Conflicts. The execution, delivery and performance by such Purchaser of this Agreement and the consummation by such Purchaser of the transactions contemplated hereby will not (i) result in a violation of the organizational documents of such Purchaser or (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, indenture or instrument to which such Purchaser is a party, or (iii) result in a violation of any law, rule, regulation, order, judgment or decree (including federal and state securities laws) applicable to such Purchaser, except in the case of clauses (ii) and (iii) above, for such that are not material and do not otherwise affect the ability of such Purchaser to consummate the transactions contemplated hereby.

(i) No Legal, Tax or Investment Advice. Such Purchaser understands that nothing in this Agreement or any other materials presented by or on behalf of the Company to the Purchaser in connection with the purchase of the Shares constitutes legal, tax or investment advice. Such Purchaser has consulted such legal, tax and investment advisors as it, in its sole discretion, has deemed necessary or appropriate in connection with its purchase of the Shares.

5. **Transfer Restrictions**. The Purchaser acknowledges and agrees as follows:

(a) None of the Shares have been registered for sale under the Securities Act, in reliance on the private offering exemption in Section 4(a)(2) thereof; the Company does not currently intend to register the Shares under the Securities Act at any time in the future; and the undersigned will not immediately be entitled to the benefits of Rule 144 with respect to the Shares.

(b) The Purchaser understands that there are substantial restrictions on the transferability of the Shares that the certificates representing the Shares shall bear a restrictive legend in substantially the following form (and a stop-transfer order may be placed against transfer of such certificates or other instruments):

> THE SECURITIES REPRESENTED HEREBY HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. SUCH SHARES MAY NOT BE SOLD, PLEDGED, OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR A VALID EXEMPTION FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.

The legend set forth above shall be removed and the Company shall issue a certificate without such legend to the holder of the Shares upon which it is stamped, if (a) such Shares are sold pursuant to a registration statement under the Securities Act, (b) such holder delivers to the Company an opinion of counsel, reasonably acceptable to the Company, that a disposition of the Shares is being made pursuant to an exemption from such registration, or (c) any other evidence reasonably requested and reasonably satisfactory to counsel to the Company to the effect that the proposed sale, pledge, or transfer of the Shares may be effected without registration under the Securities Act. The Company will not require a legal opinion (x) in any transaction in compliance with Rule 144; or (y) in any transaction in which such Purchaser distributes Shares to an Affiliate of such Purchaser for no consideration.

6. **Covenants and Other Rights**.

(a) Listing of Common Stock. The Company shall promptly secure the listing of the Shares upon each national securities exchange and automated quotation system that requires an application by the Company for listing, if any, upon which shares of Common Stock are then listed (subject to official notice of issuance) and shall maintain such listing, so long as any other shares of Common Stock shall be so listed. The Company shall use its reasonable best efforts to maintain the Common Stock's listing on the Principal Market. Neither the Company nor any of its Subsidiaries shall take any action that would be reasonably expected to result in the delisting

or suspension of the Common Stock on the Principal Market, unless the Common Stock is immediately thereafter traded on the New York Stock Exchange, the NYSE MKT, the Nasdaq Global Select Market, the Nasdaq Global Market, or the Nasdaq Capital Market. The Company shall pay all fees and expenses in connection with satisfying its obligations under this Section 6(a).

(b) Tax Treatment of Common Stock. The Company covenants and agrees that, unless required pursuant to a final determination (within the meaning of Section 1313 of the Code, (i) the Shares constitute stock that participates in corporate growth to a significant extent within the meaning of Section 1.305-5(a) of the Treasury Regulations and therefore shall not be treated as preferred stock for purposes of Section 305 of the Code and the Treasury Regulations thereunder, and (ii) for U.S. federal and applicable state income and withholding tax purposes no dividends shall be treated as having been paid with respect to the Shares unless and until paid in cash with respect to the Shares. Each of the parties hereto shall file all tax returns and determine all taxes consistent with such treatment and shall not take any action that is inconsistent with such treatment unless otherwise required by a final determination (within the meaning of Section 1313(a) of the Code).

7. **Conditions to Company's Obligations at Closing**. The Company's obligation to complete the sale and issuance of the Shares and deliver the Shares to each Purchaser on the Closing Date, shall be subject to the following conditions to the extent not waived by the Company:

(a) Representations and Warranties. The representations and warranties made by the Purchasers in Section 4 hereof shall be true and correct in all material respects when made, and shall be true and correct in all material respects on the Closing Date, as the case may be, with the same force and effect as if they had been made on and as of said date.

(b) Performance. Each Purchaser shall have performed in all material respects all obligations and covenants herein required to be performed by them on or prior to the Closing Date.

(c) Receipt of Executed Documents. Each Purchaser shall have executed and delivered to the Company each of the Transaction Documents that requires its signature.

8. **Conditions to Purchasers' Obligations at Closing**. Each Purchaser's obligation to accept delivery of the Shares and to effect the Exchange on the Closing Date shall be subject to the following conditions to the extent not waived by CRG:

(a) Representations and Warranties Correct. The representations and warranties made by the Company in Section 3 hereof shall be true and correct in all material respects (except to the extent any such representation and warranty is qualified by materiality or reference to Material Adverse Effect, in which case, such representation and warranty shall be true and correct in all respects as so qualified) as of, and as if made on, the date of this Agreement and as of the Closing Date, except to the extent any such representation or warranty expressly speaks as of an earlier date, in which case such representation or warranty shall be true and correct as of such earlier date.

(b) Performance. The Company shall have performed in all material respects all obligations and covenants herein required to be performed by it on or prior to the Closing Date.

(c) Certificate. The Chief Executive Officer of the Company shall execute and deliver to the Purchasers to the effect that the representations and warranties of the Company in Section 3 hereof are true and correct (except to the extent any such representation and warranty is qualified by materiality or reference to Material Adverse Effect, in which case, such representation and warranty shall be true and correct in all respects as so qualified) as of, and as if made on, the date of this Agreement and as of the Closing Date and that the Company has satisfied in all material respects all of the conditions set forth in this Section 8.

(d) Good Standing. The Company and each of its subsidiaries is a corporation or other business entity duly organized, validly existing, and in good standing under the laws of the jurisdiction of its formation.

(e) Judgments. No judgment, writ, order, injunction, award or decree of or by any court, or judge, justice or magistrate, including any bankruptcy court or judge, or any order of or by any governmental authority, shall have been issued, and no action or proceeding shall have been instituted by any governmental authority, enjoining or preventing the consummation of the transactions contemplated hereby.

(f) No Suspension. No suspension of trading shall have been imposed by the Nasdaq Capital Market, the SEC or any other governmental regulatory body with respect to public trading in the Common Stock.

(g) Nasdaq LAS. The Company shall have provided the Purchasers with a written confirmation from the Principal Market that the staff of the Principal Market shall have received for its review the Listing of Additional Shares Notification form submitted by the Company in connection with the transactions contemplated by this Agreement and the other Transaction Documents (the "**Listing of Additional Shares Form**").

9. **Indemnification**.

(a) The Company agrees to indemnify and hold harmless each Purchaser, and its directors, officers, shareholders, members, partners, employees and agents (and any other persons with a functionally equivalent role of a person holding such titles notwithstanding a lack of such title or any other title), each person who controls such Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, shareholders, agents, members, partners or employees (and any other persons with a functionally equivalent role of a person holding such titles notwithstanding a lack of such title or any other title) of such controlling person, from and against all losses, liabilities, claims, damages, costs, fees and expenses whatsoever (including, but not limited to, any and all expenses incurred in investigating, preparing or defending against any litigation commenced or threatened) based upon or arising out of the Company's actual or alleged false acknowledgment, representation or warranty, or misrepresentation or omission to state a material fact, or breach by the Company of any covenant or agreement made by the Company, contained herein or in any other any other disclosure materials; provided, however, that the Company will not be liable in any such case to the extent and only to the extent that any such loss, liability, claim, damage, cost, fee or expense arises out of or is based upon the inaccuracy of any representations made by such indemnified party in this Agreement.

(b) Each Purchaser, severally and not jointly, agrees to indemnify and hold harmless the Company and its directors, officers, shareholders, members, partners, employees and agents (and any other persons with a functionally equivalent role of a person holding such titles notwithstanding a lack of such title or any other title), each person who controls such indemnified person (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, shareholders, agents, members, partners or employees (and any other persons with a functionally equivalent role of a person holding such titles notwithstanding a lack of such title or any other title) of such controlling person, from and against all losses, liabilities, claims, damages, costs, fees and expenses whatsoever (including, but not limited to, any and all expenses incurred in investigating, preparing or defending against any litigation commenced or threatened, and including in settlement of any litigation, but only if such settlement is effected with the written consent of Purchaser) insofar as such losses, liabilities, claims, damages, costs, fees and expenses are primarily based upon or primarily arise out of the Purchaser's actual or alleged false acknowledgment, representation or warranty, or misrepresentation or omission to state a material fact, or material breach by the Purchaser of any covenant or agreement made by the Purchaser, contained herein or in any other document delivered by the Purchaser in connection with this Agreement.

(c) Promptly after receipt by an indemnified party under this Section 9 of notice of the commencement of any Action, such indemnified party will, if a claim in respect thereof is to be made against the indemnifying party under this Section 9, notify the indemnifying party in writing of the commencement thereof; but the omission so to notify the indemnifying party will not relieve it from any liability which it may have to any indemnified party otherwise than under this Section 9. In case any such Action is brought against any indemnified party, and it notifies the indemnifying party of the commencement thereof, the indemnifying party will be entitled to participate therein, and to the extent that it may elect by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof, with counsel satisfactory to such indemnified party; provided, however, if the defendants in any such Action include both the indemnified party and the indemnifying party and either (i) the indemnifying party or parties and the indemnified party or parties mutually agree or (ii) representation of both the indemnifying party or parties and the indemnified party or parties by the same counsel is inappropriate under applicable standards of professional conduct due to actual or potential differing interests between them, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such Action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of its election so to assume the defense of such Action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 9 for any reasonable legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed counsel in connection with the assumption of legal defenses in accordance with the proviso to the next preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the expenses of more than one separate counsel in such circumstance), (ii) the indemnifying party shall not have employed counsel satisfactory to the indemnified party to represent the

indemnified party within a reasonable time after notice of commencement of the Action or (iii) the indemnifying party has authorized the employment of counsel for the indemnified party at the expense of the indemnifying party. No indemnifying party shall (i) without the prior written consent of the indemnified parties (which consent shall not be unreasonably withheld), settle or compromise or consent to the entry of any judgment with respect to any pending or threatened Action in respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified parties are actual or potential parties to such Action) unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising out of such Action, or (ii) be liable for any settlement of any such Action effected without its written consent (which consent shall not be unreasonably withheld), but if settled with its written consent or if there be a final judgment of the plaintiff in any such Action, the indemnifying party agrees to indemnify and hold harmless any indemnified party from and against any loss or liability by reason of such settlement or judgment.

10. **[Reserved]**

11. **Termination**. This Agreement shall automatically terminate and become null and void if the Closing Date shall not have occurred on or before May 15, 2024.

12. **Binding Effect**. The Purchaser hereby acknowledges and agrees that this Agreement shall be binding upon and inure to the benefit of the parties and their heirs, executors, administrators, successors, legal representatives and permitted assigns.

13. **Independent Nature of Purchasers' Obligations and Rights**. The obligations of each Purchaser under this Agreement are several and not joint with the obligations of any other Purchaser, and no Purchaser shall be responsible in any way for the performance of the obligations of any other Purchaser under this Agreement. Nothing contained herein and no action taken by any Purchaser pursuant hereto, shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert or as a group, or are deemed affiliates (as such term is defined under the Exchange Act) with respect to such obligations or the transactions contemplated by this Agreement. Each Purchaser shall be entitled to independently protect and enforce its rights, including without limitation the rights arising out of this Agreement, and it shall not be necessary for any other Purchaser to be joined as an additional party in any proceeding for such purpose.

14. **No Third-Party Beneficiaries**. This Agreement is intended only for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person.

15. **Amendments and Waivers**. Except as set forth in Section 7 and Section 8, any term of this Agreement may be amended, terminated or waived only with the written consent of the Company and each of the Purchasers.

16. **Notices**. Any notice, consents, waivers or other communication required or permitted to be given hereunder shall be in writing and will be deemed to have been delivered: (i) upon receipt, when personally delivered; (ii) upon receipt when sent by certified mail, return receipt requested, postage prepaid; (iii) upon receipt, when sent by facsimile (provided confirmation of

transmission is mechanically or electronically generated and kept on file by the sending party); (iv) when sent, if by e-mail, (provided that such sent e-mail is kept on file (whether electronically or otherwise) by the sending party and the sending party does not receive an automatically generated message from the recipient's e-mail server that such e-mail could not be delivered to such recipient); or (v) one (1) Business Day after deposit with an overnight courier service with next day delivery specified, in each case, properly addressed to the party to receive the same. For purposes of this Agreement, "**Business Day**" means a day, other than a Saturday or Sunday, on which banks in New York City are open for the general transaction of business. The addresses, facsimile numbers and email addresses for such communications shall be:

(a) if to the Company, at

T2 Biosystems, Inc.
101 Hartwell Avenue
Lexington, MA 02421
Attention: Chief Financial Officer
E-mail: [***]

with a copy to (which shall not constitute notice):

Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116
Attention: Evan G. Smith
Email: [***]

or

(b) if to CRG, at

CRG
1000 Main Street, Suite 2500
Houston, TX 77002
Attention: General Counsel
Facsimile: 713-209-7351
Email: [***]

with a copy to (which shall not constitute notice):

Cooley LLP
101 California St., 5th Floor
San Francisco, CA 94111
Attention: Mischi a Marca
Facsimile: (415) 693-2222
Email: [***]

(or, in any case, to such other address as the party shall have furnished in writing in accordance with the provisions of this Section 16). Any notice or other communication given by certified mail shall be deemed given at the time of certification thereof, except for a notice changing a party's address which shall be deemed given at the time of receipt thereof.

17. **Assignability**. This Agreement and the rights, interests and obligations hereunder are not transferable or assignable by the Purchaser, and the transfer or assignment of the Shares shall be made only in accordance with all applicable laws.

18. **Applicable Law**. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without reference to the principles thereof relating to the conflict of laws.

19. **Arbitration**. The parties agree to submit all controversies to arbitration in accordance with the provisions set forth below and understand that:

(a) Arbitration shall be final and binding on the parties.

(b) The parties are waiving their right to seek remedies in court, including the right to a jury trial.

(c) Pre-arbitration discovery is generally more limited and different from court proceedings.

(d) The arbitrator's award is not required to include factual findings or legal reasoning and any party's right to appeal or to seek modification of rulings by arbitrators is strictly limited.

(e) The panel of arbitrators will typically include a minority of arbitrators who were or are affiliated with the securities industry.

(f) All controversies which may arise between the parties concerning this Agreement shall be determined by arbitration pursuant to the rules then pertaining to the Financial Industry Regulatory Authority in New York City, New York. Judgment on any award of any such arbitration may be entered in the Supreme Court of the State of New York or in any other court having jurisdiction of the person or persons against whom such award is rendered. Any notice of such arbitration or for the confirmation of any award in any arbitration shall be sufficient if given in accordance with the provisions of this Agreement. The parties agree that the determination of the arbitrators shall be binding and conclusive upon them. The prevailing party, as determined by such arbitrators, in a legal proceeding shall be entitled to collect any costs, disbursements and reasonable attorney's fees from the other party. Prior to filing an arbitration, the parties hereby agree that they will attempt to resolve their differences first by submitting the matter for resolution to a mediator, acceptable to all parties, and whose expenses will be borne equally by all parties. The mediation will be held in the County of New York, State of New York, on an expedited basis. If the parties cannot successfully resolve their differences through mediation within sixty (60) days from the receipt of the written notice of a matter from the notifying party, the matter will be resolved by arbitration. The arbitration shall take place in the County of New York, State of New York, on an expedited basis.

20. **Blue Sky Qualification**. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Securities for, sale to the Purchasers at the Closing under applicable securities or "**Blue Sky**" laws of the states of the United States, and shall provide evidence of such actions promptly upon request of any Purchaser.

21. **Use of Pronouns**. All pronouns and any variations thereof used herein shall be deemed to refer to the masculine, feminine, neuter, singular or plural as the identity of the person or persons referred to may require.

22. **Securities Laws Disclosure; Publicity**. The Company shall promptly, and no later than four Business Days after the date of this Agreement, file a Current Report on Form 8-K with the SEC disclosing the material terms of the transactions contemplated by the Transaction Documents (the "***Transaction Form 8-K***"). If the Company desires, the Company may also issue a press release relating to the Transaction Documents (the "***Press Release***") prior to the filing of the Transaction Form 8-K. The Company shall give the Purchasers a reasonable opportunity to review and comment on the Transaction Form 8-K and Press Release. From and after the filing of the Transaction Form 8-K or, if applicable, the earlier issuance of the Press Release, no Purchaser shall be in possession of any material, non-public information received from the Company or any of its respective officers, directors, employees or agents, that is not disclosed in the Press Release or Transaction Form 8-K, as applicable, unless a Purchaser shall have executed a written agreement regarding the confidentiality and use of such information. Each Purchaser, severally and not jointly with the other Purchasers, covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by the Company as described in this Section 22, such Purchaser will maintain the confidentiality of all disclosures made to it in connection with such transactions (including the existence and terms of such transactions).

23. **Miscellaneous**.

(a) This Agreement, together with the other Transaction Documents and any confidentiality agreement between the Purchaser and the Company, constitute the entire agreement between the Purchaser and the Company with respect to the Offering and supersede all prior oral or written agreements and understandings, if any, relating to the subject matter hereof. The terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by a written document executed by the party entitled to the benefits of such terms or provisions.

(b) The representations and warranties of the Company and the Purchasers made in this Agreement shall survive the execution and delivery hereof and delivery of the Shares.

(c) If the Shares are certificated and any certificate or instrument evidencing any Shares is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof, or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company and the Company's transfer agent of such loss, theft or destruction and the execution by the holder thereof of a customary lost certificate affidavit of that fact and an agreement to indemnify and hold harmless the Company and the Company's transfer agent for any losses in connection therewith or, if required by the transfer agent, a bond in such form and amount as is required by the transfer agent. The applicants for a new certificate or instrument under such

circumstances shall also pay any reasonable third-party costs associated with the issuance of such replacement Shares. If a replacement certificate or instrument evidencing any Shares is requested due to a mutilation thereof, the Company may require delivery of such mutilated certificate or instrument as a condition precedent to any issuance of a replacement.

(d) Each of the parties hereto shall pay its own fees and expenses (including the fees of any attorneys, accountants, appraisers or others engaged by such party) in connection with this Agreement and the transactions contemplated hereby, whether or not the transactions contemplated hereby are consummated.

(e) This Agreement may be executed in one or more original or facsimile or by an e-mail which contains a portable document format (.pdf) file of an executed signature page counterparts, each of which shall be deemed an original, but all of which shall together constitute one and the same instrument and which shall be enforceable against the parties actually executing such counterparts. The exchange of copies of this Agreement and of signature pages by facsimile transmission or in .pdf format shall constitute effective execution and delivery of this Agreement as to the parties and may be used in lieu of the original Agreement for all purposes. Signatures of the parties transmitted by facsimile or by e-mail of a document in pdf format shall be deemed to be their original signatures for all purposes.

(f) Each provision of this Agreement shall be considered separable and, if for any reason any provision or provisions hereof are determined to be invalid or contrary to applicable law, such invalidity or illegality shall not impair the operation of or affect the remaining portions of this Agreement.

(g) Paragraph titles are for descriptive purposes only and shall not control or alter the meaning of this Agreement as set forth in the text.

(h) Each Purchaser hereby agrees to furnish the Company such other information as the Company may request prior to the Closing with respect to its purchase of Shares hereunder.

24. **Public Disclosure**. No Purchaser nor any officer, manager, director, member, partner, stockholder, employee, Affiliate, affiliated person or entity of a Purchaser shall make or issue any press releases or otherwise make any public statements or make any disclosures to any third person or entity with respect to the transactions contemplated herein and will not make or issue any press releases or otherwise make any public statements of any nature whatsoever with respect to the Company without the Company's express prior approval. The Company has the right to withhold such approval in its sole discretion.

[*Signature Page to Follow*]

IN WITNESS WHEREOF, the undersigned have executed, or caused to be executed on their behalf by an agent there unto duly authorized, this Securities Purchase Agreement as of the date first above written.

COMPANY:

T2 BIOSYSTEMS, INC.

By: /s/ John M. Sprague
Name: John M. Sprague
Title: CFO

IN WITNESS WHEREOF, the undersigned have executed, or caused to be executed on their behalf by an agent there unto duly authorized, this Securities Purchase Agreement as of the date first above written.

CRG:

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 GP LLC, its General Partner

By /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

IN WITNESS WHEREOF, the undersigned have executed, or caused to be executed on their behalf by an agent there unto duly authorized, this Securities Purchase Agreement as of the date first above written.

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 /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

Witness: /s/ Valerie Preston
Name: Valerie Preston

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 /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

Witness: /s/ Valerie Preston
Name: Valerie Preston

IN WITNESS WHEREOF, the undersigned have executed, or caused to be executed on their behalf by an agent there unto duly authorized, this Securities Purchase Agreement as of the date first above written.

CRG PARTNERS III PARALLEL FUND "B" (CAYMAN) L.P.

By CRG PARTNERS III (CAYMAN) 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

Witness: /s/ Valerie Preston
Name: Valerie Preston

SCHEDULE A

Purchaser	Principal Amount (including PIK)	Back-End Fee Waived[1]	Prepayment Premium Waived[1]	Exchange Amount (total)
CRG Partners III L.P.	**$ 2,047,472.85**	$ 204,747.29	0	**$ 2,047,472.85**
CRG Partners III – Parallel Fund "A" L.P.	**$ 1,275,000.00**	$ 127,500.00	0	**$ 1,275,000.00**
CRG Partners III (Cayman) Unlev AIV I L.P.	**$ 409,500.00**	$ 40,950.00	0	**$ 409,500.00**
CRG Partners III (Cayman) Lev AIV I L.P.	**$ 4,945,242.35**	$ 494,524.24	0	**$ 4,945,242.35**
CRG Partners III Parallel Fund "B" (Cayman) L.P.	**$ 6,322,784.80**	$ 632,278.48	0	**$ 6,322,784.80**
Total	**$15,000,000.00**	**$1,500,000.00**	**0**	**$15,000,000.00**

(1) The back-end fee and prepayment premium associated with the principal being Exchanged are waived upon Closing.

CONSENT AND AMENDMENT NO. 11 TO TERM LOAN AGREEMENT

THIS CONSENT AND AMENDMENT NO. 11 TO TERM LOAN AGREEMENT, dated as of May 3, 2024 (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, 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, as further amended by Amendment No. 8, dated as of November 10, 2022, as further amended by Amendment No. 9, dated as of October 18, 2023, and as further amended by Amendment No. 10, dated as of April 12, 2024, 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 has requested, and the Lenders have agreed, to convert $15,000,000 of the outstanding principal amount of the Loans into common Equity Interests of Borrower (the "***Conversion***"), pursuant to the terms of the Securities Purchase Agreement, dated as May 3, 2024, by and among Borrower and the Lenders (the "***Purchase Agreement***");

WHEREAS, Borrower has (i) used that certain account of Borrower, ending in x5268 (the "***Provo Account***"), for purposes other than solely for the purpose of payroll, employee benefits, security deposit, withholding tax or other similar trust or fiduciary purposes, thus causing the Provo Account to no longer be an Excluded Account; (ii) failed to grant Administrative Agent a first-priority perfected lien on the Provo Account; (iii) failed to deliver notice of the occurrence of Events of Default as a result of the actions described in clauses (i), (ii) and (iv); and (iv) made certain representations and warranties that may be incorrect or misleading due to the events set forth in the foregoing clauses (i) and (ii), and (iii) (collectively, the "***Specified Defaults***");

WHEREAS, Borrower has requested that Administrative Agent and the Lenders waive the Specified Defaults; and

WHEREAS, subject to the terms and conditions set forth herein, the Administrative Agent and the Lenders, in accordance with **Section 13.04** of the Loan Agreement, have agreed to such requests.

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. Consent, Waiver and Amendment. Subject to **Section 3** of this Amendment:

(a) the Administrative Agent and the Lenders hereby agree to the Conversion. After giving effect to the transactions contemplated by the Purchase Agreement, the outstanding principal amount of the Loans as of May 3, 2024 shall be equal to $11,864,922. For the avoidance of doubt, any accrued but unpaid interest on any principal amounts converted pursuant to the Purchase Agreement shall continue to be outstanding and shall be payable or added to the principal amount of the Loans on the next Payment Date in accordance with the Loan Agreement.

(b) Administrative Agent and the Lenders hereby waive the Specified Defaults, and the parties hereto agree that Borrower shall by May 8, 2024 (or such longer period as agreed to by Administrative Agent in its sole discretion), transfer all funds in the Provo Account that do not meet the requirements of an Excluded Account to another account of the Borrower that is subject to a control agreement in favor of Administrative Agent. The failure to transfer such excess funds as set forth in this Section 2(b) within the foregoing timeline shall automatically result in an Event of Default.

(c) the following definition in Section 1.01 of the Loan Agreement is hereby amended and restated in its entirety as follows:

"***Change of Control***" means (a) the acquisition of ownership, directly or indirectly, beneficially or of record, by any Person or group of Persons acting jointly or otherwise in concert of capital stock representing more than 35% of the aggregate ordinary voting power represented by the issued and outstanding capital stock of Borrower or (b) the acquisition of direct or indirect Control of Borrower by any Person or group of Persons acting jointly or otherwise in concert, in each case whether as a result of a tender or exchange offer, open market purchases, privately negotiated purchases or otherwise; *provided*, for each of clauses (a) and (b), that entities affiliated with any holder of more than 10% of Borrower's issued and outstanding capital stock as of the Closing Date may collectively acquire, directly or indirectly, beneficially or of record, up to 40% of the aggregate ordinary voting power represented by the issued and outstanding capital stock of Borrower so long as such acquisition is not effected in connection with a transaction as a result of which Borrower ceases to have Equity Interests listed on a national securities exchange or otherwise ceases to be public reporting company; *provided further*, that (i) the acquisition of any capital stock of Borrower by the Lenders or any of their Affiliates in excess of the thresholds set forth in clause (a) of this definition and/or (ii) the acquisition of direct or indirect Control of Borrower by the Lenders or any of their Affiliates shall not, in each case of the of the foregoing clauses (i) or (ii), constitute a Change of Control.

SECTION 3. Conditions of Effectiveness. The effectiveness of **Section 2** of this Amendment shall be subject to the following conditions precedent:

(a) Borrower, Subsidiary Guarantors, Administrative Agent and the Lenders shall have duly executed and delivered this Amendment pursuant to **Section 13.04** of the Loan Agreement;

(b) Borrower and the Lenders shall have entered into the Purchase Agreement and the conditions for closing in Sections 7 and 8 of the Purchase Agreement shall have been satisfied or waived;

(c) Lenders shall have purchased the Shares (as defined in the Purchase Agreement) in accordance with the terms of the Purchase Agreement prior to May 15, 2024 and

(d) 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 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 the Borrower's board of directors and, if required, by all necessary shareholder (or the equivalent thereof) 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) Immediately after giving effect to this Amendment, the representations and warranties in **Section 7** of the Loan Agreement (other than the representations and warranties in **Section 7.04(b)** and **Section 7.11**) 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) Immediately after giving effect to this Amendment, 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 Amendment, except as expressly provided herein. By executing this Amendment, each Obligor acknowledges that it has read, consulted with its attorneys regarding, and understands, this Amendment.

SECTION 5. 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 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 AMENDMENT.

SECTION 6. Release of Claims. Each Obligor hereby absolutely and unconditionally releases and forever discharges Administrative Agent and each Lender, and any and all participants, 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 Amendment, 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 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 M. Sprague
Name: John M. Sprague
Title: CFO

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 /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

Witness: /s/ Valerie Preston
Name: Valerie Preston

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 /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

Witness: /s/ Valerie Preston
Name: Valerie Preston

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 Hukill
Name: Nathan Hukill
Title: Authorized Signatory

Witness: /s/ Valerie Preston
Name: Valerie Preston

Exhibit 99.1

T2 Biosystems Announces First Quarter 2024 Financial Results

Achieved double-digit growth in sepsis product revenue and reduced debt by approximately 80% compared to the prior year period

LEXINGTON, Mass., May 6, 2024 (GLOBE NEWSWIRE)— T2 Biosystems, Inc. (NASDAQ:TTOO) (the "Company"), a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, today announced unaudited financial and operational results for the first quarter ended March 31, 2024.

Recent Financial and Operational Highlights

- Achieved first quarter 2024 sepsis product revenue of $2.1 million, representing growth of 25% compared to the prior year period and sequential growth of 23% compared to the fourth quarter of 2023, led by T2Candida Panel sales and strong T2Resistance Panel sales internationally.
- Executed contracts for 8 T2Dx® Instruments during the first quarter, including 5 T2Dx Instruments from outside the U.S. and 3 T2Dx Instruments from the U.S.
- Strengthened balance sheet by converting $30.0 million of term loan debt with CRG Servicing LLC ("CRG") in exchange for shares of T2 Biosystems equity, reducing both total debt and quarterly interest payments to CRG by approximately 80% percent from the balance as of May of 2023.
- Extended multi-year capital equipment supplier agreement with Vizient, Inc., the largest member-driven health care performance improvement company in the U.S., through March 31, 2025.
- Signed an international distribution agreement in Qatar to further expand commercialization in the Middle East.
- Cash and cash equivalents totaled $6.2 million as of March 31, 2024.

Recent Pipeline and Clinical Highlights

- Received FDA 510(k) clearance for the expanded T2Bacteria Panel to include the detection of *Acinetobacter baumannii.*
- Advanced discussions with potential LDT partners to initiate commercialization the T2Lyme Panel in the third quarter of 2024 as a laboratory developed test (LDT).
- Submitted a 510(k) premarket notification to the U.S. FDA to expand the use of the T2Candida Panel to include pediatric testing.
- Advanced the T2Resistance Panel toward U.S. FDA 510(k) submission, expected to occur during the third quarter of 2024.
- Engaged Dr. Robin Robinson, former Director of BARDA and former Deputy Assistant Secretary for ASPR, as a strategic advisor to aid in commercialization of the T2Biothreat Panel.
- Real-world use of the T2Resistance Panel in the EU published in the *Journal of Clinical Microbiology*, demonstrated the T2Resistance Panel's high sensitivity and specificity, reductions in the time to detect resistance by approximately 90% compared to standard methodology and positive impacts to clinical decisions for antimicrobial therapy.
- New data presented at the ECCMID 2024 conference found improved patient outcomes with T2Candida compared to conventional blood culture testing and the ability for T2Bacteria to detect persistent *S. aureus* infections better than blood culture.

"We believe T2 Biosystems has reached an inflection point, having achieved double digit sepsis product sales growth in the first quarter, made significant advances across the product pipeline that we anticipate will drive further growth in 2024, and transformed the Company's balance sheet to better support the continued advancement of our corporate priorities," stated John Sperzel, Chairman and CEO of T2 Biosystems. "Looking ahead, we plan to launch T2Lyme Panel and file the FDA submission for the T2Resistance Panel during the third quarter of 2024. We are extremely excited about the future of T2Biosystems and believe the Company is well positioned for growth."

First Quarter 2024 Financial Results

Sepsis product revenue for the first quarter of 2024 was $2.1 million, representing a 25% increase compared to the prior year period, led by T2Candida Panel sales and strong T2Resistance Panel sales internationally.

Cost of product revenue for the first quarter of 2024 was $4.2 million, a 5% increase compared to the prior year period driven by increased sales volume. Research and development expenses were $3.7 million, a 17% decrease compared to the prior year period, driven by decreased BARDA contract activities. Selling, general and administrative expenses were $6.7 million, an 8% decrease compared to the prior year period driven by decreased headcount.

Net loss for the first quarter of 2024 was $13.5 million, $2.66 per share, compared to a net loss of $18.0 million, or $131.77 per share, in the prior year period.

Cash and cash equivalents totaled $6.2 million as of March 31, 2024, compared to $15.7 million as of December 31, 2023. The Company raised $2.2 million in net proceeds through ATM sales in the first quarter of 2024. In the past 12 months the Company has reduced its total outstanding indebtedness from $50.5 million to $10.5 million as of May 6, 2024, a 79% reduction.

Reiterated 2024 Financial Outlook

The Company continues to expect full year 2024 total sepsis product revenue of $10.0 million to $11.0 million, representing growth of 49% to 64%, compared to $6.7 million in 2023. The Company's 2024 revenue guidance consists entirely of sepsis product revenue and does not include potential sales of the T2Biothreat Panel or the T2Lyme Panel.

Webcast and Conference Call Information

The Company's management team will host a conference call today, May 6, 2024, beginning at 4:30 pm ET. Investors interested in listening to the call may do so by dialing 888-506-0062 for domestic callers or 973-528-0011 for International callers and using conference ID 160751 approximately five minutes prior to the start time. A live and recorded webcast of the call will be available on the "Investors" section of the Company's website at www.t2biosystems.com.

About T2 Biosystems

T2 Biosystems, a leader in the rapid detection of sepsis-causing pathogens and antibiotic resistance genes, is dedicated to improving patient care and reducing the cost of care by helping clinicians effectively treat patients faster than ever before. T2 Biosystems' products include the T2Dx® Instrument, the T2Bacteria® Panel, the T2Candida® Panel, the T2Resistance® Panel, and the T2Biothreat™ Panel, and are powered by the proprietary T2 Magnetic Resonance (T2MR®) technology. T2 Biosystems has an active pipeline of future products, including the U.S. T2Resistance Panel, the Candida auris test, and the T2Lyme™ Panel. For more information, please visit www.t2biosystems.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the likelihood that commercialization of the T2Lyme Panel will occur in the third quarter of 2024, the ability of the Company to provide T2Lyme results to U.S. reference laboratories nationwide, the Company's ability to expand the use of the T2Candida Panel to include pediatric testing, the timeline for the U.S. FDA 510(k) submission for the T2Resistance Panel in the third quarter of 2024, management's expectations for future growth of the Company, the likelihood that the growing dataset for T2Resistance will be a catalyst for increased adoption in countries where the T2Resistance Panel is currently available for purchase, and , as well as statements that include the words "expect," "may," "should," "anticipate," and similar statements of a future or forward-looking nature. These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, (i) any inability to (a) realize anticipated benefits from commitments, contracts or products; (b) successfully execute strategic priorities; (c) bring products to market; (d) expand product usage or adoption; (e) obtain customer testimonials; (f) accurately predict growth assumptions; (g) realize anticipated revenues; (h) incur expected levels of operating expenses; (i) continue as a going concern; or (i) increase the number of high-risk patients at customer facilities; (ii) failure of early data to predict eventual outcomes; (iii) failure to make or obtain anticipated FDA filings or clearances within expected time frames or at all; or (iv) the factors discussed under Item 1A. "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the U.S. Securities and Exchange Commission, or SEC, on April 1, 2024, and other filings the Company makes with the SEC from time to time, including our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While the Company may elect to update such forward-looking statements at some point in the future, unless required by law, it disclaims any obligation to do so, even if subsequent events cause its views to change. Thus, no one should assume that the Company's silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

Investor Contact:

Philip Trip Taylor, Gilmartin Group
ir@T2Biosystems.com
415-937-5406

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 6,208	$ 15,689
Accounts receivable, net	1,588	1,420
Inventories	4,670	4,819
Prepaid expenses and other current assets	3,094	3,261
Total current assets	15,560	25,189
Property and equipment, net	1,611	1,658
Operating lease right-of-use assets	7,031	7,395
Restricted cash	551	551
Other assets	2	4
Total assets	$ 24,755	$ 34,797
Liabilities and stockholders' deficit		
Current liabilities:		
Notes payable to related party	$ 41,666	$ 41,284
Accounts payable	1,887	1,527
Accrued expenses and other current liabilities	4,231	4,905
Accrued final payment fee on Term Loan with related party	4,767	4,807
Operating lease liability	1,651	1,616
Derivative liability related to Term Loan with related party	1,662	1,554
Warrant liabilities	207	235
Deferred revenue	185	224
Total current liabilities	56,256	56,152
Operating lease liabilities, net of current portion	6,180	6,598
Deferred revenue, net of current portion	92	83
Total liabilities	62,528	62,833
Commitments and contingencies		
Stockholders' deficit		
Preferred stock, $0.001 par value; 10,000,000 shares authorized: Series B Convertible Preferred Stock, 10,875 shares designated on March 31, 2024, 10,875 and 93,297 shares issued and outstanding on March 31, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 5,512,332 and 4,058,381 shares issued and outstanding on March 31, 2024 and December 31, 2023, respectively	6	4
Additional paid-in capital	560,051	556,256
Accumulated deficit	(597,830)	(584,296)
Total stockholders' deficit	(37,773)	(28,036)
Total liabilities and stockholders' deficit	$ 24,755	$ 34,797

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

	Three Months Ended March 31,	
	2024	2023
Revenue:		
Product revenue	$ 2,061	$ 1,655
Contribution revenue	—	423
Total revenue	2,061	2,078
Costs and expenses:		
Cost of product revenue	4,202	3,995
Research and development	3,721	4,471
Selling, general and administrative	6,738	7,299
Total costs and expenses	14,661	15,765
Loss from operations	(12,600)	(13,687)
Other income (expense):		
Interest expense to related party	(1,179)	(1,522)
Change in fair value of derivative related to Term Loan with related party	(108)	(770)
Change in fair value of warrant liabilities	28	(1,304)
Other, net	325	(682)
Total other income (expense)	(934)	(4,278)
Net loss	$ (13,534)	$ (17,965)
Net loss per share — basic and diluted	$ (2.66)	$ (131.77)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	5,094,809	136,333
Other comprehensive loss:		
Net loss	$ (13,534)	$ (17,965)
Total other comprehensive income, net of taxes	—	—
Comprehensive loss	$ (13,534)	$ (17,965)

Trip Taylor, IR

Thank you, operator. I would like to remind everyone that comments made by management today and answers to questions will include forward-looking statements. Those include statements related to T2 Biosystems' future financial and operating results and plans for developing and marketing new products.

Forward-looking statements are based on estimates and assumptions as of today and are subject to risks and uncertainties that may cause actual results to differ materially from those expressed or implied by these statements, including the risks and uncertainties described in T2 Biosystems' annual report on Form 10-K filed with the SEC on April 1, 2024, and other filings the company makes with the SEC from time to time. The company undertakes no obligation to publicly update or revise any forward-looking statements, except as required by law.

With that, I would like to turn the call over to Chairman and CEO, John Sperzel. John?

John Sperzel, CEO

Thank you all for joining our first quarter 2024 results call. I will start with an update on our Nasdaq compliance plan and our capital plans, and then discuss our first quarter progress across our three corporate priorities, before turning the call over to John Sprague, our Chief Financial Officer, who will review our financial results and outlook for 2024. I will then provide closing remarks and opening the call for questions and answers.

On March 12, 2024, we announced that the Nasdaq Hearings Panel had granted our request for continued listing on the Nasdaq Stock Market, subject to the Company demonstrating compliance with Nasdaq's market value of listed securities ("Market Value") requirement, as set forth in Nasdaq Listing Rule 5550(b)(2) (the "Rule") on or before May 20, 2024. The Rule requires that the Company maintain a closing Market Value of at least $35.0 million for a minimum of ten consecutive business days.

As I outlined in our recent investor update call, an important part of our Nasdaq compliance plan included the conversion of debt to equity. In April 2024, the Company converted $15 million of its term loan with entities affiliated with CRG Servicing LLC (“CRG”), our lender, into T2 Biosystems equity. Today, the Company announced the conversion of an additional $15 million of its term loan with CRG, for a total debt to equity conversion of $30 million in the past thirty days, which we believe significantly improves the probability of meeting the Nasdaq listing requirements. In the past 12 months, we have reduced our debt, and associated quarterly interest payments, by approximately 80%.

Earlier today, we filed an S-1 registration statement that included our plan to raise up to $10 million in capital through the issuance of new securities. We believe the Company is at an inflection point, transforming from an internally focused research and development company to an externally focused commercial company, and this capital is necessary for general working capital and to help us achieve our goals, including increasing our sepsis product sales, launching the T2Lyme Panel, and advancing the T2Resistance Panel. Simultaneously, we intend to reduce operating costs, reduce inventory, and increase production volumes.

Today, we are applying our technology to sepsis, Lyme disease, and bioterrorism. These three areas share the need for rapid pathogen detection and faster targeted antimicrobial treatment.

Our core opportunity, sepsis, continues to impose an enormous human and economic toll. Sepsis is the leading cause of death in U.S. hospitals, claiming the lives of 270,000 Americans annually, with an additional 80,000 who die in hospice each year. Sepsis also represents the leading expense of U.S. hospitalization, costing our healthcare system an estimated $62 billion annually. Lastly, sepsis is the leading cause of 30-day U.S. hospital readmission, with 19% of sepsis survivors re-hospitalized within 30 days and 40% within 90 days. Rapid detection of sepsis-causing pathogens is crucial, as mortality risk

increases by up to 8% for each hour of delayed, targeted antimicrobial treatment. As we have discussed, T2 Biosystems has developed and commercialized the only FDA-cleared products able to detect sepsis-causing pathogens directly from blood, in just 3-5 hours, without the need to wait days for a positive blood culture.

Competitive products – like those marketed by bioMerieux, BD, and Accelerate – first require a positive blood culture, which can take days. So, when those competitors claim that they can produce species identification or antibiotic susceptibility ("AST") results in 1-3 hours, it is after they wait 1-5 days for a positive blood culture. And when blood culture produces false negative results, due to lack of sensitivity or inhibition due to prior antimicrobial treatment, those culture-dependent technologies provide little to no value.

A meta-analysis of 14 controlled studies, published in a peer-reviewed medical journal, compared T2 Biosystems' sepsis tests to blood culture-based diagnostics, and showed that T2 Biosystems' products provided: faster time to detection (e.g., species identification 77 hours faster), faster targeted therapy (e.g., patients testing positive with T2 Biosystems receiving targeted antimicrobial therapy 42 hours faster), and reduced length of stay (e.g., 5.0 fewer days in the ICU and 4.8 fewer days in the hospital).

Thanks to the strong efforts of our team during the first quarter of 2024, we made considerable progress across our three corporate priorities: 1) accelerating our sales, 2) enhancing our operations, and 3) advancing our pipeline.

Starting with our first corporate priority — accelerating our sales.

In the first quarter of 2024, our team achieved sepsis product revenue of $2.1 million, representing growth of 25% compared to the prior year period. Our team also achieved sequential quarterly growth of 23% compared to the fourth quarter of 2023. The growth in the first quarter was led by sales of our T2Candida Panel globally, and sales of our T2Resistance Panel internationally. We added 8 T2Dx Instrument contracts, continuing to grow our installed base, with 5 sold in international markets and 3 in the U.S. market.

We are seeing strong momentum in the U.S. market, including 4 hospital go-lives during the first quarter from prior account closes. We are focused on growing revenue in our current U.S. hospital accounts through improved focus and coordination between medical affairs, sales, and field applications.

The strong global performance of T2Bacteria Panel during the quarter is also encouraging. As we gained FDA clearance in February of this year to expand T2Bacteria Panel to include the detection of *Acinetobacter baumannii*, we anticipate even further utilization of the T2Bacteria Panel moving forward.

During the quarter, we further expanded our international distribution network in the Middle East by signing a new distribution agreement in Qatar, which includes the T2Dx® Instruments, the T2Bacteria® Panel, the T2Candida® Panel, and the T2Resistance® Panel. Qatar's National Sepsis Program is a collaboration between the Ministry of Public Health and leading medical centers that guides the national sepsis prevention efforts in the country. Qatar's strong focus on sepsis care is demonstrated by sepsis mortality rates among the best in the world and a regular National Sepsis Symposium. The introduction of the T2Dx Instrument and sepsis test panels into Qatar will allow rapid detection of sepsis-causing pathogens and antibiotic resistance genes, in hours instead of days, enabling clinicians to achieve faster, targeted therapy. We expect to continue to expand into new geographies and broaden our international distributor network throughout 2024.

We also extended our existing multi-year capital equipment supplier agreement with Vizient, the largest group purchasing organization in the United States until March 31, 2025. This extension ensures that members continue to have access to and benefit from contracted pricing for our T2Dx Instrument, the T2Bacteria Panel, and the T2Candida Panel. This move emphasizes the demand among hospitals for more efficient rapid diagnostics that enable faster targeted therapy. It also highlights the significant value proposition our products offer to patients suspected of sepsis.

Generating compelling clinical data that demonstrates the value of our technology is a core part of our strategy. During the first quarter of 2024, we announced the publication of the strongest evidence to date in support of the T2Resistance Panel in a real-world hospital setting. Published in *The Journal of Clinical Microbiology,* the study highlights high accuracy for the T2Resistance Panel, faster detection times, and the impact of faster test results on clinical interventions based on T2 sepsis test results. This compelling data not only strengthens our position in CE Mark-adopting countries where the T2Resistance Panel is already available, but also sets the stage for our future entry into the U.S. market. New data was also presented at ECCMID 2024 showing improved patient outcomes with the T2Candida Panel compared to blood culture-based diagnostics, and the ability for the T2Bacteria Panel to detect persistent *S. aureus* infections better than blood culture.

Finally, to advance our commercial opportunities for the T2Biothreat Panel, we have entered into an agreement with Dr. Robin Robinson to serve as a strategic advisor. Dr. Robinson has significant experience and expertise leading U.S. Government entities in the areas of medical countermeasures and biodefense, including serving as director of the Biomedical Advanced Research and Development Authority, or BARDA, and the Deputy Assistant Secretary in the Office of the Assistant Secretary for Preparedness and Response, or ASPR, within the U.S. Department of Health and Human Services. We believe Dr. Robinson's vast network across multiple U.S. Government agencies – including CDC, ASPR, BARDA, Department of Defense, and National Institutes of Health – coupled with his expertise in medical countermeasures and biodefense, will be invaluable as we pursue government contracts to procure the T2Biothreat Panel and protect our nation from the consequences of deliberate of accidental exposure to biothreats. It is important to note that T2Biothreat Panel sales are not in our current 2024 revenue guidance, so potential sales during 2024 represent upside to that guidance.

Moving to our second corporate priority — enhancing our operations.

We are committed to improving the profitability of the business. This requires continued product sales growth, reduced operating costs, and improved cost of product revenue – all of which we are prioritizing.

We are pleased to have eliminated the product backorder and have been working to reduce inventory levels as an operational priority. We are driving improvements in manufacturing efficiency, as we scale production, and are working to improve product gross margins. From an operating expense perspective, we will continue to balance investing appropriately in commercial and development resources to support future growth, while being prudent with expenses to preserve cash.

Moving to our third corporate priority — advancing our pipeline.

We have three tests in our pipeline – including the U.S. T2Resistance Panel, the T2Lyme Panel, and the Candida auris test — each of which has received Breakthrough Device designation from the U.S. Food and Drug Administration. These three tests, or test panels, share a critical requirement for rapid pathogen detection and targeted antimicrobial treatment.

T2Resistance Panel

The T2Resistance Panel is a direct-from-blood molecular diagnostic test that runs on the FDA-cleared T2Dx Instrument and simultaneously detects 13 antibiotic resistance genes, in just 3-5 hours, without the need to wait days for a positive blood culture. We believe the T2Resistance Panel will be a significant catalyst to drive broader adoption of our T2Dx Instrument and our T2Bacteria Panel.

In March, we issued a press release to announce the results of a new study that was published in the *Journal of Clinical Microbiology*, highlighting the performance and clinical benefits of the T2Resistance Panel. The prospective study included 59 patients at two sites, and intended to determine the clinical sensitivity, time to detection, and clinical impact of the T2Resistance Panel compared to blood culture and conventional microbiology methods. Highlights included:

High Accuracy: The T2Resistance Panel demonstrated clinical sensitivity of 94.7% and specificity of 97.4% (adjudicated). This is consistent with the clinical performance of our two FDA-cleared sepsis panels: the T2Bacteria Panel and the T2Candida Panel.

Rapid Turnaround Time: The T2Resistance Panel results were available on average in 4.4 hours compared to 58.3 hours with blood culture-based methods. The T2Resistance Panel provided a 92% improvement in time to result compared to blood culture-based diagnostics (i.e., 4.4 hours vs. 2.2 days).

Clinical Impact: There were 49 clinical interventions in 24 of the 59 patients, resulting in 17 antibiotic escalations and 32 discontinuations of unnecessary antibiotics. The use of the T2Resistance Panel led to a change in antibiotic therapy for 41% of the patients in this study, as those patients were on the wrong or unnecessary antibiotics.

These results demonstrate the strongest clinical impact of the T2Resistance Panel to date in a real-world hospital setting. We believe this performance data demonstrates the enormous potential of this unique and highly differentiated product — to reduce cost, improve patient outcomes, and reduce the threat of antibiotic resistance. We expect this to be a catalyst for greater adoption of the T2Resistance Panel in countries where we currently market under CE mark.

We also believe the international experience with the direct-from-blood detection of antibiotic resistance genes is an important precursor to our launch in the U.S. market. As a reminder, we plan to submit a 510(k) premarket notification to the U.S. Food and Drug Administration, or FDA, during the third quarter of 2024, and we have previously received Breakthrough Device designation from the FDA, which provides for a prioritized FDA review upon submission.

T2Lyme Panel

The T2Lyme Panel is a direct-from-blood molecular diagnostic test designed for the early detection of *Borrelia burgdorferi*, the bacterium that causes Lyme disease in the U.S.

Lyme disease is the leading vector-borne disease in America, with an estimated 3.4 million tests performed each year. The current diagnostic process is a two-tiered antibody test algorithm that relies on the presence of antibodies and can only be used accurately four to eight weeks after infection. If left untreated, the bacteria may spread throughout the body and become much harder to eradicate and treat effectively. Although early symptoms of Lyme disease are similar to the flu, *Borellia burgdorferi* infections can lead to chronic, debilitating disease.

To address this critical unmet need, we have developed an extremely sensitive diagnostic test for the detection of early Lyme disease, with an analytical sensitivity that is in line with our FDA-cleared sepsis tests. We believe our test will detect Lyme disease within the first 30 days after infection, compared to antibody tests that can take 30-60 days after infection.

We plan to launch our T2Lyme Panel as a Laboratory Developed Test, or LDT, during the third quarter of 2024, and we believe there are numerous potential advantages of launching the T2Lyme Panel in this format, including: 1) faster time to market, 2) higher test throughput, and 3) stronger product contribution margins.

Importantly, in a LDT format, we can run the test without the T2Dx Instrument, which can provide the potential to process hundreds of Lyme tests per day. This is because the individual components of our underlying technology can be leveraged to process a higher volume of samples. Given the LDT format does not require the T2Dx Instrument, or the costs associated with a cartridge, we expect to realize strong product contributions margins. Our market research confirms that reference laboratories often charge greater than $250 for two-tiered antibody Lyme tests, and greater than $250 for PCR Lyme tests.

Our ultimate objective is to provide early Lyme disease results to major U.S. reference laboratories. We believe we can utilize their retail networks to collect patient samples, which would allow us to provide testing to Lyme patients across the country. These samples would then be sent to our LDT partner to perform the T2Lyme Panel in their lab. It is important to note that T2Lyme Panel sales are also not in our current 2024 revenue guidance, so any potential sales during 2024 represent upside to that guidance.

Candida auris test

The *Candida auris* test is a direct-from-blood molecular diagnostic test designed to detect *Candida auris* species, in just 3-5 hours, without the need to wait days for a positive blood culture. We believe the addition of a *Candida auris* test will strengthen the value proposition of our T2Candida Panel and lead to increased adoption.

Candida auris is a multidrug-resistant fungal pathogen that has a mortality rate of up to 60% and is recognized as a serious global health threat by the CDC and the World Health Organization. The CDC estimates the costs associated with U.S. fungal diseases are as high as $48 billion annually and has called on public health professionals to help lower the burden of fungal disease by continuing to raise awareness of the life-saving benefits of early detection and proper treatment.

Candida species are a major contributor to morbidity and mortality in hospitalized children and present as a significant burden to the U.S. healthcare system with a mean increased hospital length of stay of 21 days, and an estimated $92,000 in excess hospital costs for children with invasive candidiasis. A 2022 *Journal of Clinical Microbiology* study conducted at the Bambino Gesù hospital in Rome, Italy found that pediatric patients suspected of fungal bloodstream infections that were tested with the T2Candida Panel received species identification results 121.8 hours faster compared to blood culture-based diagnostics.

Finally, we are also pursuing expanded claims for our FDA-cleared T2Candida Panel and T2Bacteria Panel, to include pediatric testing. In December 2023, we submitted a 510(k) premarket notification to the FDA to expand the use of the T2Candida Panel to include pediatric testing, and we expect to submit a 510(k) premarket notification to the FDA to expand the use of the T2Bacteria Panel to include pediatric testing during 2024.

With that, I will now turn the call over to John Sprague to provide a detailed update on our first quarter financial results.

John Sprague

Thank you, John.

First quarter 2024 revenues were $2.1 million, all from sepsis product sales, a 25% increase compared to the prior year period and sequential growth of 23% compared to the fourth quarter of 2023 led by T2Candida Panel sales and strong international T2Resistance Panel sales.

First quarter 2024 cost of product revenue were $4.2 million, a 5% increase compared to the prior year period, driven by sales volume. Research and development expenses were $3.7 million, a 17% decrease compared to the prior year period, driven by decreased BARDA contract activities. Selling, general and administrative expenses were $6.4 million, a 13% decrease compared to the prior year period driven by decreased spending.

The first quarter 2024 net loss was $13.5 million, $2.66 per share, compared to a first quarter 2023 net loss of $18.0 million, $131.77 per share.

Cash and cash equivalents were $6.2 million as of March 31, 2024, and we raised $2.2 million in net proceeds from ATM sales in the quarter. The CRG debt conversation has reduced our debt and interest expense by almost 80% compared to a year ago.

We continue to expect total sepsis and related product revenues to grow between 49% and 64% to $10.0 million to $11.0 million in 2024 over 2023 and this target excludes any potential sales from our T2Biothreat or T2Lyme Panel panels.

Thank you and back to John Sperzel for the closing remarks.

John Sperzel

It is an extremely exciting time for the Company as we have been taking measures to significantly reduce our debt, strengthen our balance sheet, and position the company for sustained growth. We are nearing four catalysts that we expect to be growth drivers: 1) the T2Lyme Panel, which we may launch sooner than anticipated via a partnership; 2) the T2Biothreat Panel, which we are pursuing initial sales to government agencies and have engaged a U.S. Government expert; 3) the T2Candida Panel to include pediatric testing which is pending FDA 510(k) clearance; and 4) the U.S. T2Resistance Panel, which we expect to submit for FDA 510(k) clearance during the third quarter of 2024.

With that I'd like to turn the call back over to the operator to open the line for questions. Operator?