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): April 12, 2022

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 Global 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 7.01 Regulation FD Disclosure.

On April 12, 2022, T2 Biosystems, Inc. (the "Company") hosted a virtual analyst and investor meeting and made available on its website the presentation materials attached as Exhibit 99.1 to this Current Report on Form 8-K to be presented during the meeting.

The furnishing of the attached presentation is not an admission as to the materiality of any information therein. The information contained in the slides is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures. For important information about forward looking statements, see the slide titled "Forward Looking Statements" in Exhibit 99.1 attached hereto.

The information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 and in the presentation attached as Exhibit 99.1 to this Current Report shall not be incorporated by reference into any filing with the SEC made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Company Slide Presentation
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: April 12, 2022

T2 BIOSYSTEMS, INC.

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

Exhibit 99.1

Analyst and Investor Day

(NASDAQ: TTOO)

April 12, 2022

T2Biosystems

Forward-Looking Statements

This presentation contains forward-looking statements. Such statements reflect the current views of senior management of T2 Biosystems, Inc. ("we", "us", "our", "T2", "T2 Biosystems" or the "Company") and include those about T2's goals, strategies, plans, objectives, prospects, milestones, future operations, business and industry, anticipated product benefits, future events and conditions and potential scenarios. Such statements and those that include the words “expect,” “intend,” “plan,” “believe,” “project,” “forecast,” “estimate,” “may,” “should,” “anticipate” and similar statements of a future or forward-looking nature identify forward-looking statements for purposes of the federal securities laws or otherwise. Forward-looking statements address matters that involve risks and uncertainties. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including, for example: (i) our status as an early commercial-stage company and expectation to incur losses in the future; (ii) our ability to obtain marketing authorization from the FDA or regulatory clearance for additional product candidates in the United States or abroad; (iii) the market acceptance of our technology; (iv) our ability to timely and successfully develop and commercialize existing and future product candidates; (v) our lengthy and variable sales cycle and lack of sales history; (vi) our ability to successfully manage growth; (vii) federal, state and foreign regulatory requirements; (viii) our uncertain future capital needs and ability to raise future capital; (ix) dependence on third parties; (x) recruiting, training and retaining key personnel; (xi) competitive factors; (xii) manufacturing and other product risks; (xii) risks related to intellectual property; and (xiii) other risk factors included in our annual report on form 10-K filed with the Securities and Exchange Commission (SEC) on March 23, 2022 and other documents we file with the SEC from time to time. Accordingly, there are or will be important factors that could cause our actual results to differ materially from those indicated in these statements. The statements made herein speak only as of the date of this presentation. We do not undertake, and specifically disclaim, any obligation to update any forward-looking statements contained in this presentation.

Agenda

Company Overview – 5 min.
John Sperzel, Chairman and CEO

Panel Discussion: Culture-Independent Diagnostics – 30 min.
Aparna Ahuja, MD, Chief Medical Officer
James Snyder, PhD, DABMM, FAAM
Thomas Walsh, MD, PhD

Commercial Strategy – 10 min.
Brett Giffin, Chief Commercial Officer

Product Pipeline – 10 min.
Roger Smith, Senior VP Science R&D

Financial Summary – 5 min.
John Sprague, Chief Financial Officer

Q&A – 30 min.
Management Team

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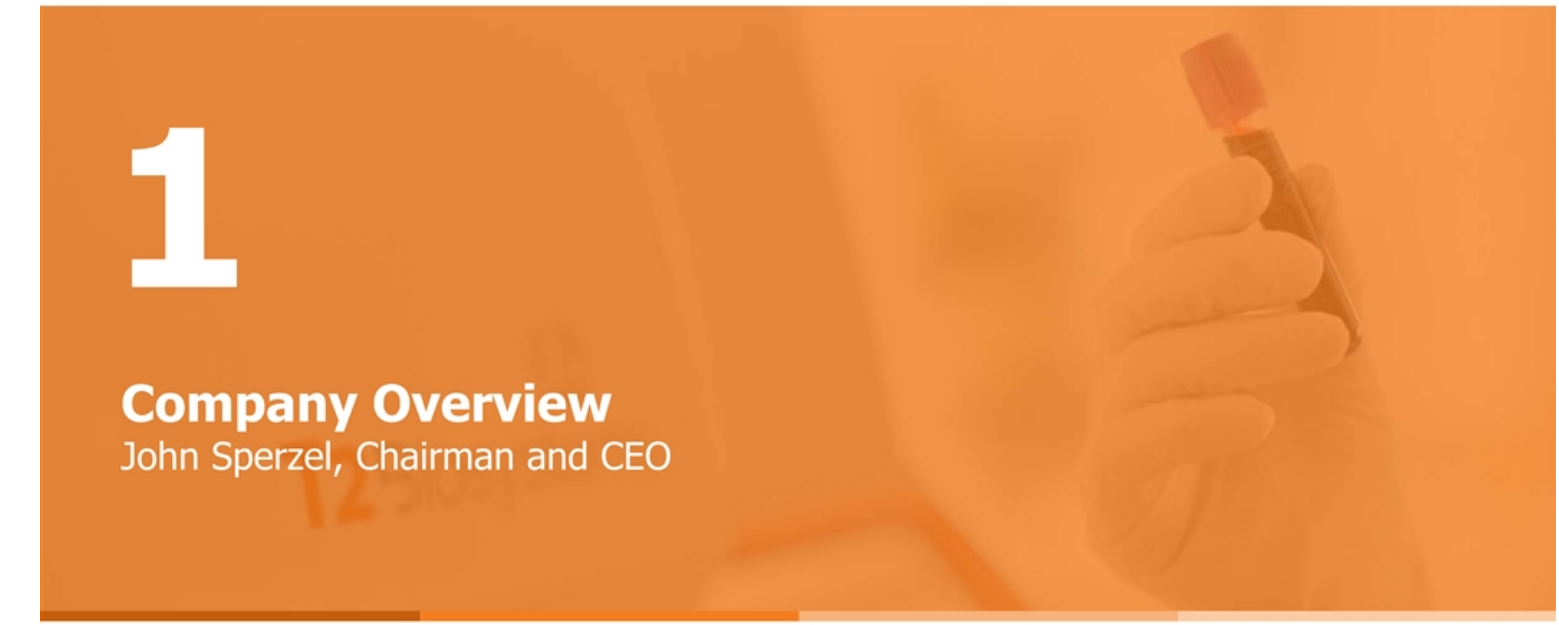
Company Overview

John Sperzel, Chairman and CEO



T2 Biosystems®

Our mission is to fundamentally change the way medicine is practiced through **transformative culture-independent diagnostics** that improve the lives of patients around the world

Investment Highlights

Proprietary Platform

Innovative proprietary technology platform (magnetic resonance)

Novel Diagnostics

Direct from blood ID in 3-5 hours (culture independent)

Large Market Opportunity

Initial target market $2 billion+

Established Reimbursement

U.S. hospital in-patient testing is covered (DRG payment system)

Robust Product Pipeline

BARDA contract may fund up to $69 million (milestone-based)

Commercially Focused

Commercial focus on hospital market

1. Proprietary technology platform with potential to become standard of care in sepsis management

Significant Economic and Human Toll from Sepsis

Sepsis is the leading cost, cause of death, and cause of readmission in U.S. hospitals

- Sepsis is the #1 cost of U.S. hospitalization
  ($62 billion annually)[1]
- Sepsis is the #1 cause of death in U.S. hospitals
  (270,000 deaths annually)[2]
- Sepsis is the #1 cause of 30-day readmission in U.S. hospitals
  (~20% readmission)[1]

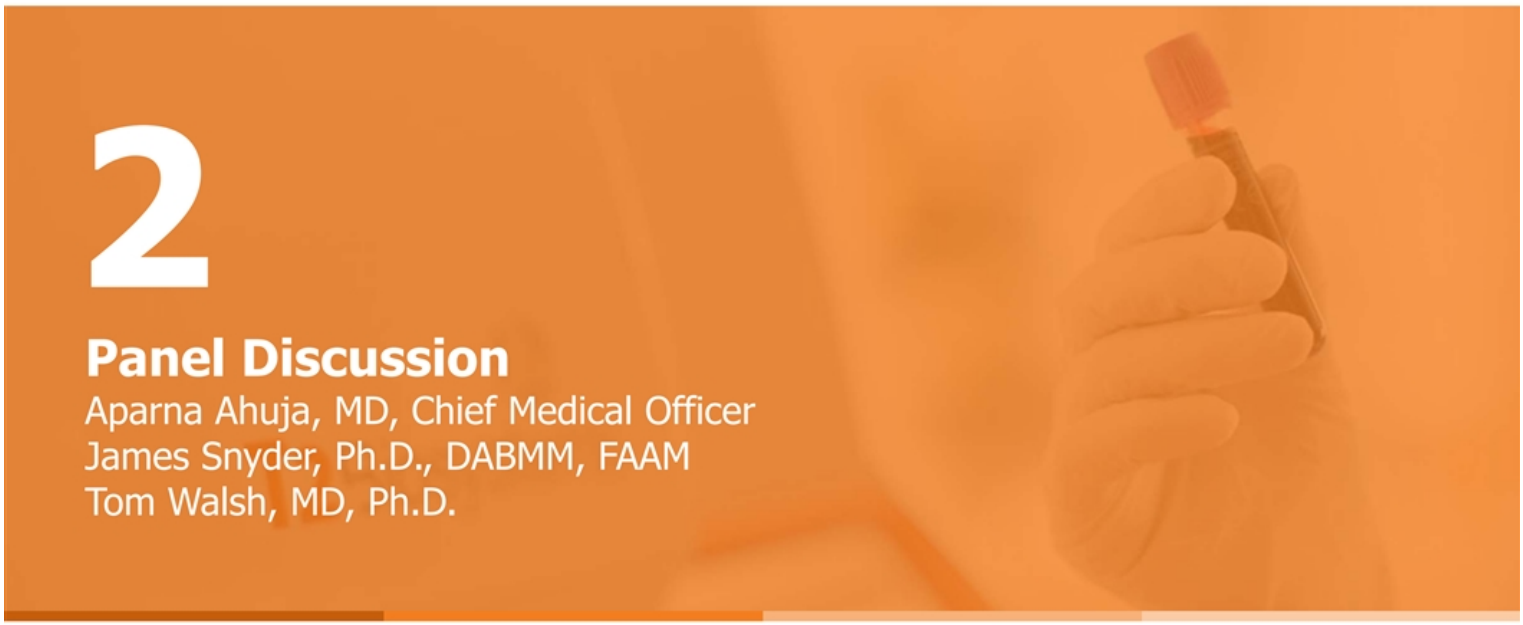
1. https://journals.lww.com/ccmjournal/FullText/2020/03000/Sepsis_Among_Medicare_Beneficiaries__3__The.4.aspx
2. Centers for Disease Control and Prevention.

2022 Corporate Priorities

ACCELERATE SALES

ENHANCE OPERATIONS

ADVANCE PIPELINE



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Panel Discussion

Aparna Ahuja, MD, Chief Medical Officer
James Snyder, Ph.D., DABMM, FAAM
Tom Walsh, MD, Ph.D.

Sepsis Represents $62 Billion in U.S. Healthcare Costs

Claims more U.S. lives each year than the top three cancers combined: lung, colorectal, breast[2,3]

Costs the U.S. healthcare system $62 billion annually[1]

Claims more lives each year than the three top cancers combined (lung, colorectal, breast)[2,3]

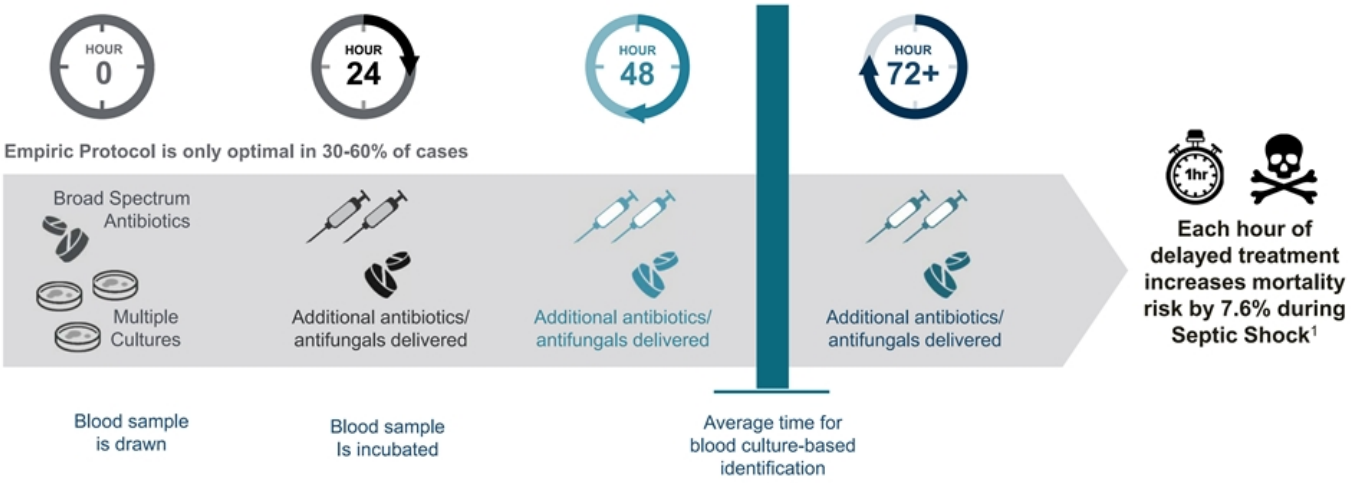
Causes the death of nearly 270,000 Americans annually[2]

Hospitalized COVID-19 patients face a 22 percent higher risk of developing sepsis and are 113 percent more likely to experience septic shock compared to hospitalized influenza patients[4]

1. Buchman TG, et al. Sepsis Among Medicare Beneficiaries: 3. The Methods, Models, and Forecasts of Sepsis, 2012-2018. Crit Care Med. 2020 Mar;48(3):302-3188l 2. Centers for Disease Control and Prevention [Internet]. c2020. Sepsis: Clinical Information. Available from: https://www.cdc.gov/sepsis/clinicaltools/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fsepsis%2Fdatareports%2Findex.html; 3. Centers for Disease Control and Prevention [Internet]. c2021. An Update on Cancer Deaths in the United States. Available from: https://www.cdc.gov/cancer/dcpc/research/update-on-cancer-deaths/. 4. Epic Health Research Network [Internet]. c2021. Sepsis Mortality Rates are Higher in Patients Hospitalized for COVID-19 Than for Influenza. Available from: https://ehrn.org/articles/sepsis-and-mortality-rates-are-higher-in-patients-hospitalized-for-covid-19-than-for-influenza

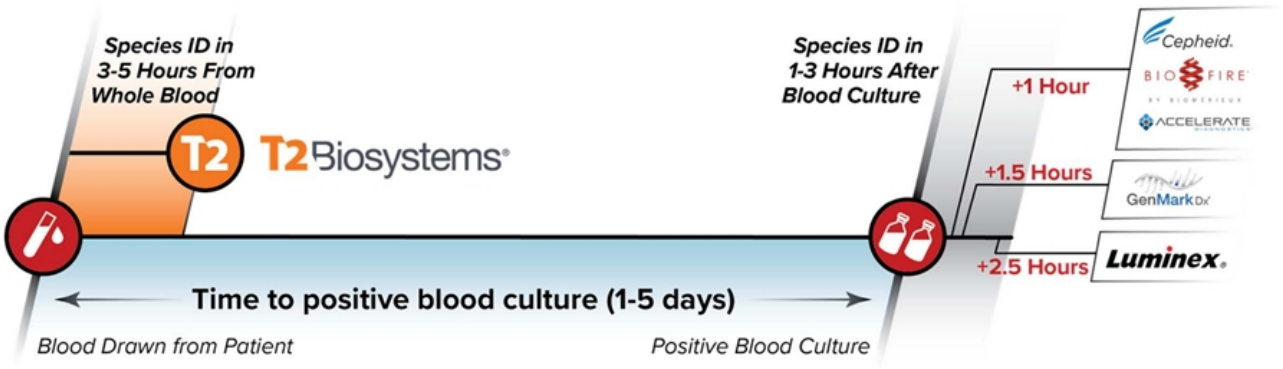
The Challenge of Detecting Sepsis-Causing Pathogens

The current standard is a race against time, relying on empiric probability-based protocols



1. Kumar, A., Roberts, D., Wood, K.E., et al, (2006). Duration of hypotension before initiation of effective antimicrobial therapy is the critical determinant of survival in human septic shock. Critical care medicine, 34(6), 1589-1596.

Rapid Detection of Sepsis-Causing Pathogens is Critical



T2 Biosystems provides species and resistance gene identification **directly from whole blood within 3-5 hours of the first blood draw**, often before the second dose of broad-spectrum antibiotics is delivered, enabling clinicians to achieve targeted therapy faster than the current standard of care.

1. Peker, N., et al. Table 1. Clin Microb & Inf, 2018

Novel Culture-Independent BSI and AMR Diagnostics

Fully-automated T2Dx Instrument, Sepsis Test Panels and SARS-CoV-2 Panel

Rapid:
Results in 3-5 hours

Easy-to-use:
No sample preparation required

Sensitive and Specific:
~1 CFU/mL LoD and >98% Specificity

T2Candida®	T2Bacteria®	T2Resistance®	T2SARS-CoV-2™
Sensitivity: 91%[1] Specificity: 99%[1]	Sensitivity: 90%[2] Specificity: 98%[2]	Sensitivity: ≥ 99%[3] Specificity: ≥ 99%[3]	PPA: 95%[4] NPA: 100%[4]
C. albicans *C. tropicalis* *C. parapsilosis* *C. krusei* *C. glabrata*	*E. faecium* *S. aureus* *K. pneumoniae* *P. aeruginosa* *E. coli*	*mecA/C* *vanA/B* CTXM-14/15 KPC OXA-48 Group NDM, VIM, IMP AmpC (CMY/DHA)	Detects all emerging variants** 900 GE/mL – contrived 2000 GE/mL – patient samples
FDA-Cleared **CE-marked** 1-3 CFU/mL LoD	**FDA-Cleared** **CE-marked** 2-11 CFU/mL LoD	**RUO* (US only)** **CE-marked** 3-11 CFU/mL LoD	**FDA - For Emergency Use Authorization only** **alpha, beta, gamma, delta, lambda, mu, iota, omicron

*T2Resistance is not FDA cleared

1. Mylonakis E, et al. T2 magnetic resonance assay for the rapid diagnosis of candidemia in whole blood: a clinical trial. Clin Infect Dis. 2015 Mar 15;60(6):892-9; 2. Nguyen MH, et al. Performance of the T2Bacteria panel for diagnosing bloodstream infections: a diagnostic accuracy study. Ann Intern Med. 2019 Jun 18;170(12):845-852; 3. T2Resistance data on file; 4. T2SARS-CoV-2 data on file.

Meta-analysis of 14 Controlled Studies (Peer-Reviewed)

Highlights benefits of T2 Biosystems sepsis technology vs. blood culture

Title: Antimicrobial and Resource Utilization with T2 Magnetic Resonance for Rapid Diagnosis of Bloodstream Infections: Systematic Review with Meta-analysis of Controlled Studies (2021)

Authors: Maddalena Giannella, George A. Pankey, Renato Pascale, Valerie M. Miller, Larry E. Miller, Tamara Seitz
Journal: Expert Review of Medical Devices

Seven Outcomes Evaluated

- Time to **detection 81 hours faster** with T2MR
- Time to **species identification 77 hours faster** with T2MR
- Patients testing positive on T2MR **received targeted antimicrobial therapy 42 hours faster**
- Patients testing negative on T2MR **de-escalated from empirical therapy 7 hours faster**
- Length of **ICU stay 5 days shorter** with T2MR
- Length of **hospital stay 4.8 days shorter** with T2MR
- Mortality rates were comparable between T2MR and BC

Giannella M, et al. Antimicrobial and resource utilization with T2 magnetic resonance for rapid diagnosis of bloodstream infections: systematic review with meta-analysis of controlled studies. Expert Rev Med Devices. 2021 May;18(5):473-482.

Panel Discussion: Culture-Independent Diagnostics

DR. APARNA AHUJA

Chief Medical Officer
T2 Biosystems

DR. JAMES SNYDER

Chief of Microbiology
University of Louisville Medical Center

DR. THOMAS WALSH

Director
Center for Innovative Therapeutics & Diagnostics

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Commercial Strategy

Brett Giffin, Chief Commercial Officer

Commercial Strategy

Increase instrument installed base and expand sepsis testing

UNITED STATES MARKET

- Installed base: 90 T2Dx Instruments
- Sales force expansion
- Enhanced training programs
- Instrument placement programs
- Transition COVID-driven instruments to sepsis testing

INTERNATIONAL MARKET

- Installed base: 55 T2Dx Instruments
- Sales force expansion
- Geographic expansion (EU/ME, APAC, LATAM)
- Enhanced distributor training and support

Collaboration with Medical Affairs to increase sepsis test utilization and clinical value awareness

Growing Independent Support for T2 Technology

Included in dozens of independent, real-world clinical case studies demonstrating clinical utility of T2Bacteria and T2Candida (www.t2biosystems.com)

U.S. Food & Drug Administration granted breakthrough device designation for T2Resistance™ Panel

U.S. Centers for Medicare & Medicaid Services (CMS) established T2Bacteria® as first diagnostic product to gain incremental reimbursement through its New Technology Add-on Payment (NTAP)

U.S. Department of Health and Human Services (i.e., BARDA) awarded T2 Biosystems with up to $69 million in milestone-based product development funding

Vizient, Inc. awarded T2 Biosystems with Innovative Technology contract, providing access to more than 50 percent of the nation's acute care hospitals, 95 percent of all academic medical centers and 20 percent of the country's ambulatory market

1. United States CMS FY 2020 inpatient prospective system final rule

Implementation Strategy

Execution - Sales, Medical Affairs, Service

Education

Clinical and economic value proposition

Identify Use Cases

Patient selection criteria: Hematology/Oncology, ICU, Transplant

Implementation

Secure approval for go-live and incorporation into sepsis protocol

Routine Testing

Establish patient sample and results reporting workflow

Post go live customer support

Instrument installation

Prepared to run clinical samples

Routine clinical use

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Product Pipeline

Roger Smith, Senior VP Science R&D

T2 Biosystems' Product Pipeline

Product Name	Collaborator	Phase I (Feasibility)	Phase II (Development)	Phase III (Verification)	Phase IV (Clinical/Regulatory)	Phase V (Commercial Launch)
T2Resistance® Panel	BARDA				Initiated U.S. Trial (Q4 2021)	Launched (EU) - CE mark
T2Biothreat® Panel	BARDA				Initiated U.S. Trial (Q4 2021)	
Comprehensive BSI & AMR Panel	BARDA		Ongoing			
Next-Generation Instrument	BARDA		Ongoing			
T2Cauris® Panel	Self-funded					
T2Lyme® Panel	Self-funded					

T2Resistance® Panel

The first direct-from-blood detection of antibiotic resistance markers

- Detection of **13 antibiotic resistance genes** from both Gram-positive and Gram-negative pathogens direct-from-blood, without the wait for blood culture
- Performed on the T2Dx® Instrument with **results in 3-5 hours**
- Obtained CE Mark and launched in Europe
- Granted "**Breakthrough Device**" designation by FDA
- Initiated U.S. clinical trial in December 2021
- Proposed submission to FDA in 2022

- Covers the **most clinically important antibiotic resistance pathogens**
  - Carbapenem-resistant *Acinetobacter*
  - Carbapenem-resistant Enterobacteriaceae (CRE)
  - Extended-spectrum Beta-lactamase (ESBL) producing Enterobacteriaceae
  - Vancomycin-Resistant *Enterococci* (VRE)
  - Methicillin-Resistant *S. aureus* (MRSA)
- The CDC estimates that these infections result in over **590,000 hospitalizations** and **25,000 deaths** annually in the US[1]
- ~46% of patients are given inappropriate empiric therapy, many associated with antimicrobial resistance infections[2]
- Rapid diagnosis of patients with resistance infections is essential to getting them on appropriate therapy and reducing mortality[2]

1. https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf
2. Paul M, Shani V, Muchtar E, Kariv G, Robenshtok E, Leibovici L. Systematic review and meta-analysis of the efficacy of appropriate empiric antibiotic therapy for sepsis. *Antimicrob Agents Chemother*. 2010;54(11):4851-4863. doi:10.1128/AAC.00627-10

T2Biothreat® Panel

Novel direct-from-blood detection of biothreat pathogens

- Simultaneously **detects 6 biothreat pathogens**[1] direct-from-blood, without the wait for blood culture
- Proposed to be an aid in the diagnosis of anthrax, tularemia, melioidosis, glanders, typhus fever and plague
- Bioterrorism is a real threat to U.S. security
  - 1984 - Russia was reported to have used bioterrorism in Afghanistan
  - 2001 - U.S. congressional members attacked with anthrax – over 22 illnesses and 5 deaths
  - 2022 - U.S. Government warns of potential use of biological weapons by Russia in Ukraine
- Based on reported data, the panel is expected to be more sensitive than other FDA cleared molecular tests
- Proposed submission to FDA in 2022

1. Noted by the CDC to be Category A or B biothreat agents

Comprehensive Panel

Bloodstream Infections (BSI) and Antimicrobial Resistance (AMR)

- Direct-from-blood test panel with results in approximately 3 hours
- Detects a combination of genus, complex, species and resistance markers
- Proposed to detect **>95% of blood stream infections** from a single blood sample

Market Research: Infectious Disease Physician and Pharmacist Responses

"I think this is very exciting technology and I would be excited to have something like that brought on to my institution, so I could definitely see this advantageous for having available for our sepsis patients."

"..is this [comprehensive panel] helpful to me as a clinician for faster treatment and antimicrobial stewardship? – There is no doubt!"

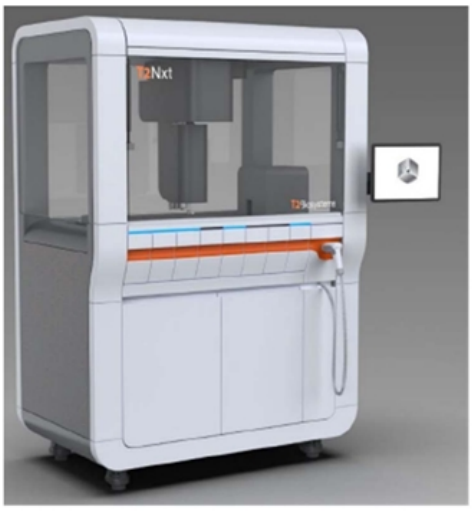
"I could see broad interest in this. Our hospitalist and intensivists would want to use this."

Market Research Data on File

Next-Generation Instrument

Design specifications

- Random access, fully-automated system able to process multiple samples simultaneously
- Designed in parallel with comprehensive panel for BSI and AMR
- Requires no up-front sample processing
- Processes whole blood samples
- Utilizes a self-contained consumable for easy loading and disposal



3D graphic image rendering is subject to change

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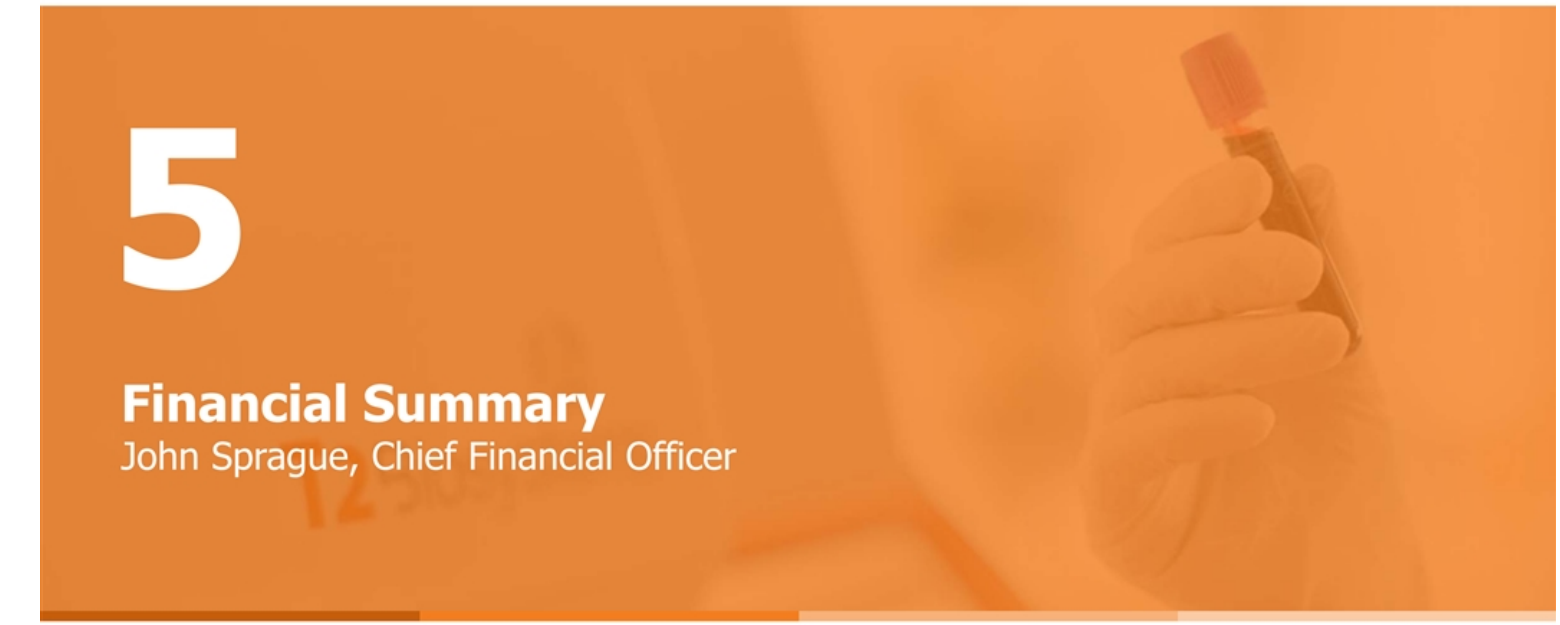
Financial Summary

John Sprague, Chief Financial Officer



Financial Summary

	2022 Guidance[1]	2021	2020	% Change
Total Revenue	$28-31 million	$28.1 million	$18.1 million	55%
Product Revenue	$16-17 million	$16.6 million	$11.7 million	42%
R&D Revenue	$12-14 million	$11.4 million	$6.4 million	78%
T2Dx Instruments	60-70	32	57	
Cash Balance		$33.8 million[2]		

1. Guidance assumes a decrease in sales of COVID-19 tests compared to 2021 and doubling core sepsis business compared to 2021
2. Includes $1.5 million restricted cash.

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Q&A

T2 Biosystems Management Team