

# Corporate Presentation

(NASDAQ: TT00)

August 2024

# 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; (xiii) risks related to intellectual property; and (xiv) other risk factors included in our annual report on form 10-K filed with the Securities and Exchange Commission (SEC) on April 1, 2024 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.

# Investment Highlights

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



## Cutting-Edge Diagnostics

Innovative proprietary Magnetic Resonance technology, novel culture-independent diagnostics for sepsis



## Large Market Opportunity

Initial target market +\$2 billion, U.S. hospital inpatient testing is covered (DRG payment system)




## Global Footprint

T2 Biosystems products are currently sold in 45 countries around the globe, including in the United States, Europe, the Middle East, and Asia

# Innovative Hospital Partners

Our partner hospitals include those in  
“**World’s Best 250 Hospitals**” and “**Best Hospitals**” in the United States

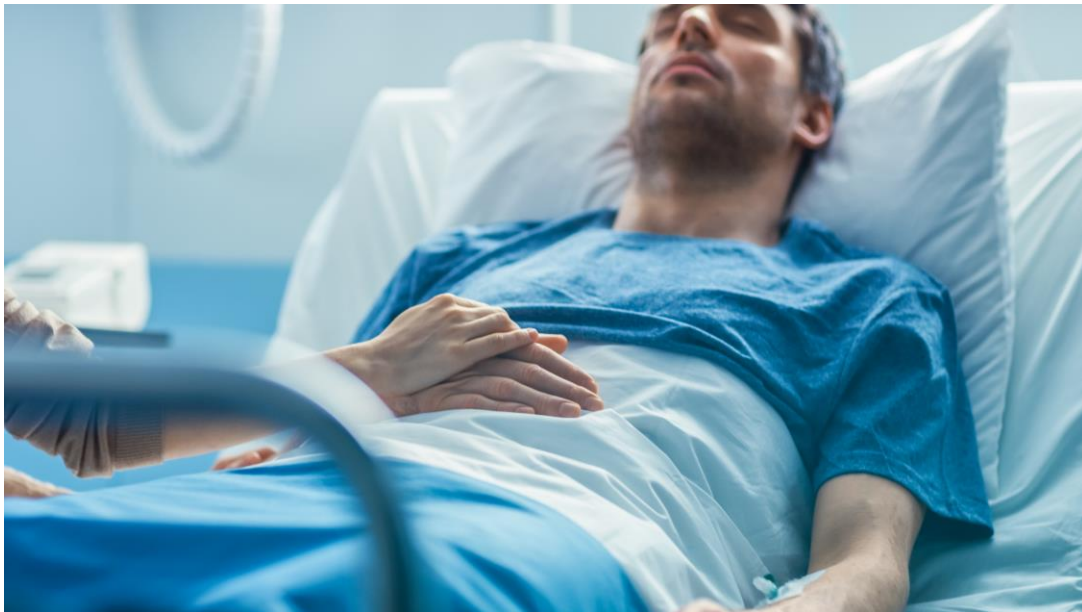




We are advancing our mission by pioneering **life-saving diagnostic innovations** that enable faster, targeted antimicrobial therapy.

# Sepsis: A Growing Global Concern

Each year, sepsis causes more deaths globally than all cancers combined.<sup>1,2</sup>



**\$62 billion**

in U.S. healthcare costs annually<sup>3</sup>



**11 million**

worldwide deaths, annually<sup>1</sup>



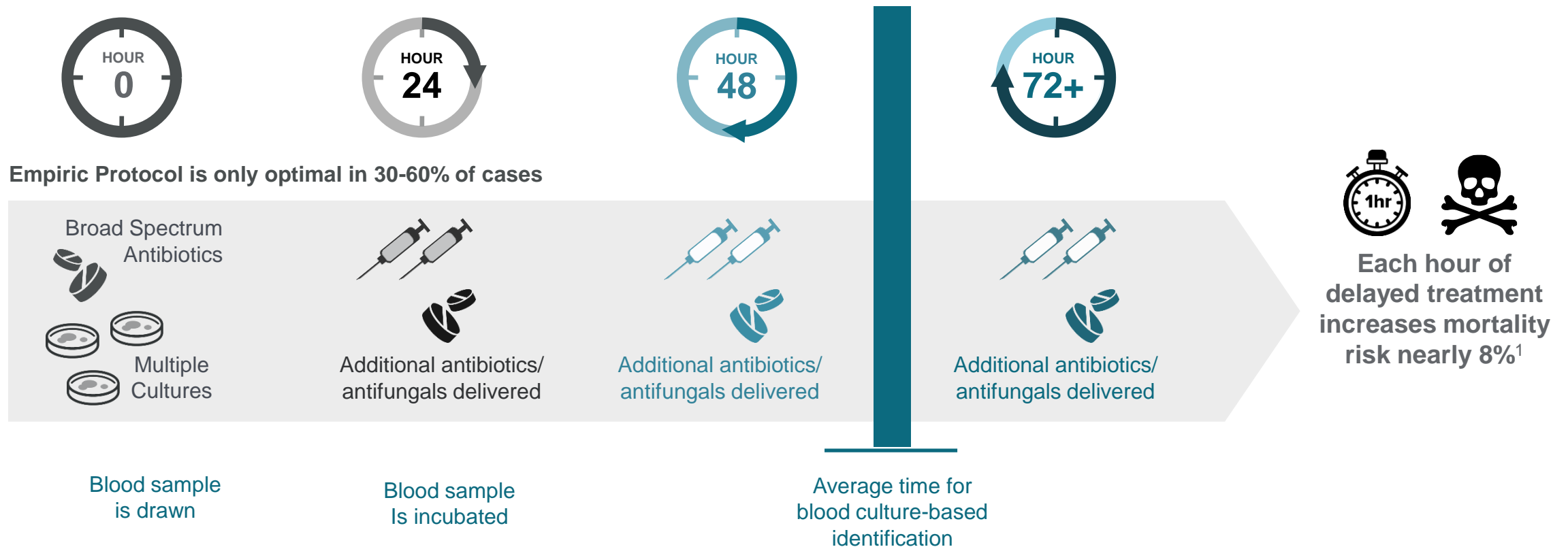
**270,000**

U.S. hospital deaths annually<sup>4</sup>

1. Rudd, KE, et al. Lancet. 2020  
2. Cancer, World Health Organization. 2018. [https://www.who.int/health-topics/cancer#tab=tab\\_1](https://www.who.int/health-topics/cancer#tab=tab_1)  
3. [https://journals.lww.com/ccmjournals/FullText/2020/03000/Sepsis\\_Among\\_Medicare\\_Beneficiaries\\_3\\_The.4.aspx](https://journals.lww.com/ccmjournals/FullText/2020/03000/Sepsis_Among_Medicare_Beneficiaries_3_The.4.aspx)  
4. Centers for Disease Control and Prevention

# The Challenge of Detecting Sepsis-Causing Pathogens

It is a race against time, as each hour of delayed treatment increases mortality by up to 8%<sup>1</sup>



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.

# T2 Impact on Time to Species ID

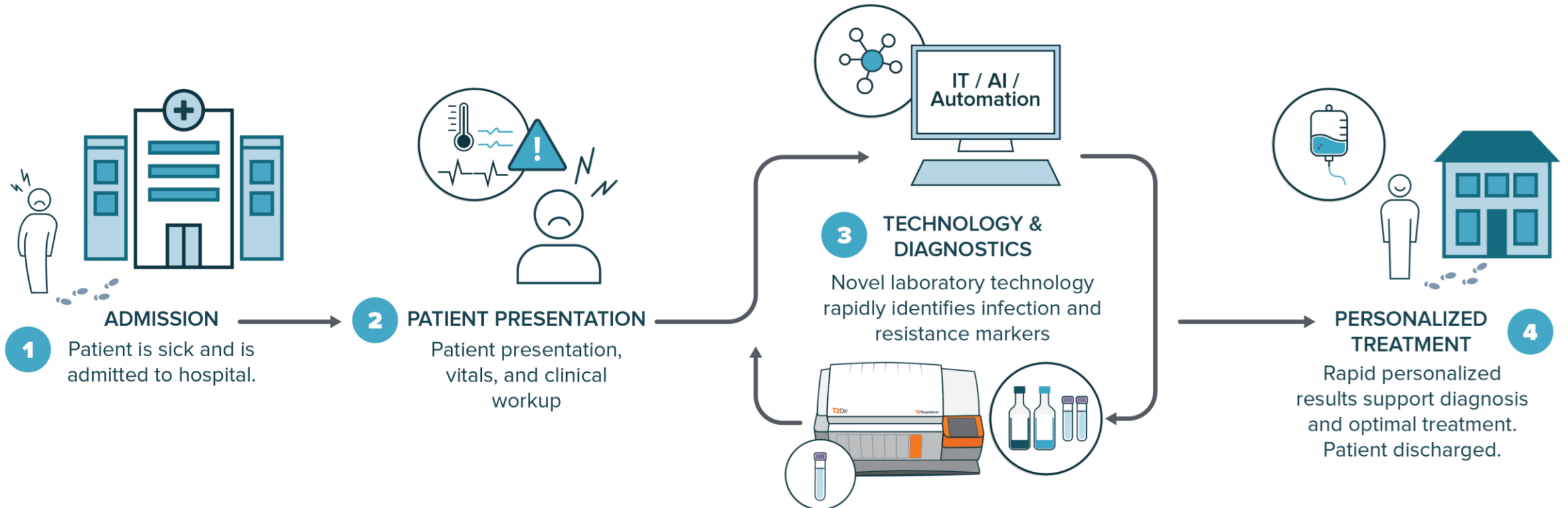


Peker, N., et al. Table 1. Clin Microb & Inf, 2018

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# The Future of Sepsis Care



# The Only FDA-Cleared Direct-From-Blood Sepsis Tests

Fully-automated T2Dx® Instrument and Sepsis Tests are Rapid, Easy-to-Use and Reliable

- Rapid: results in 3 to 5 hours
- Simple: no sample preparation
- Ultra-sensitive: as low as 1 CFU/mL
- T2MR® technology is not inhibited by prior antimicrobial administration<sup>1</sup>



T2Candida®	T2Bacteria®	T2Resistance®
Sensitivity: 91% <sup>2</sup> Specificity: 99% <sup>2</sup>	Sensitivity: 90% <sup>3</sup> Specificity: 98% <sup>3</sup>	FDA Breakthrough Device CE-mark/RUO 2019
<i>C. albicans</i> <i>C. tropicalis</i> <i>C. parapsilosis</i> <i>C. krusei</i> <i>C. glabrata</i>	<i>E. faecium</i> <i>S. aureus</i> <i>K. pneumoniae</i> <i>A. baumannii</i> <i>P. aeruginosa</i> <i>E. coli</i>	<i>mecA/C</i> <i>vanA/B</i> CTXM-14/15 KPC OXA-48 Group NDM, VIM, IMP AmpC (CMY/DHA)
FDA-Cleared CE marked 1-3 CFU/mL LoD	FDA-Cleared CE marked 2-11 CFU/mL LoD	U.S. Clinical Trial (patient enrollment complete) CE marked 3-11 CFU/mL LoD

1. T2Candida and T2Bacteria Instructions for Use, refer to Performance Characteristics: Interfering Substances

2. Mylonakis, E., Clancy, C.J., Ostrosky-Zeichner, L., et al. (2015). Clinical Infectious Diseases

3. Nguyen H, et al. Performance of the T2Bacteria Panel for Diagnosing Bloodstream Infections: A Diagnostic Accuracy Study. Ann Intern Med. 2019.

# Growing Independent Support for T2 Biosystems' Products



Included in dozens of independent, real-world clinical case studies demonstrating clinical utility of T2Bacteria<sup>®</sup> and T2Candida<sup>®</sup>



U.S. Food & Drug Administration granted breakthrough device designation for the T2Resistance<sup>®</sup> Panel, the T2Lyme<sup>™</sup> Panel and the *Candida auris* test



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)<sup>1</sup>



BARDA provided T2 Biosystems \$31 million in product development funding (2019-2023) to advance the T2Biothreat Panel, T2Resistance Panel, and next-generation sepsis products



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



U.S. Department of Health and Human Services and the Steven & Alexandra Cohen Foundation named T2 Biosystems a Phase 1 and 2 winner in LymeX Diagnostics Prize

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

# 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*



## FASTER TIME TO DETECTION

- Time to detection **81 hours faster** with T2MR
- Time to species identification **77 hours faster** with T2MR



## FASTER TARGETED THERAPY

- Patients testing negative on T2MR de-escalated from empirical therapy **7 hours faster**
- Patients testing positive on T2MR received targeted antimicrobial therapy **42 hours faster**



## REDUCED LENGTH OF STAY

- Length of ICU stay **5 days shorter** with T2MR
- Length of hospital stay **4.8 days shorter** with T2MR

# Patient Case Studies



## Emergency Department

### 70-year-old Male

Presenting with shortness of breath



### Positive T2Bacteria

T2Bacteria was positive for *E. faecium* bloodstream infection

Infection not covered by typical broad-spectrum antibiotics

If untreated, mortality up to 50%

**Clinical Action:** Targeted therapy **20 hours faster**



## Oncology Unit

### Female Oncology Patient

Presenting with persistent spiking fevers



### Positive T2Candida

T2Candida was positive for *Candida albicans/tropicalis* fungal bloodstream infection

Infection not covered by typical broad-spectrum antibiotics

If untreated, mortality up to 40%

**Clinical Action:** Targeted therapy and **patient discharged**

# 2024 Corporate Priorities

Our priorities are aimed at achieving organizational goals, fostering growth, and driving innovation



ACCELERATE  
SALES



ENHANCE  
OPERATIONS



ADVANCE  
PIPELINE

# 1

**ACCELERATE SALES**

# Commercial Go-To-Market Strategy

Increase T2Dx Instrument installed base and expand sepsis testing



## UNITED STATES MARKET

- Installed base: 94 T2Dx Instruments
- Instrument placement programs
- Commercialize T2Biothreat Panel
- Commercialize T2Lyme as an LDT
- Continued enhancement of customer training program



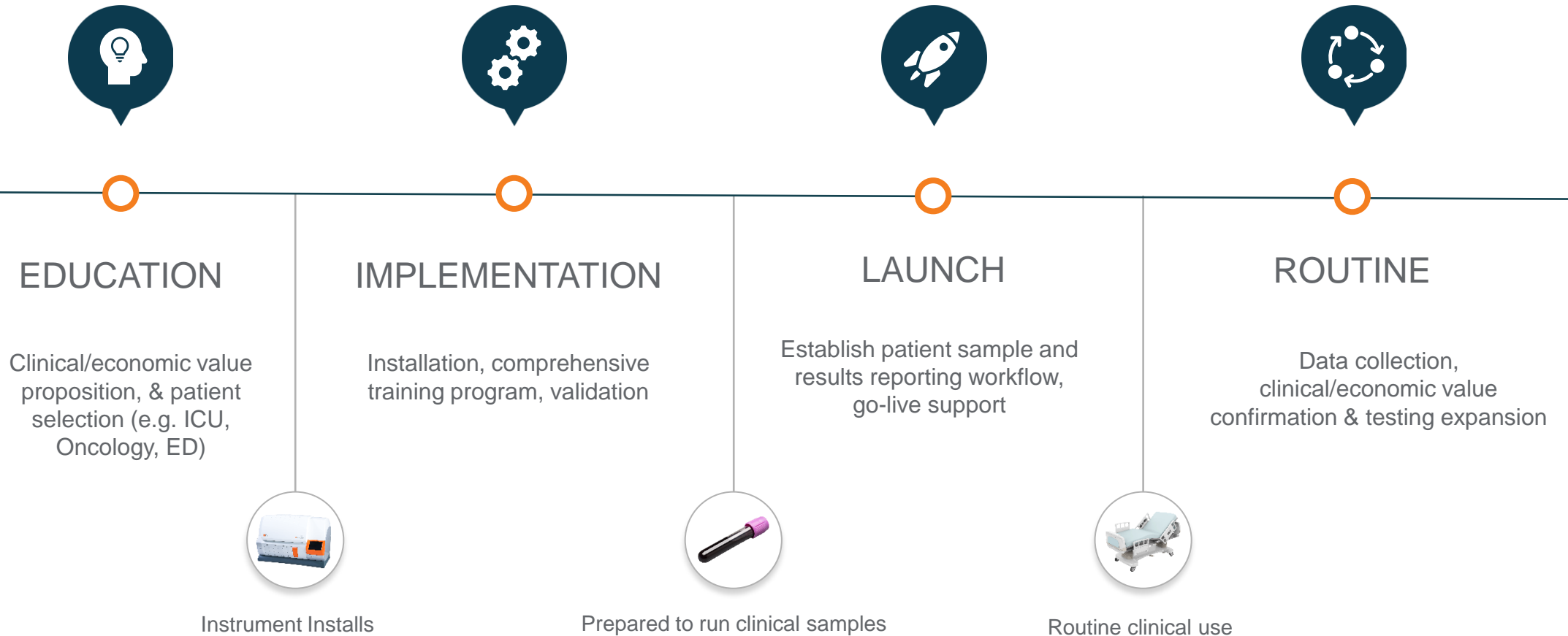
## INTERNATIONAL MARKETS

- Installed base: 97 T2Dx Instruments
- Pursue geographic expansion in EU/ME, APAC, and LATAM
- Continued enhancement of customer training and support program



# Commercial Execution – Sepsis Products

Driving changes to the standard of care



# 3 Pillars to Increase our Sepsis Test Utilization

New  
Customers



1

Faster  
Implementation



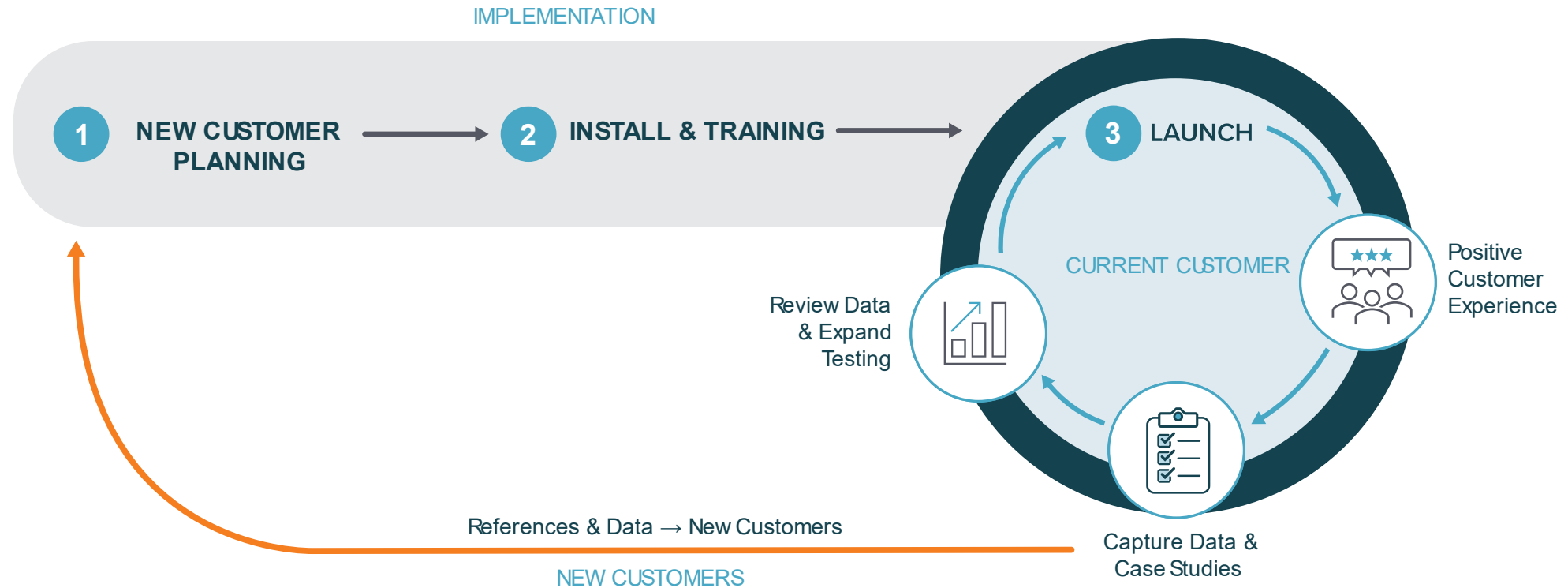
2

Expand Testing -  
Current Customers



3

# Creating a Sepsis Flywheel to Drive Growth



# T2Biothreat Panel: Detects Six Biothreat Agents

- The T2Biothreat Panel is an FDA-cleared qualitative, multiplexed, molecular diagnostic intended to be run on the T2Dx<sup>®</sup> Instrument, directly for whole blood samples
- The T2Biothreat Panel is intended to test individuals with signs and symptoms of infection from biothreat agents and/or individuals who are at risk for exposure or may have been exposed to these agents
- T2Biothreat Panel can detect six (6) bacterial Biothreat Agents of Interest



<i>Species</i>	<i>Disease</i>
<i>Bacillus anthracis</i>	Anthrax
<i>Burkholderia mallei</i>	Glanders
<i>Burkholderia pseudomallei</i>	Melioidosis
<i>Francisella tularensis</i>	Tularemia (rabbit fever)
<i>Rickettsia prowazekii</i>	Epidemic typhus
<i>Yersinia pestis</i>	Plague

# T2Biothreat Panel is Highly Differentiated



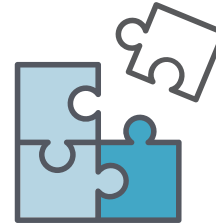
**UNPARALLELED ACCURACY**  
High sensitivity and specificity,  
direct from a 4mL K2EDTA tube  
of whole blood.



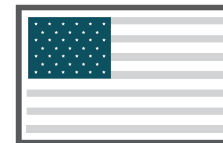
**RAPID TURNAROUND**  
Results ~3x to 30x faster than  
blood culture standard of care.<sup>1</sup>



**RESPONSE READY**  
Multi-target Panel of 6  
biothreat species recognized by  
the ASPR PHEMCE High Priority  
Biological Threats List.<sup>2</sup>



**PROVEN PLATFORM**  
Utilizes the same automated  
T2Dx® Instrument as the FDA-  
cleared T2Bacteria® and  
T2Candida® Panels.



**U.S. MADE**  
Proudly developed and  
manufactured in the United  
States of America.

1. Pearson, A., et al. Analytical testing of a rapid, direct from patient sample assay for biothreat pathogens using a fully automated assay platform. Poster ASM 2022  
2. <https://aspr.hhs.gov/PHEMCE/2022-SIP/Pages/Appendix-B-PHEMCE-High-Priority-Threats.aspx>

# T2Lyme Panel LDT – Early Lyme Detection

Partnering with ECO Laboratory, a Massachusetts-based clinical laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA).



## T2 Lyme Panel

- Direct detection of *Borrelia burgdorferi*
- Sample type: 4 mL whole blood
- Highly Sensitive: 4 cells/mL Limit of Detection
- Patient population: Patients <30 days from tick bite

## LDT Format

- Completed clinical studies required for 3Q24 launch
- No instrument requirement enables,
  - Faster time to market
  - Higher throughput
  - Stronger product contribution margins

# 2

## ENHANCE OPERATIONS

# Operational Objectives



Achieve on-time delivery targets



Reduce operating costs



Improve product gross margins



Scale manufacturing processes



Maintain ISO recertification



Improve use of Oracle ERP system



# 3

## ADVANCE PIPELINE

# Menu Expansion Initiatives for the FDA Cleared T2Dx Instrument

SEPSIS	PANEL EXPANSION	BIOTHREAT	TICK-BORNE
<b>T2Candida®</b> FDA-cleared & CE-marked (2014)	<b>T2Candida® for Pediatric Use</b> FDA 510(k) premarket notification (2023)	<b>T2Biothreat®</b> FDA-cleared (2023)	<b>T2Lyme™</b> "Breakthrough Device" on T2Dx (2022) LDT Commercialization (2024)
	<b>T2Candida® + <i>C. auris</i></b> "Breakthrough Device" (2023)		
<b>T2Bacteria®</b> FDA-cleared & CE-marked (2018)	<b>T2Bacteria® + <i>A. baumannii</i></b> FDA-cleared (2024)		
<b>T2Resistance®</b> CE-marked & Research Use Only (RUO), "Breakthrough Device" (2019)			

# Rising Healthcare Concerns



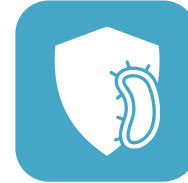
## Lyme Disease

With an estimated 476,000 cases annually, Lyme disease is by far the leading vector-borne disease in America. The current diagnostic process, a two-tiered antibody testing algorithm originally developed in 1994 for disease surveillance and not as a stand-alone diagnostic test, relies on the presence of antibodies and can only be used accurately four to six weeks after infection. Early diagnosis of Lyme disease is critical. If left untreated, the debilitating disease can become harder to eradicate and spread throughout the body.



## *Candida auris*

*Candida auris* is a multidrug-resistant fungal pathogen recognized as a serious global health threat with a mortality rate of up to 60%, and is difficult to identify with standard laboratory methods, which can lead to inappropriate treatment. The CDC estimates the costs associated with U.S. fungal diseases, in general, 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.



## Antimicrobial Resistance (AMR)

Antimicrobial Resistance is a growing global concern, especially in the wake of the COVID-19 pandemic. According to a study published in *The Lancet*<sup>1</sup>, there were 1.27 million global deaths related to antimicrobial resistance in 2019. 73% of those deaths were caused by just six pathogens. Resistant bacteria pathogens can lead to sepsis, and compared to susceptible strains, they are more costly, contribute to longer length of stays, and are associated with higher mortality rates. For example, resistant strains of *E.coli*, *A. baumannii*, *K. pneumoniae*, and *S. aureus* are at least 2x as deadly<sup>2</sup> as their susceptible counterparts, and antimicrobial resistance could cost healthcare systems worldwide \$300 billion to more than \$1 trillion annually by 2050.<sup>3</sup>

1. Murray, C., et al. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. *The Lancet*. 2022

2. Burden of Antibiotic Resistance. ReAct Group. 2012 – <https://www.reactgroup.org/wp-content/uploads/2018/03/1.7-ReAct.-Burden-of-antibiotic-resistance.pdf>

3. Dadgostar, P., Antimicrobial Resistance: Implications and Costs. *Infect Drug Resist*. 2019

# The T2Lyme Panel



## Overview of T2Lyme Panel

- Direct detection of *Borrelia burgdorferi*
- Sample type: 4 mL whole blood
- Highly Sensitive: 4 cells/mL Limit of Detection
- Patient population: Patients <30 days from tick bite

The U.S. Department of Health and Human Services and the Steven & Alexandra Cohen Foundation selected T2 Biosystems as a Phase 1 & 2 winner in the LymeX Diagnostics Prize

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The T2Lyme Panel has received Breakthrough Device Designation from the FDA

# The T2Resistance® Panel



## Overview of T2Resistance Panel

- A direct from whole blood diagnostic able to identify molecular markers (genotypic) with high sensitivity and a limit of detection as low as 3 CFU/mL
- Detects thirteen molecular markers of resistance and categorizes them into the following seven groups:
  - *blaKPC*
  - *blaCTX-M 14/15*
  - *blaNDM / blaVIM / blaIMP*
  - *blaOXA-48* Group
  - *vanA / vanB*
  - *mecA / mecC*
  - AmpC (*blaCMY / blaDHA*)

The T2Resistance Panel has received Breakthrough Device Designation from the FDA

# T2Candida® Panel Expansion: *Candida auris* & Pediatrics



- Plans to add *Candida auris*, a multidrug-resistant pathogen, to the FDA-cleared T2Candida Panel
- 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) to include pediatric testing on the T2Candida Panel

The T2*Candida auris* test has received Breakthrough Device Designation from the FDA

# Financial Summary (as of June 30, 2024)

	Q2'24 Results
<b>Total Revenue</b>	\$2.0 million
<b>Product Revenue</b>	\$2.0 million
<b>Instruments</b>	2
<b>Cash Balance</b> (as of June 30, 2024)	\$4.2 million

## Recent Highlights

- Achieved record 2Q'24 and 2H24 sepsis test revenue, representing growth of 27% and 25% respectively compared to the prior year periods, led by T2Bacteria® and T2Resistance® panel sales.
- Reduced total debt and quarterly interest payments to CRG by approximately 80% percent from the balance as of May of 2023
- Signed multiple international distribution agreements in the Middle East and Asia, including Qatar, Hong Kong, Malaysia, Indonesia, and Macau.
- Raised \$8.0 million in gross proceeds through a private placement stock sale executed in May of 2024.
- Completed clinical studies required to commercialize the T2Lyme Panel as a laboratory developed test (LDT), launch planned for 3Q'2024