



Rapid Micro Biosystems

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Rob Spignesi, President & CEO | January 11, 2024



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Our vision

We are transforming a critical, regulated part of the global pharmaceutical manufacturing process, bringing microbial quality control into the 21st century.

**Creating the
future of microbial
quality control**



Rapid Micro Biosystems is creating the future of rapid, secure microbial quality control automation to drive sustainable, long-term growth and shareholder value

A traditional Microbial Quality Control (MQC) lab



**Subjective and
Prone to Human Error**

**High Volume Testing and
Mandated by Regulators**

**Manual, Paper-based
and Slow**

**Insecure and Lacking
Data Integrity**

Introducing a revolution in MQC

FACTORS DRIVING CHANGE

Scientific and
technology
innovation

+

Growing demand
for more complex
therapies

+

Faster & leaner
manufacturing

+

Data integrity &
security focus

+

Regulatory
scrutiny

TODAY



Discovery & research

HIGH-THROUGHPUT R&D AUTOMATION

TODAY



QC & ANALYSIS

TODAY



Bioprocessing & manufacturing

FLEXIBLE SINGLE USE TECHNOLOGIES

Growth Direct® platform bringing Micro QC into the 21st Century

The only fully automated,
high-throughput and secure MQC solution...



Proprietary
Consumables



Data &
Software



Global Validation &
Support Services

THE GROWTH DIRECT® (GD) PLATFORM

...delivering a compelling value proposition...



Data
Integrity

Supports global quality **regulatory compliance** and improved data handling and management



Operational
Efficiency

Enables **faster decision making** by accelerating time to results by 50% or faster compared to the traditional method



Insight &
Accuracy

Eliminate human quality control errors, preventing costly recalls and regulatory interventions

...driving global adoption²

140+

cumulative
systems placed

70%

of top 20
global pharma
are customers¹

100%

of approved CAR-T
manufacturers
have GD systems
placed

120+

cumulative
systems validated

4.5M+

cumulative
consumables sold

Growth Direct[®] transforms and modernizes MQC

Manual workflow



- ❌ Manual & subject to error
- ❌ 15 steps
- ❌ 5-14 days to result / test
- ❌ Unsecured

GROWTH DIRECT[®]

Automated workflow

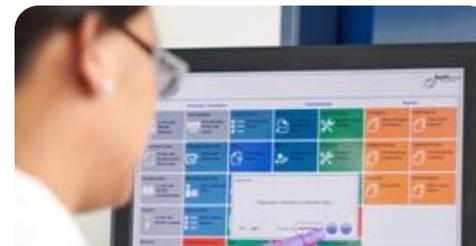
1 Prepare sample & automated loading



2 Automated incubation and analysis & Data handling



✓ Results



- ✓ Automated & accurate
- ✓ 2 steps
- ✓ Results in half the time
- ✓ Full data integrity

The Growth Direct[®] System: The future of microbial quality control

FACTORS DRIVING CHANGE

Scientific and
technology
innovation

+

Growing demand
for more complex
therapies

+

Faster & leaner
manufacturing

+

Data integrity &
security focus

+

Regulatory
scrutiny

TODAY



Discovery & research

HIGH-THROUGHPUT R&D AUTOMATION

TODAY

QC & ANALYSIS



TODAY



Bioprocessing & manufacturing

FLEXIBLE SINGLE USE TECHNOLOGIES

Business model and unit economics driving significant durable growth

INITIAL PURCHASE ORDER VALUE²

\$ 500 - \$ 600 K +

System, LIMS
Software &
Validation Services

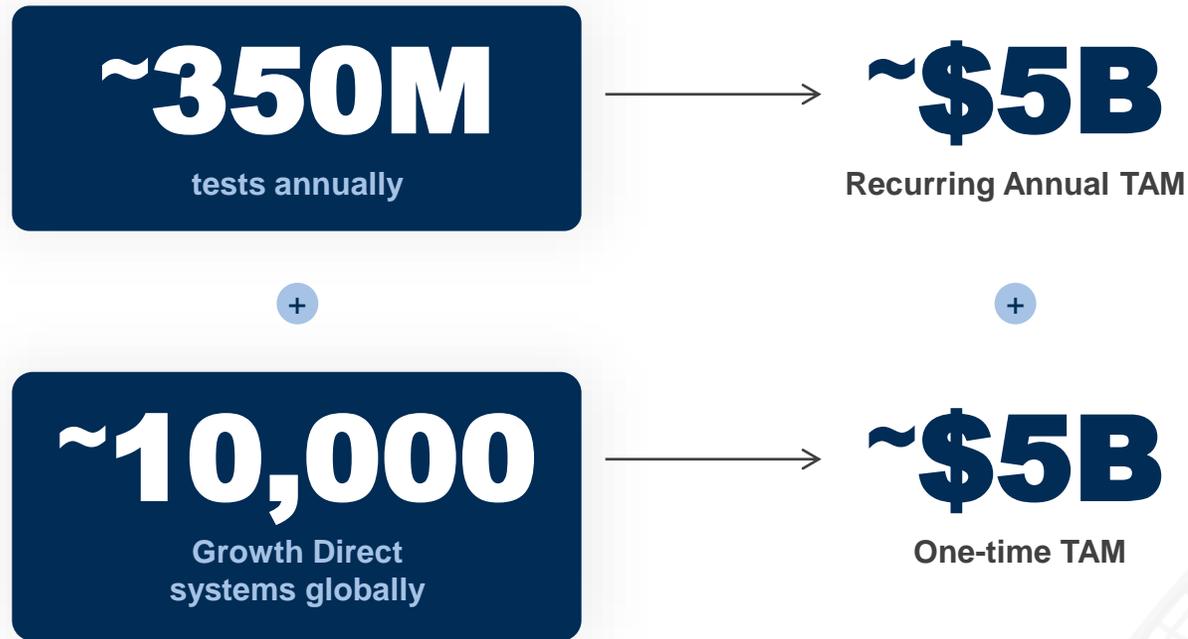
AVERAGE ANNUAL RECURRING REVENUES^{1,2}

\$ 200 - \$ 250 K +

High-Yielding
Consumables &
High-Attach Rate
Service Contracts

1. Indicative of expected average consumable usage by a system in routine customer use assuming an annual service contract but excluding any recurring software revenue; specific per-system consumable usage varies.
2. All values are approximate.

The addressable market for MQC testing is large and growing



MQC TAM GROWTH (CAGR 2021 – 2026)

TOTAL MARKET:

8%

BIOLOGICS
(INCL. CELL & GENE):

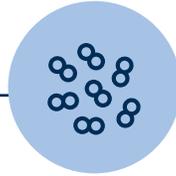
13%+

Automated MQC market is supported by persistent tailwinds



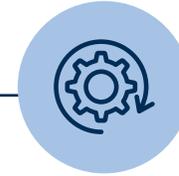
Regulatory

Increasing regulatory scrutiny and enforcement around **data integrity and quality.**



Industry

Growth in complex biologics, cell, and gene therapies which require **faster, more accurate, higher throughput testing capabilities.**



Supply chain

Significant global demand for drugs colliding with supply chain disruptions to **drive need for improved quality and predictability.**

Customer base includes 70% of the top 20 global pharma companies¹ with significant growth potential

GLOBAL SITES WITH GROWTH DIRECT SYSTEMS

85

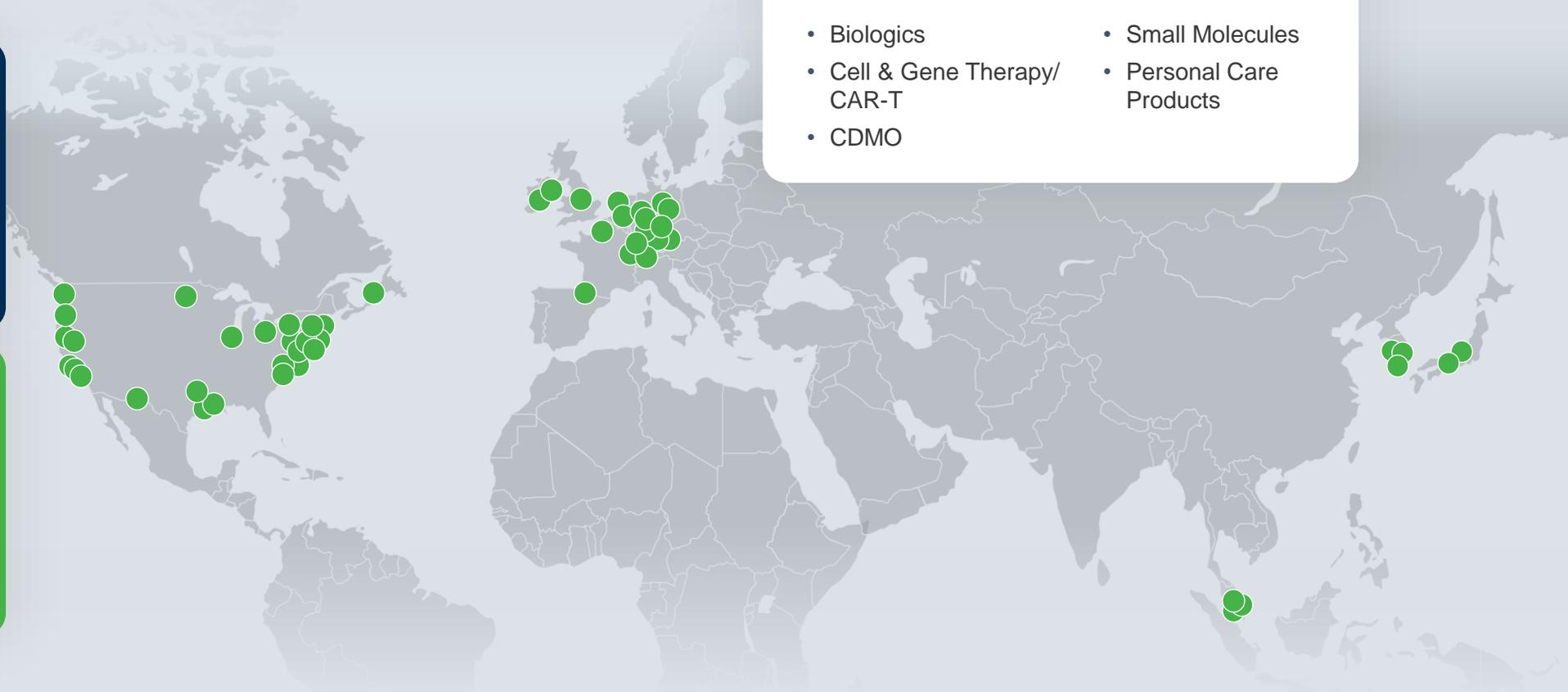
Customer
Manufacturing sites

140+

systems
placed globally

CUSTOMER SEGMENTS WITH ESTABLISHED USE

- Biologics
- Cell & Gene Therapy/
CAR-T
- CDMO
- Small Molecules
- Personal Care
Products



Announcing Upcoming Availability of the Growth Direct Rapid Sterility Application



Growth Direct System



Rapid Sterility Test Kit

Platform Technology



- Growth Direct is the only fully automated, non-destructive, growth-based system for multiple quality control test applications including water, bioburden & environment...
- **And now offering a Rapid Sterility application.**

Benefits



- Faster test results
 - Allows for faster product release
- Enhanced data integrity and sample security
- Automation reduces human error
- Lower hands-on labor costs

Growth Direct Rapid Sterility is expected to be available by mid-year 2024

Growth Direct Rapid Sterility – Breakthrough Technology

Rapid Sterility Test Kit



An FDA required sterility test performed by manufacturers before final product can be released for commercial sale

GROWTH DIRECT RAPID STERILITY

COMPENDIAL METHOD

Time to Detection (TTD)

As little as
12 hours

3 – 5 Days

Time to Results (TTR)

As little as
1 – 3 Days

14 Days

Compelling differentiation compared to current rapid sterility products

Clear path to attractive gross margins

- Investments in manufacturing, supply chain and service infrastructure made to serve top-tier global customer base
- Business scale not yet covering these costs, impacting current margin profile
- Targeting several other areas to increase margins including:
 - Reduced product costs (materials and labor)
 - Increased manufacturing efficiency
 - Increased service productivity and efficiency

Gross Margin Improvement Drivers			
	Systems	Consumables	Service
Business scale / volume leverage			
Product cost reduction			
Increased manufacturing efficiency			
Increased productivity & efficiency			

Expect positive gross margins in 2024 with expansion to 50 – 60% as business continues to scale

2023 revenue guidance exceeded with strong fourth quarter

SELECT HIGHLIGHTS – Q4 2023

Fourth quarter revenue of \$6.2M to \$6.4M, representing growth of ~45% from the prior year; fifth quarter in a row exceeding revenue guidance

Placed six new Growth Direct systems

Growth Direct selected by Samsung Biologics to automate microbiology quality control testing

Growth Direct systems now placed with 100% of commercially approved CAR-T therapy manufacturers

Completed validation of nine new systems

Cash² runway at least into 2H 2026

Results¹

FY 2023¹

Total Revenue

\$22.4M - \$22.6M
>30% growth

System Placements

16

Systems Validated

18

Year-end Cash Balance²

\$95M



Thank you

