

# Rapid Micro Biosystems

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SEPTEMBER 2021



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# Leadership

Strong leadership with deep domain expertise

## COMPANY LEADERSHIP TEAM



**Rob Spignesi**  
President & CEO



**Sean Wirtjes**  
CFO



**John Wilson**  
COO



**Vicki Vezina**  
Chief HR Officer



**Gurinder Grewal**  
SVP of Strategy



**Jonathan Paris**  
SVP & General Counsel



**Scott White**  
VP of Global Sales



**Steve Raters**  
VP of Customer Support



**Kristine Williams**  
VP of R&D

## BOARD MEMBERS



**Jeffrey Schwartz**  
Bain Capital Life Sciences



**David Hirsch**  
Longitude Capital



**Melinda Litherland**  
Independent Director



**Rob Spignesi**  
President & CEO



**Richard Kollender**  
Quaker Partners



**Alexander Schmitz**  
Endeavour Vision



**Nat Ricciardi**  
Independent Director

## COLLECTIVE EXPERIENCE



# Our vision

We are revolutionizing a critical, regulated part of the global pharmaceutical manufacturing process, bringing microbial quality control into the 21<sup>st</sup> century

**Creating the future of  
microbial quality  
control**



# Microbial quality control (MQC) market is poised for disruption



**\$1 trillion**

Global prescription drug market



**55%**

Biologics share of top 100 prescription drug sales by 2026



**1,000+ trials  
13 approved**

Cell and gene therapy pipeline



**350 million**

MQC tests annually in pharma to ensure the safety of drugs



**95%+**

Share of current MQC tests performed with a manual, slow process subject to human error



**Increasing  
regulatory  
scrutiny**

Mandated by FDA / global regulators; 4x increase in number of FDA warning letters per year with data integrity findings after 2015

## ANNUAL GLOBAL MQC TEST VOLUME BY GEOGRAPHY





# Growth Direct™ platform fully automates and modernizes MQC

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



THE GROWTH DIRECT PLATFORM



Proprietary  
Consumables



Data &  
Software



Global  
Validation  
& Support  
Services

...delivering a compelling value proposition...

Data  
Integrity



Operational  
Efficiency



Insight &  
Accuracy

- Supports global quality **regulatory compliance** and improved data handling and management
- Enables **faster decision making** by accelerating time to results by 50% or faster compared to the traditional method
- **Eliminate human quality control errors**, preventing costly recalls and regulatory interventions

...driving rapid global adoption

100+

cumulative  
instruments placed

1M+

cumulative  
consumables sold

>50%

of top 20 pharma  
companies as  
customers\*

~60%

customers with  
multiple systems



**~70**  
MANUFACTURING  
SITES

**Our top-tier customer base  
includes the majority of top  
20 global pharma\***

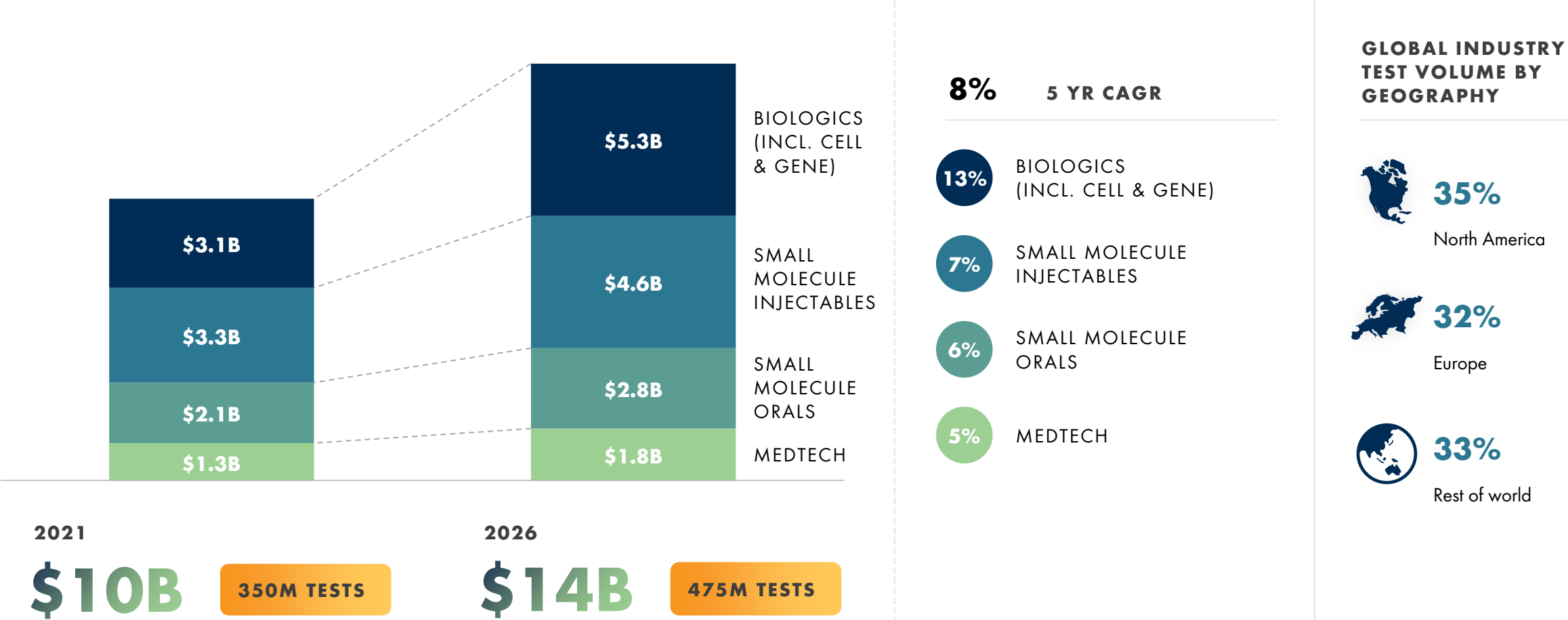
#### CUSTOMER SEGMENTS WITH ESTABLISHED USE

- Biologics
- Cell & Gene Therapy/ CAR-T
- CDMO
- Small Molecules
- 503B Compounders
- Personal Care Products

#### GEOGRAPHIES WITH SOLD INSTRUMENTS



# The addressable market for MQC testing is large and growing



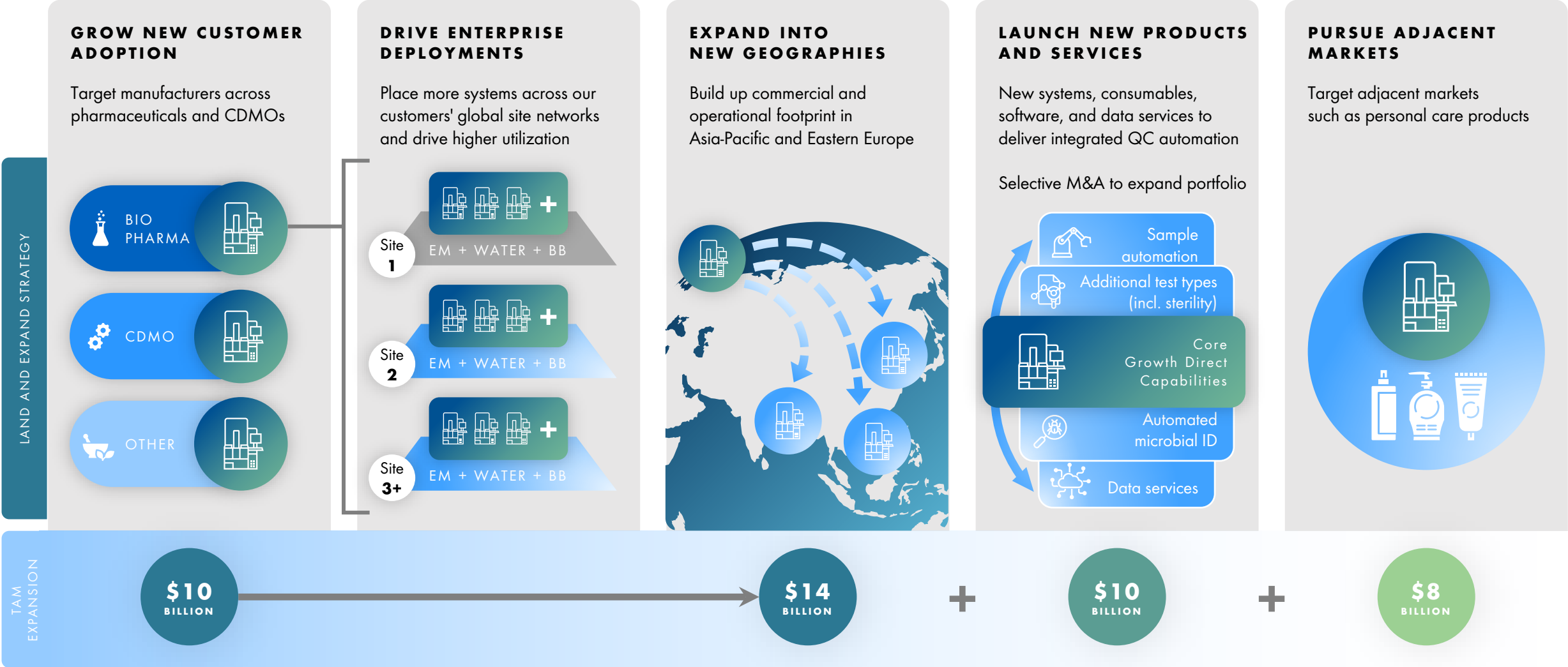


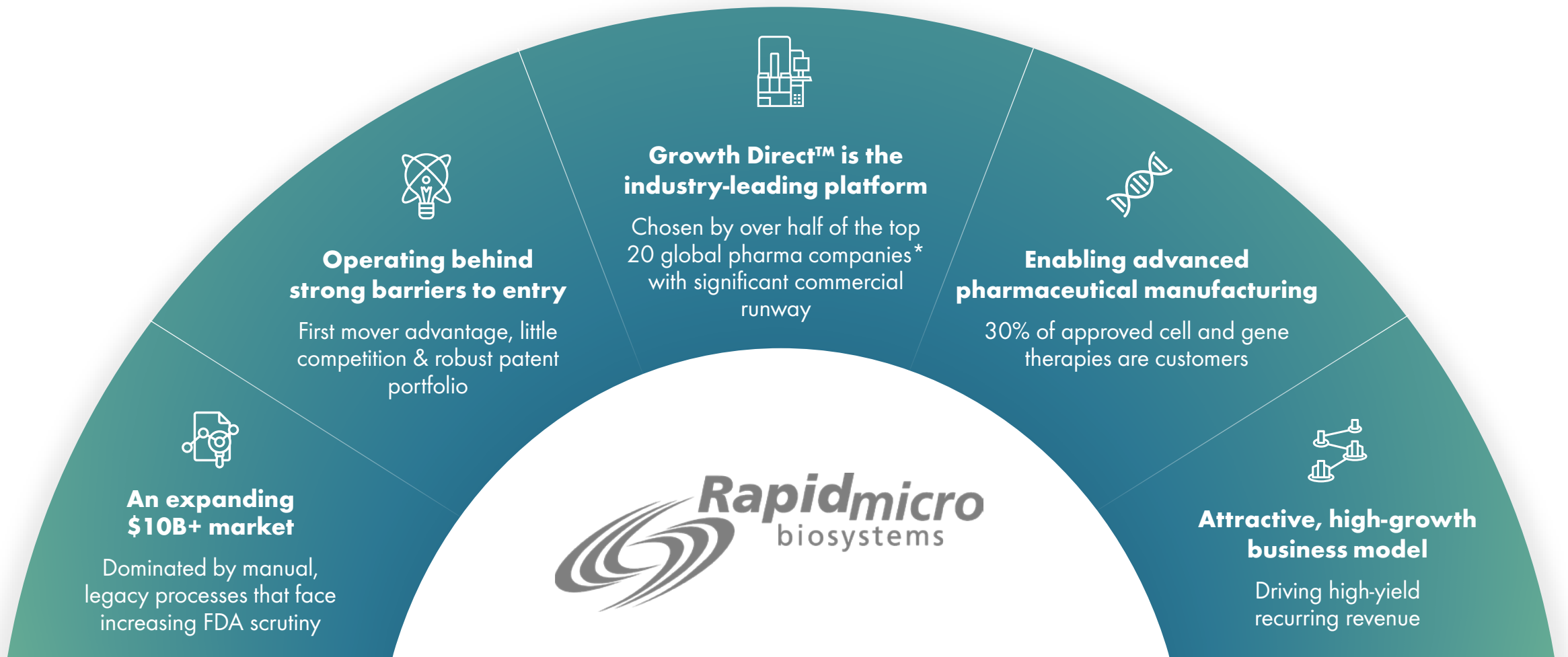
# Investing to unlock major TAM expansion opportunities



# Our growth strategy

Our growth strategy unlocks a total TAM = **\$32 billion**





Rapid Micro Biosystems is creating the future of rapid, secure microbial quality control automation to enable advanced pharmaceutical manufacturing





**Legacy MQC**

**vs**

**Growth Direct**

MANUAL	.....	AUTOMATED
15 STEPS	.....	2 STEPS
5-14 DAYS TO RESULT	.....	50%+ FASTER
UNSECURED / REGULATORY RISK	.....	DATA INTEGRITY ENABLED





# Today's MQC labs utilize antiquated manual testing practices

## High-Volume Manual Testing

MQC ensures the final product is safe through the continuous testing of raw materials, the production environment, and the product itself for microbial contaminants

## FDA Mandated

MQC testing is required by the FDA and other global regulatory agencies for all pharmaceutical products

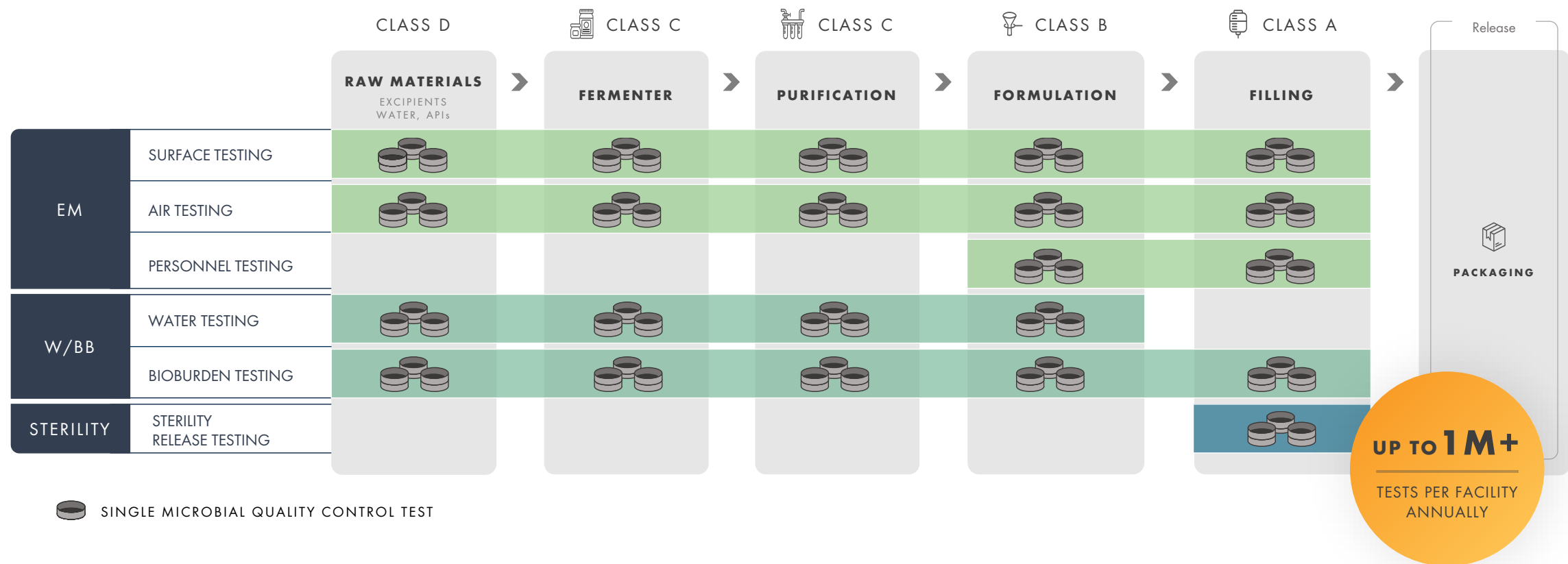
## Laborious, Slow and Subject to Human Error

MQC testing is currently conducted in centralized labs using laborious and inefficient manual workflows



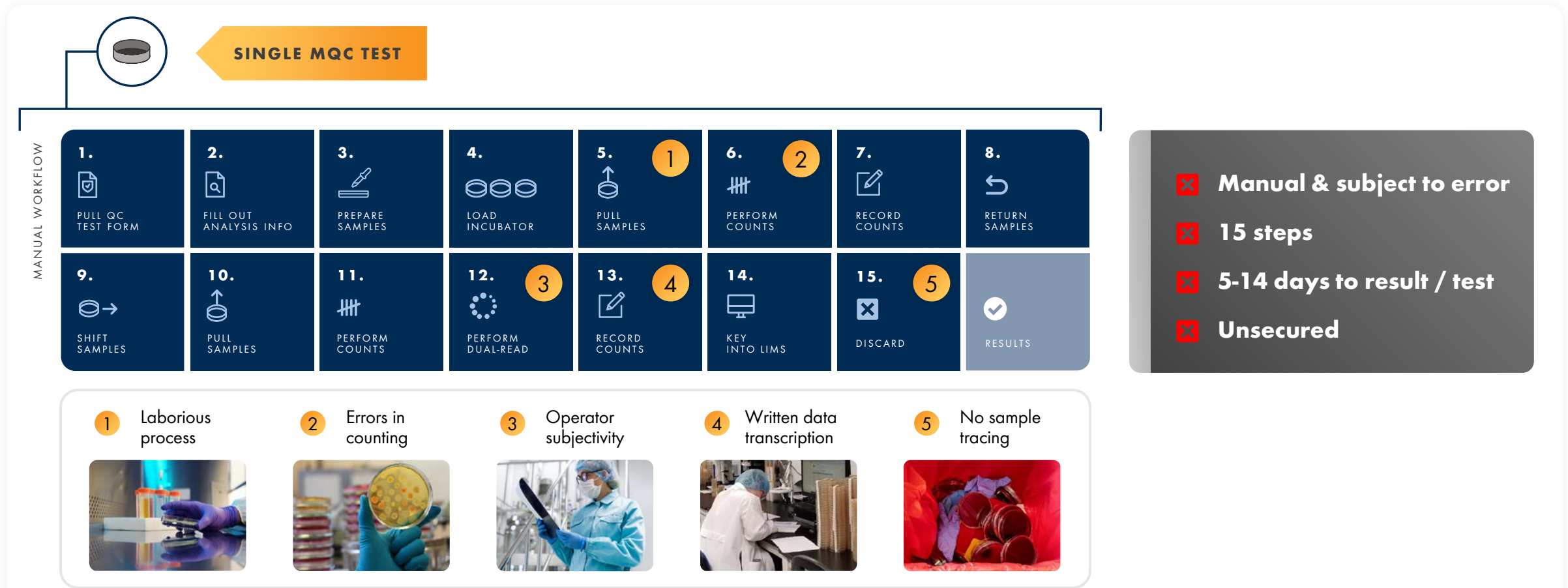


# MQC is pervasive throughout pharmaceutical production



MQC testing is constantly performed at high volumes throughout production to maintain quality control

# Every single MQC test poses multiple costs, risks and failure points



Multiplied at scale, manual MQC is vastly inefficient and costly

# Outdated MQC processes are costing organizations

Lapses in legacy MQC processes increase cost, regulatory scrutiny, and organizational risk



## FDA enforcement actions

such as 483s, warning letters and consent decrees



**40-50%**

of all warning letters issued globally contain a data integrity component



**6-24 months**

to resolve FDA 483s and investigations



**Up to \$100M**

annual product loss per company due to MQC issues



**Billions of dollars**

in potential shareholder value destruction due to MQC issues

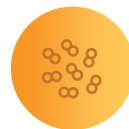
Potential risks have elevated MQC testing to the C-suite



# Persistent industry tailwinds further drive need for automated MQC



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

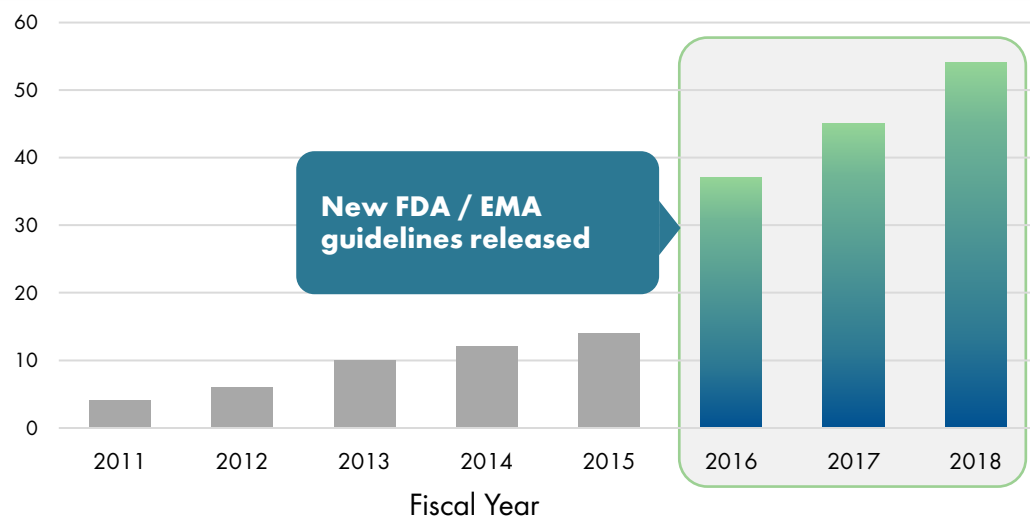


Growth in complex biologics, cell, and gene therapies which require **faster, more accurate, higher throughput testing capabilities**

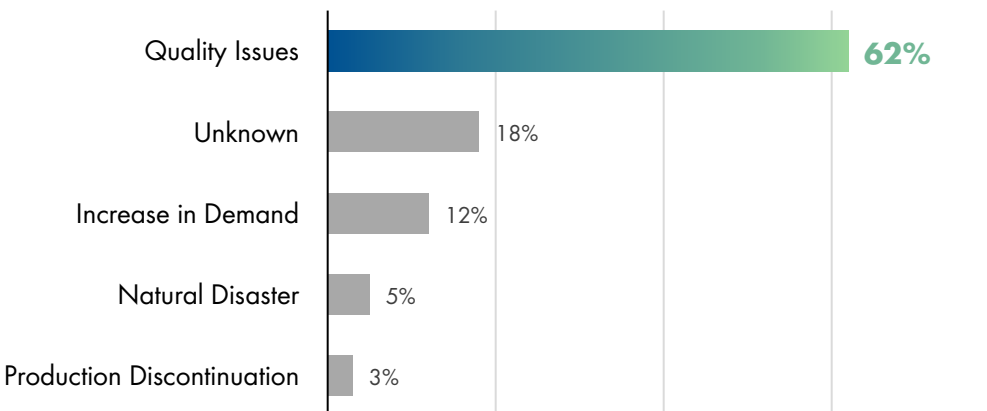


Significant global demand for drugs colliding with supply chain disruptions to **drive need for improved quality**

FDA WARNING LETTERS ISSUED DUE TO DATA INTEGRITY FINDINGS



PERCENTAGE OF DRUGS IN SHORTAGE BY REASON (CY 2013-2017)



# 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

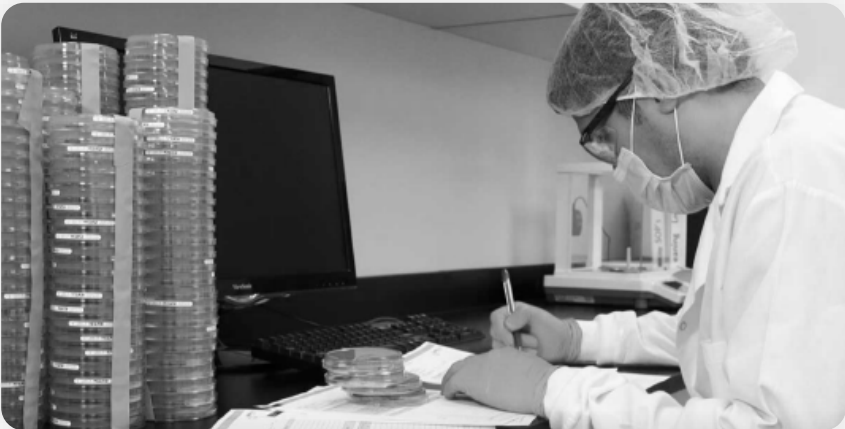
DISCOVERY  
& RESEARCH



HIGH-THROUGHPUT R&D AUTOMATION

TODAY

QC & ANALYSIS



TODAY

BIOPROCESSING  
& MANUFACTURING



FLEXIBLE SINGLE USE TECHNOLOGIES





# 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 &  
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TODAY

DISCOVERY  
& RESEARCH



HIGH-THROUGHPUT R&D AUTOMATION

TODAY

## QC & ANALYSIS



TODAY

BIOPROCESSING  
& MANUFACTURING

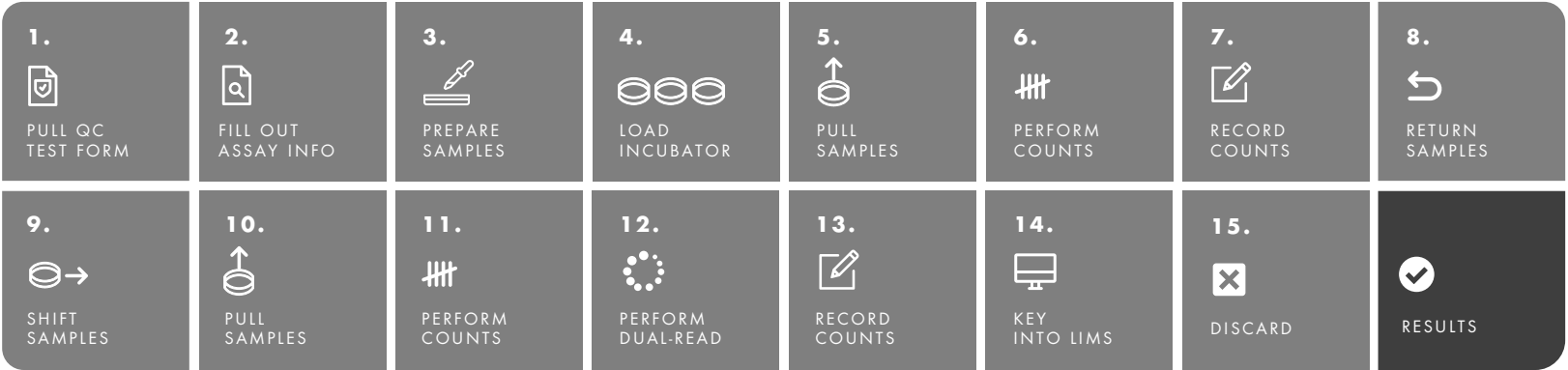


FLEXIBLE SINGLE USE TECHNOLOGIES



# 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



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

# Growth Direct's compelling value proposition is driving rapid global adoption



## Data Integrity



Secure critical data to ensure **global quality** and **regulatory compliance**



## Operational Efficiency



Deliver faster automated results for **improved decision making** and **business performance**

## Insight & Accuracy



Eliminate human quality control errors and **reduce business risk**



# Our robust business model generates multiple and recurring revenue streams



## Growth Direct

Purpose-built high-throughput MQC automation



## Proprietary Consumables

Broad application suite

- Environmental monitoring
- Water
- Bioburden



## Global Validation & Support Services

Full installation, validation and maintenance services



## Data & Software

Two-way LIMS interface enabling fully paperless workflow



# Strong commercial traction driving our business growth

100+

CUMULATIVE SYSTEMS  
PLACED

>1 million

CUMULATIVE  
CONSUMABLES SHIPPED

~60%

CUSTOMERS WITH  
MULTIPLE SYSTEMS

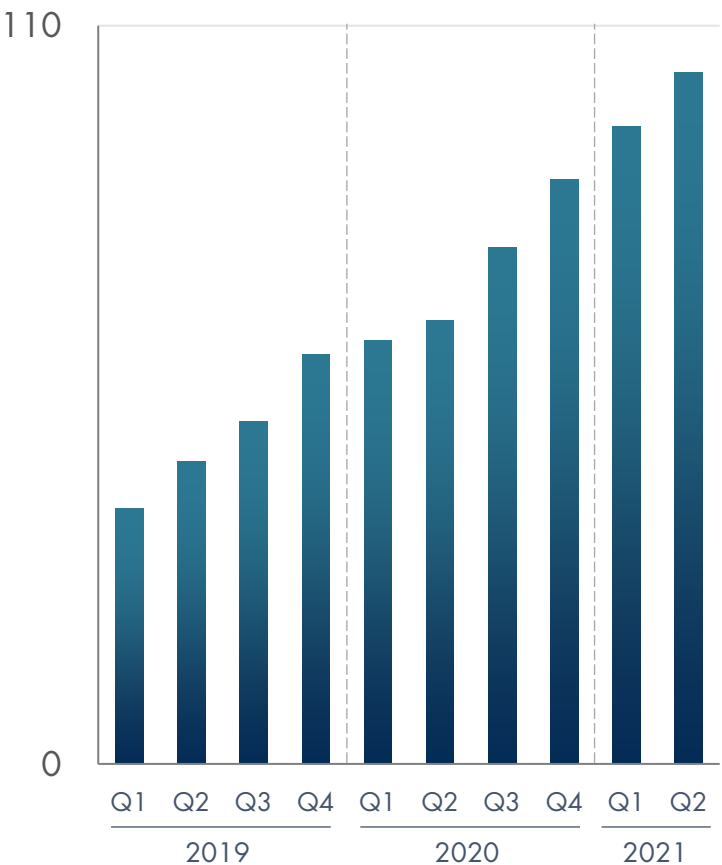
~50%

CUSTOMERS WITH SYSTEMS  
IN MULTIPLE SITES

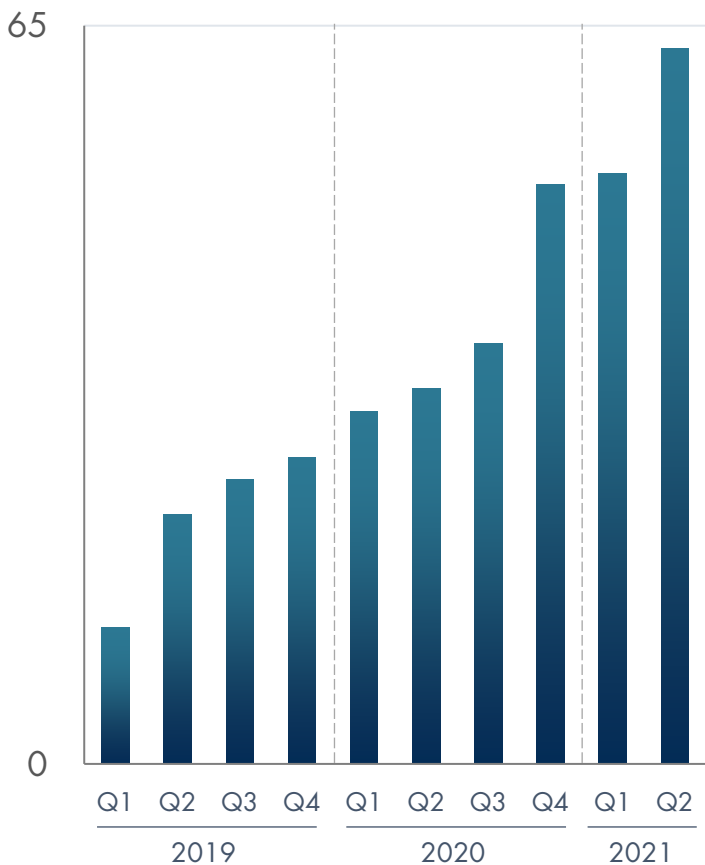
>50%

OF TOP 20 GLOBAL  
PHARMA\* ARE CUSTOMERS

CUMULATIVE SYSTEM PLACEMENTS\*\*



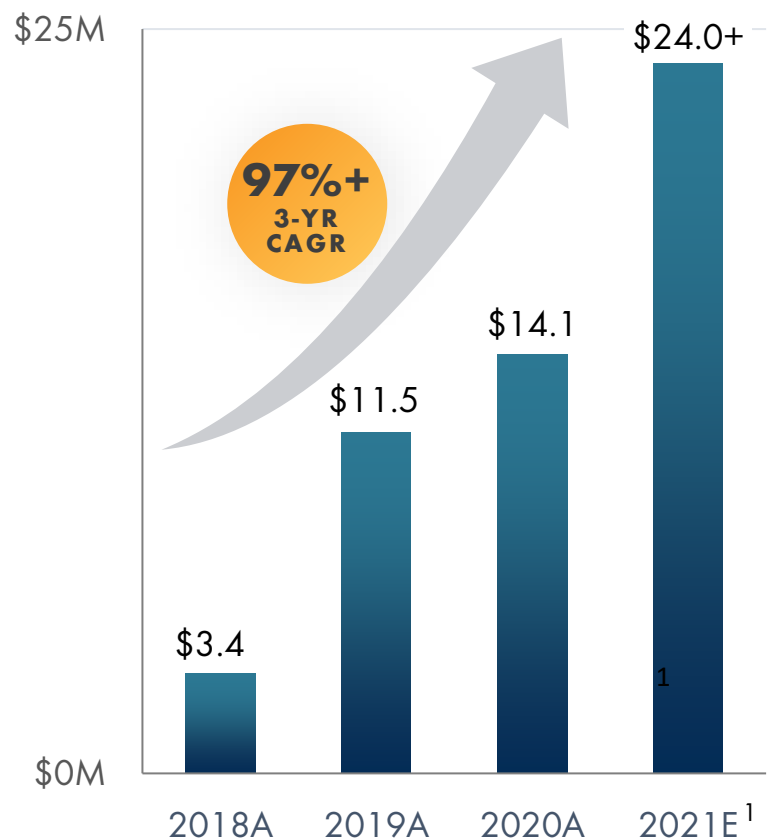
CUMULATIVE SYSTEMS VALIDATED\*\*





# Financial highlights

## COMMERCIAL REVENUE



## SUMMARY P&L DATA

In \$M	Q2		H1	
	2020	2021	2020	2021
Product Revenue	\$1.7	\$4.1	\$2.8	\$7.8
Service Revenue	\$0.7	\$1.6	\$1.2	\$2.7
Commercial Revenue	\$2.4	\$5.7	\$4.0	\$10.5
<b>Year-over-Year Growth</b>		<b>135%</b>		<b>161%</b>
Non-commercial Revenue	\$0.2	\$0.4	\$1.6	\$0.6
Total Revenue	\$2.6	\$6.1	\$5.6	\$11.1
Gross Margin %	(61)%	(29)%	(63)%	(35)%
Operating Expenses	\$4.4	\$9.1	\$9.7	\$16.7
Loss from Operations	\$(6.0)	\$(10.9)	\$(13.2)	\$(20.6)

<sup>1</sup> - 2021 commercial revenue guidance provided August 26, 2021



# Strategic opportunity to own the QC & Analysis workflow



# Rapid Micro Biosystems (RMB)

## Investment Highlights

- Growing **\$10 billion+ market** under pressure to automate and modernize
- **Proprietary technology** platform with **captive ecosystem** offering best-in-class automated and secure MQC testing
- **First mover advantage and little competition** bolstered by investment and patent-protected innovation across multiple technology disciplines
- Chosen by over half of the **top 20 global pharma** companies\* with significant growth potential
- Deep integration into heavily regulated advanced pharmaceutical manufacturing processes, especially bioprocessing of **biologics, cell and gene therapies**
- Highly attractive business model leveraging growing installed base of systems to generate **high-yield recurring revenues**
- Exciting product development and market opportunities to **significantly expand our TAM**
- **Experienced management team** and workforce with deep domain knowledge

