



## 2024 INVESTOR DAY

OCTOBER 15, 2024



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## UNLOCKING. CROWTH

## Establishing

## CareDx as the Most Innovative Company in Diagnostics

John Hanna

President and CEO





John Hanna President & CEO



Jessica Meng
Chief Commercial Officer



Robert Woodward, PhD
Chief Scientific Officer



**Keith Kennedy**Chief Operating Officer



**Abhishek Jain**Chief Financial Officer



Marica Grskovic, PhD
Chief Strategy Officer

## **TODAY'S AGENDA**

8:00-8:25	Establishing CareDx as the Most Innovative Company in Diagnostics	John Hanna
8:25-8:45	Unlocking Building Blocks of Growth	Jessica Meng
8:45-9:00	Securing Coverage & Adoption Through Evidence	Robert Woodwar
9:00-9:15	Driving Operational Leverage	Keith Kennedy
9:15- 9:25	Charting a Clear Path to Profitable Growth	Abhishek Jain
9:25-9:45	Expanding Our Footprint Beyond \$8B TAM	Marica Grskovic
9:45-10:00	Activating Our Strategy	John Hanna



## **OBSERVATIONS OVER FIRST 100 DAYS**

TEAM

**MARKET** 

**PRODUCTS** 











## **TEAM PASSIONATE ABOUT INNOVATION** & PATIENT CARE

650

CareDx Employees Globally Headquartered in South San Francisco & Stockholm

110

Scientists & Researchers **Building the Next Innovations** in Transplant

180

Commercial Employees **Supporting our Customers** and Patients

**Software Programmers Building Our Digital** Solutions



John Hanna President & CEO

veracyte. IBM

PacBi•



**Keith Kennedy** Chief Operating Officer

✓ veracyte.





Jessica Meng Chief Commercial Officer

**B** DELFI

Genentech

MYOVANT



Abhishek Jain Chief Financial Officer

Agilent Technologies



Marica Grskovic, PhD Chief Strategy Officer







Robert Woodward, PhD Chief Scientific Officer

University of Missouri

GLADSTONE INSTITUTES



Jing Huang, PhD Chief Data and AI Officer

veracyte.

Stanford University



Jeff Novack, JD General Counsel

\* NYU



Stacey Follon Head of Human Resources

Bloomberg S&P



**Kashif Rathore** Head of Software Engineering Chief Information Officer

ORACLE Cerner



GS Jha

ThermoFisher **AMGEN** 

## LARGE TRANSPLANT MARKET

250

US Transplant Centers
Cardiothoracic & Abdominal



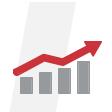
\$50B

Transplant Services Market



46K

**Transplants Annually** 



6%

Annual Growth in Transplants

## CAREDX IS THE ESTABLISHED SOLUTIONS PROVIDER TO TRANSPLANT CENTERS

~1M

Rejection Monitoring Tests Performed ~200K

HLA Typing Kits Sold Annually 70%

Centers Use One Or More Software Products

150K

Rx Filled Annually by Transplant Pharmacy



# PRELIMINARY RESULTS FOR Q3 2024



#### **Third Quarter Revenue**

Expected to be in the range of \$82M to \$83M, an increase of approximately 23% year-over-year



#### **Testing Services Revenue**

Expected to be in the range of \$60M to \$61M, an increase of approximately 26% year-over-year. Testing Services volume expected to be 44.6K, an increase of approximately 16% year-over-year



#### **Digital & Lab Products**

Revenue for Digital and Patient Solutions is expected to be \$11.9M and Products expected to be \$10.2M, up 20% and 7%, year-over-year respectively



#### **Strong Cash Balance**

Cash, cash equivalents, and marketable securities of approximately \$240M, with no debt



### **GUIDING PRINCIPLES**

#### BUILDING A SUCCESSFUL & ENDURING HEALTHCARE SERVICES BUSINESS



**Strong execution starts** with a strong team



We must put our customer at the center of everything we do



Investing in product and business innovation will deliver breakthrough growth



### UNIQUE POSITION IN MOLECULAR DIAGNOSTICS

#### MOLECULAR DIAGNOSTIC PROFITABILITY FORMULA

#### **Most Molecular Diagnostic Companies**



**Multiple Large Disease Indications** 



**Potential Revenue Growth** 



**Operational Scale** 

= **Profitability?** 

#### CareDx



**Concentrated Transplant Market** 



**Customer Acquisition Cost** 



**Cross-Sell Products and Services** 

= Profitable Growth



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**Concentrated Transplant Market** 



**Customer Acquisition Cost** 



**Cross-Sell Products and Services** 

= Profitable Growth



### **CAREDX STRATEGIC PRIORITIES**

**PROFITABLE GROWTH OPERATIONAL EXCELLENCE DEFINE TRANSPLANT+ ELEVATE PERFORMANCE CULTURE** 



## UNLOCKING. CROWTH

## **Unlocking**Building Blocks of Growth

Jessica Meng

Chief Commercial Officer



## UNLOCKING **OUR PATIENT IMPACT**

46K Transplants in 2023

400K Organ Transplant Patients in the U.S.

100K +Transplant Wait List



## **UNLOCKING THE TRANSPLANT MARKET TAM: \$8B**

LONG-TERM PLAN

\$8B+ TAM

**DIGITAL SOLUTIONS** 

~\$1B+

LAB PRODUCTS

~**\$1B**+

**TESTING SERVICES** 

~\$6B+



### **BUILDING BLOCKS OF GROWTH**

- 4 PRODUCT PIPELINE
- 3 PATIENT ADHERENCE
- 2 CUSTOMER ADOPTION
- 1 TRANSPLANT VOLUME



### FORCES DRIVING TRANSPLANT VOLUME GROWTH



#### **Growing government efforts**

are working to expand transplantation access

The New york Times

U.S. Organ Transplant System, Troubled by Long Wait Times, Faces an Overhaul

**IOTA Model** 

Increasing Organ Transplant Access

THE WALL STREET JOURNAL.

Biden Administration Launches Overhaul of Organ-Transplant System

**OPTN** 

Organ Procurement and Transplantation Network



#### **Technological advances**

are improving organ viability

#### THE LANCET

Hypothermic oxygenated perfusion of the donor heart in heart transplantation: the short-term outcome from a randomised, controlled, open-label, multicentre clinical trial



A Randomized Phase 2 Trial of Felzartamab in Antibody-Mediated Rejection



## SYNERGISTIC PORTFOLIO DRIVES CUSTOMER ADOPTION

ORGAN MATCHING/WAIT LISTING

**CARE QUALITY/SYSTEM EFFICACY** 

**GRAFT HEALTH** 











#### SOLUTIONS ACROSS PATIENT JOURNEY

#### LAB PRODUCTS

- HLA Typing
- Lab Management Software
- Waitlist Management

#### TRANSPLANT CENTER

- Transplant EMR
- Quality Reporting
- Staff Augmentation

#### PATIENT DX & SOLUTIONS

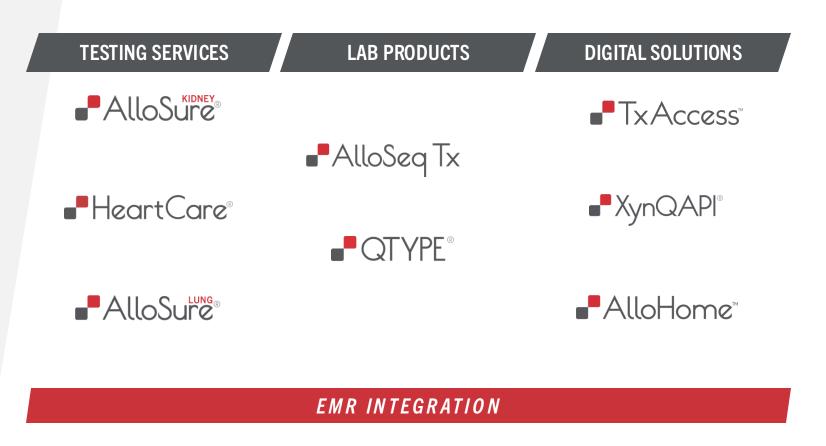
- Remote Monitoring
- Graft Health Assessment
- Tissue Diagnosis





### **CUSTOMER ADOPTION EXAMPLE**









## **MULTI-SOLUTION ACCOUNTS GENERATE 2x TESTING SERVICES REVENUE**

#### <3 SOLUTIONS

29%

Average new transplant patient acquisition for testing \$600K

Average transplant center revenue from testing

3+ SOLUTIONS

Average new transplant patient acquisition for testing \$1.2M

Average transplant center revenue from testing

Accounts that have 3 or more CareDx solutions have higher average patient acquisition, 2x the absolute testing volume increase and, ultimately, 2x the testing services revenue



## OPPORTUNITY TO IMPROVE PATIENT ADHERENCE

	Number of tests/patient per center protocol in first 3 years	Current number of tests/patient in first 3 years
AlloSure KIDNEYS	15	7
HEART HEART	38	24
LUNGS	20	10



## EXAMPLE: LEVERAGE PORTFOLIO TO IMPROVE PATIENT ADHERENCE

#### **TESTING SERVICES**

#### **DIGITAL SOLUTIONS**

















Better Adherence







### PIPELINE FUELS ADDITIONAL GROWTH

2025

2026

#### **Expanded Indications**





Simultaneous pancreas and kidney (SPK) transplantation



#### **AlloSure Heart PEDS**

Validated for patients <15 years old

#### Launch New Dx



#### **AlloMap Kidney**

Gene-expression profiling complements AlloSure Kidney



#### HistoMap

Provides molecular read-out of biopsy



#### **UroMap**

Urine-based test for patients with high BKV viremia



### **BUILDING BLOCKS OF GROWTH**

- 4 PRODUCT PIPELINE
- 3 PATIENT ADHERENCE
- 2 CUSTOMER ADOPTION
- 1 TRANSPLANT VOLUME



## UNLOCKING. CROWTH

# Securing Coverage and Adoption Through Evidence

Robert Woodward, PhD

Chief Scientific Officer



**EVIDENCE GENERATION INCREASES COVERAGE AND ADOPTION** INCREASING COVERAGE

**Meta-analysis of Clinical Studies** 

**Outcomes Clinical Utility** 

**Decision Impact Clinical Utility** 

**Physician Adoption** 

**Clinical Validation** 



## SHORE RESULTS DEMONSTRATE THE VALUE OF HEARTCARE

### Dual Positive HeartCare Results Associated with Highest Incidence of Acute Cellular Rejection (ACR)

**Outcomes Registry** 

## Dual Positive HeartCare Results Associated with

The Journal of Heart and Lung Transplantation

Surveillance with dual noninvasive testing for

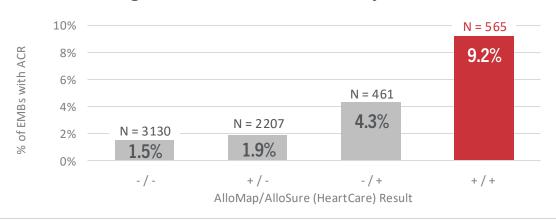
Outcomes from the Surveillance HeartCare

acute cellular rejection after heart transplantation:

#### KEY FINDINGS



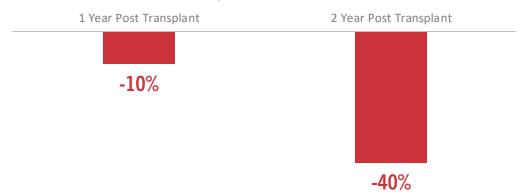
HeartCare outperforms dd-cfDNA alone in detecting rejection





Patients experienced excellent outcomes with fewer biopsies

#### Reduction in Biopsies Over Time 2017-2021



#### naturemedicine

Cell-free DNA for the detection of kidney allograft rejection

## LANDMARK NATURE MEDICINE PUBLICATION DEMONSTRATES UTILITY OF ALLOSURE KIDNEY

#### KEY FINDINGS



Surveillance monitoring with AlloSure independently predicts allograft rejection

Variable	# of biopsies	Odds ratio		Р	
AlloSure	1911	H■H	<b>2.32</b> (2.08, 2.59)	<0.001	

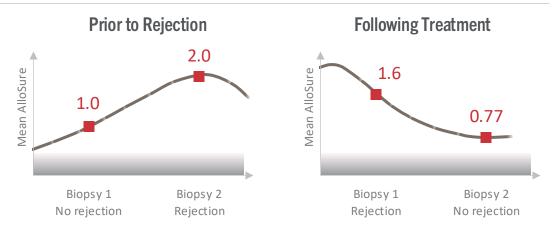


AlloSure detected subclinical rejection in clinically stable patients



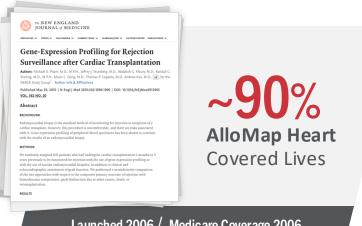


AlloSure dd-cfDNA levels elevated prior to rejection and declined in response to treatment





## **COVERAGE GROWS WITH INTENTIONAL APPROACH**



Launched 2006 / Medicare Coverage 2006







~30% **AlloSure Lung** Covered Lives

Launched 2021 / Medicare Coverage 2023

#### BCBS FEDERAL EMPLOYEES

#### POLICY:

Positive coverage for AlloSure Heart

#### STUDY:

HeartCare SHORE data, J Heart Lung Transplant

#### HIGHMARK BLUES

#### POLICY:

Positive coverage for AlloSure Kidney

#### STUDY:

AlloSure Kidney Nature Medicine

Sources: Total Medicare and Commercial covered lives for CareDx products. Data on file; Khush et al., J Heart Lung Transplant. 2024. doi:10.1016/j.healun.2024.05.003; Aubert et al., Nat Med. 2024. doi:10.1038/s41591-024-03087-3.



### ADDRESSING UNMET NEEDS IN TRANSPLANT CARE

	GENERATING EVIDENCE	PRIMARY STUDY	STUDY COMPOSITION
HEART	<ul><li>Pediatrics Validation</li><li>5-year Survival</li><li>Directing Therapeutic Treatment</li></ul>	SHORE	<ul><li>&gt;2,700 patients</li><li>5-year follow-up</li><li>67 sites, HARTS protocol</li></ul>
KIDNEY	<ul><li>Procedure Decision Making</li><li>Treating Subclinical Rejection</li><li>3-year Survival</li></ul>	KOAR	<ul><li>&gt;3,600 patients</li><li>3-year follow-up</li><li>56 sites, ARTS protocol</li></ul>
LUNG	<ul><li>Surveillance Outcomes</li><li>Subclinical Rejection</li><li>All Transplant Coverage</li></ul>	ALAMO	<ul><li>500 patients</li><li>5-year follow-up</li><li>19 sites, ALRTS protocol</li></ul>



## **Driving**Operational Leverage

Keith Kennedy
Chief Operating Officer





1 DRIVE VOLUME

Make it easy for physicians and patients to order our tests

2 SCALE OPERATIONS

Scale operations to drive long-term predictability of margins

3 LEVERAGE TECHNOLOGY

Deploy best-in-class technology to drive efficient throughput 4 ACCELERATE PROFITABILITY



1

### DRIVE VOLUME

## Make it easy for physicians and patients to order our tests

- Integrate commercial strategy
- Maximize EMR integrations-Epic, Cerner, and other EMRs
- Integrate proprietary portals from acquired companies

2

## SCALE OPERATIONS

## Scale operations to drive long-term predictability of margins

- Unlock efficiencies through our supply chain
- Automate lab workflows and streamline testing platforms
- Assess geographic opportunities to improve cost and turn-around times

3

#### LEVERAGE TECHNOLOGY

#### Deploy best-in-class technology to drive efficient throughput

- Deploy low key automation across workflows
- Integrate lab information systems (LIMS) with enterprise data warehouse and Business Intelligence (BI) tools

4

### ACCELERATE PROFITABILITY

- Deliver value on coverage and contracting
- Improve eligibility, prior authorizations, and appeals processes
- Improve margin on a cost-pertest basis



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### DRIVING OPERATIONAL LEVERAGE

DRIVE VOLUME

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ACCELERATE PROFITABILITY

## Leverage evidence and clinical utility to improve realization per test with an eye on cost control

- Deliver value on coverage and contracting
- Improve eligibility, prior authorizations, and appeals processes
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### DRIVING OPERATIONAL LEVERAGE

1

### DRIVE VOLUME

### Make it easy for physicians and patients to order our tests

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4

### ACCELERATE PROFITABILITY

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- Deliver value on coverage and contracting
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### **DRIVING SHAREHOLDER VALUE THROUGH KPIs**

	STRATEGIES				
KPIs	Drive Volume	Scale Operations	Leverage Technology	Accelerate Profitability	
Volume					
Revenue					
Gross Margin					
ОрЕх					
EBITDA					



## IMPACT OVER THE NEXT 24 MONTHS









## UNLOCKING. CROWTH

## Charting a Clear Path to Profitable Growth

**Abhishek Jain** 

Chief Financial Officer



## CHARTING A PATH TO PROFITABLE GROWTH AND STRATEGIC CAPITAL ALLOCATION

#### **PROFITABLE GROWTH**



- Compounded Annual Growth Rate (CAGR)
- Gross Margin

#### **PROFITS AND CASH**



- Adjusted EBITDA
- Cash Generation

### **CAPITAL ALLOCATION**



- M&A
- Invest in Core Business
- Share Buyback



### **DRIVING PROFITABLE GROWTH**

15%

3-Year Revenue **CAGR Target** 

>70% 2027 Gross Margin Target



## DRIVING PROFITS AND CASH

20%

2027 Adjusted EBITDA Target

+\$100M

3-Year Incremental Cash Target



## STRATEGIC CAPITAL ALLOCATION

**BUSINESS DEVELOPMENT AND M&A** 

**CORE BUSINESS** 

**SHARE BUY BACK** 



## UNLOCKING. CROWTH

## Expanding Our Footprint Beyond \$8B TAM

Marica Grskovic, PhD

**Chief Strategy Officer** 



STRATEGY TO EXPAND BEYOND \$8B TAM

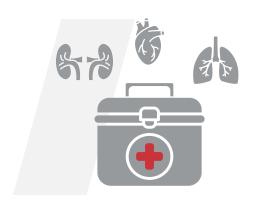
**New Indications for Transplant Biomarkers** 

**Extending Beyond Solid Organ Transplant Monitoring** 

**Capitalizing on Our Expansive Multidimensional Transplant Data** 



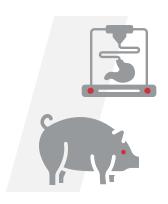
### **NEW INDICATIONS FOR TRANSPLANT BIOMARKERS**







IMMUNOSUPPRESSION DRUGS

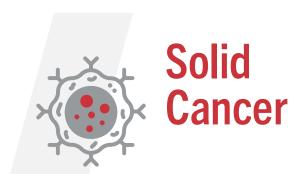


XENOTRANSPLANTATION/ BIOENGINEERED



## EXTENDING BEYOND SOLID ORGAN TRANSPLANT MONITORING







**Autoimmune Disorders** 



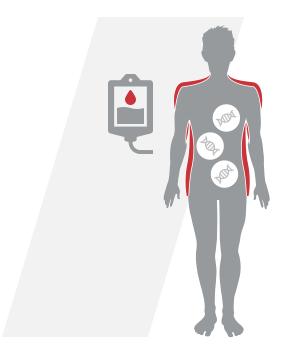
### **CAR-T CELL THERAPY PATIENT MONITORING**

### **ALLOCELL SURVEILLANCE**

Universal assay based on DNA differences between cell therapy product and patient

### **EARLY CLINICAL DATA**

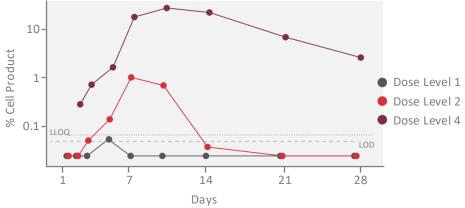
**Demonstrated AlloCell clinical** performance in cell therapy trials



### Analyzes cells in blood



Standardized Pharmacokinetics (PK) Assessment







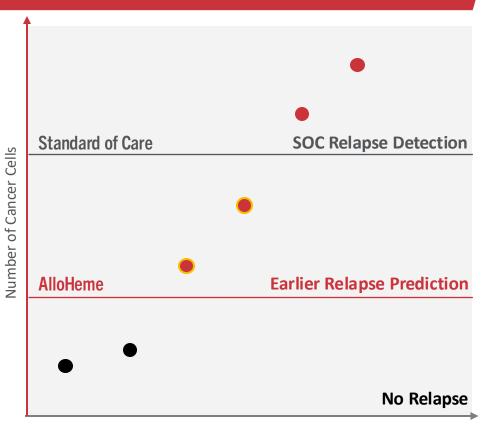
### EARLY DETECTION OF CANCER RELAPSE

### ALLOHEME DETECTS CANCER RELAPSE POST-STEM CELL TRANSPLANT









Time After Hematopoietic Stem Cell Transplantation



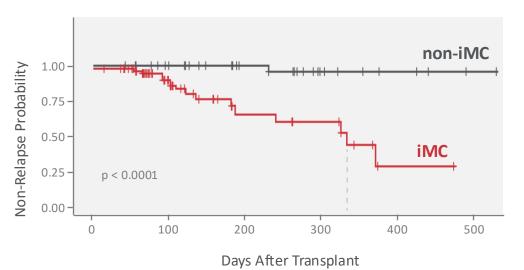






### **EARLY CLINICAL DATA**

### AlloHeme correlates with risk of relapse in blood cancer patients



#### TANDEM MEETINGS

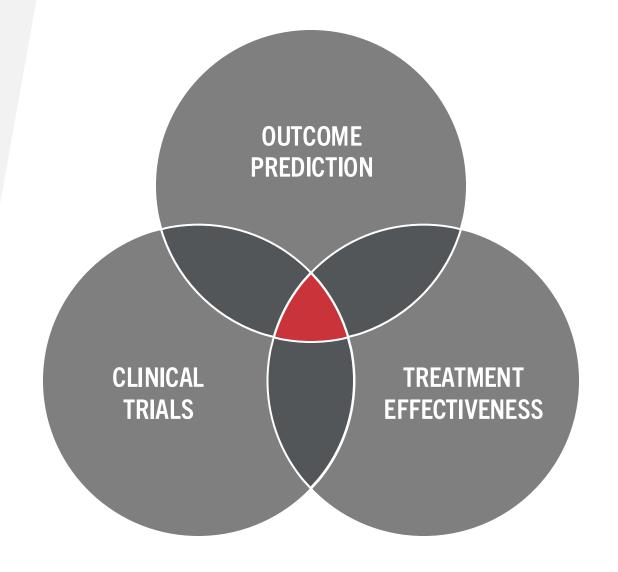


# CAPITALIZING ON OUR EXPANSIVE MULTIDIMENSIONAL TRANSPLANT DATA REPOSITORY

		PATIENTS	RECORDS	
	PRE-TRANSPLANT/WAIT LIST	185K	>9M	
	PERI-TRANSPLANT/QUALITY	735K	>220M	
	POST-TRANSPLANT/ DX TESTING	150K	>920k	
	POST-TRANSPLANT/ MEDICATION MANAGEMENT	130K	>20M	
	POST-TRANSPLANT/ REMOTE MONITORING	1K	>1M	
		>1M	>250M	



### POWER OF APPLYING AI TO OUR EXPANSIVE MULTIDIMENSIONAL DATA-SET





STRATEGY TO EXPAND BEYOND \$8B TAM

**New Indications for Transplant Biomarkers** 

**Extending Beyond Solid Organ Transplant Monitoring** 

**Capitalizing on Our Expansive Multidimensional Transplant Data** 



## Activating Our Strategy

John Hanna

President and CEO





### **CAREDX STRATEGIC PRIORITIES**

**PROFITABLE GROWTH OPERATIONAL EXCELLENCE DEFINE TRANSPLANT+ ELEVATE PERFORMANCE CULTURE** 

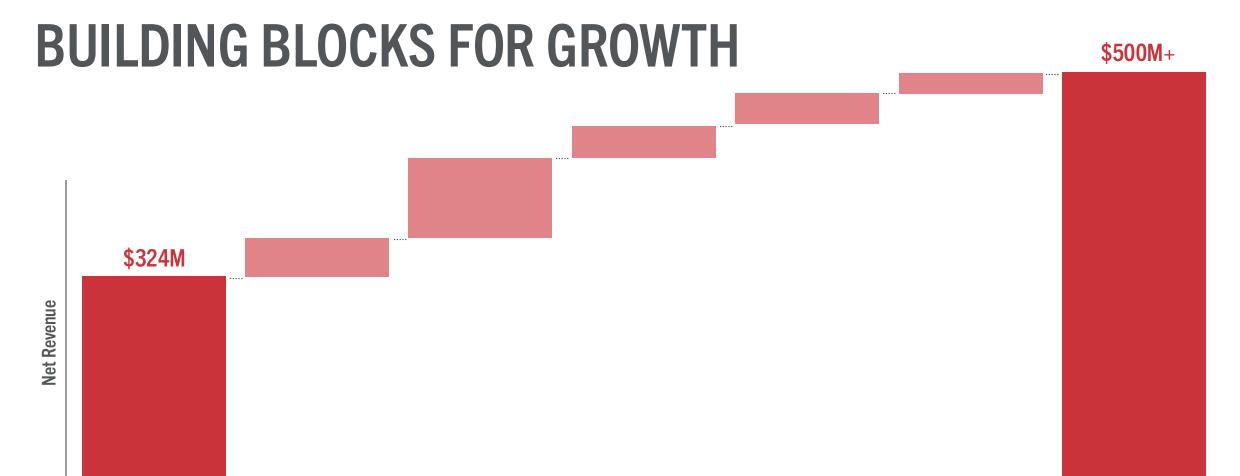


2024

**TOTAL REVENUE** 

**TRANSPLANT** 

**VOLUME** 



**PATIENT** 

**ADHERENCE** 

**AVERAGE SELLING** 

PRICE (ASP)

PRODUCT PIPELINE 2027

**TOTAL REVENUE** 

**CUSTOMER** 

**ADOPTION** 



## 2027 FINANCIAL TARGETS

\$500M

2027 Revenue Target 20%

2027 Adjusted EBITDA Target +\$100M

3-Year Incremental Cash Target



### **ACTIVATING OUR STRATEGY**



### **PUT IN PLACE THE RIGHT TEAM**



**IDENTIFIED THE MARKET OPPORTUNITIES** 



LAUNCHING INNOVATIVE SOLUTIONS TO RESOLVE UNMET MEDICAL NEEDS

THE MOST INNOVATIVE COMPANY IN DIAGNOSTICS

