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# Corporate Presentation

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mdxhealth provides highly accurate and clinically actionable urologic solutions to inform patient diagnosis and treatment while improving healthcare economics for payers and providers



#### mdxhealth

### mdxhealth fundamentals for growth

### **Fundamentals in place**

- Compelling and comprehensive menu in prostate cancer
- Robust clinical data
- Established reimbursement and guidelines inclusion



### Levers for growth

- Expansion of mdxhealth clinical pathway for prostate cancer (acquisition of Genomic Prostate Score)
- Expanding coverage of current menu (Select mdx LCD published)
- Expanding US commercial footprint

### **Established focus & execution**

- World-class CLIA certified multi-state lab operations
- Experienced and expanded channel into urology
- Urinary Tract Infection opportunity validated



### **Potential opportunities**

- Opportunistic decentralization of menu as appropriate
- Expanded channel outside of urology
- Menu Expansion: Monitor mdx and business development opportunities

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### **Experienced leadership team**

Track record of success



#### Michael K. McGarrity

Chief Executive Officer

Joined mdxhealth in 2019 Nanosphere (Luminex/DiaSornin) Stryker Ron Kalfus

**Chief Financial Officer** 

Joined mdxhealth in 2019 Rosetta Genomics Mabcure

#### John Bellano

Chief Commercial Officer

Joined mdxhealth in 2019 Assurex Health (Myriad Genetics) Third Wave Technologies (Hologic) Roche Diagnostics Molecular Diagnostics

### Joseph Sollee

Executive Vice President Corp. Dev. General Counsel

Joined mdxhealth in 2008 Triangle Pharmaceuticals TherapyEdge

#### Miriam Reyes

Executive Vice President Laboratory Operations

Joined Mdxhealth in 2011 CombiMatrix Agendia Lab `Corp

### Jason Poole

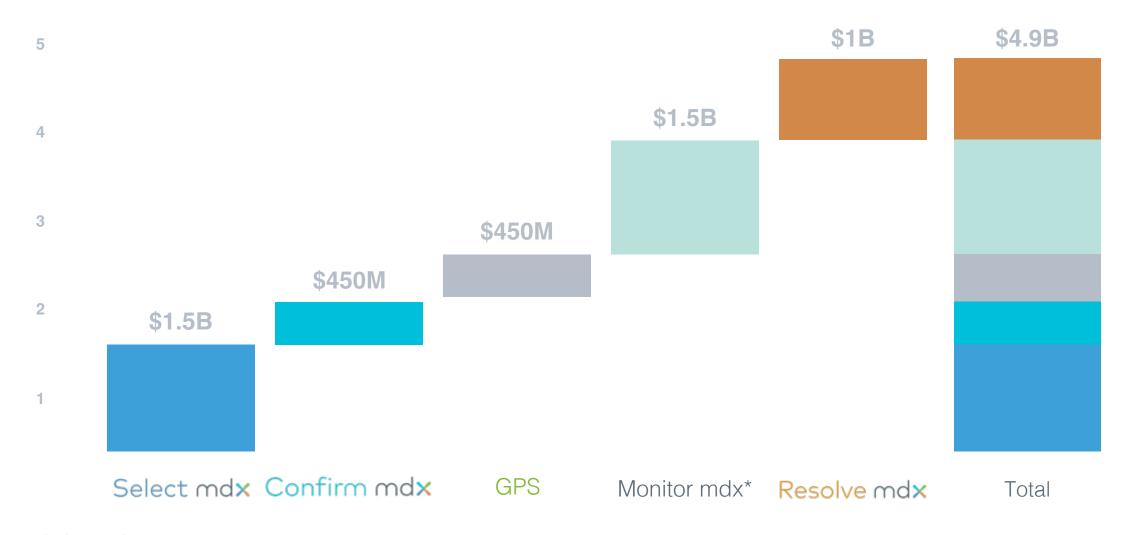
Chief Scientific Officer

Joined Mdxhealth in 2023 Active Motif Biocept Trovagene

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## Our menu addresses a \$4.9B U.S. market opportunity

### Comprehensive Urology Menu



#### md×health\* \*In development (Based on management estimates)

## **Commercial levers to drive growth**

One of the most compelling, comprehensive and accurate menus in urology Standardized laboratory partner for urology group practice

- One rep
- One laboratory
- **One** patient support program
- **ONE PARTNER** in the diagnosis and treatment of prostate cancer and other urologic diseases

Acquired Exact Sciences' Genomic Prostate Score (GPS) test

- Established brand with broad customer base
- Covered by Medicare and included in NCCN guidelines

Validated advanced Urinary Tract Infection (UTI) opportunity

• Launched in second half of 2021

Experienced distribution channel and broad KOL network

• Expanded commercial team to >70 people

#### Genomic Prostate Score

Acquired August 2022

Resolve mdx for Urinary Tract Infection UTI test launched 2021

#### mdxhealth

## **Current challenges with** diagnosing prostate cancer



#### Prostate cancer screening

3 million elevated PSA results annually (1-2)

60% of biopsies DO NOT reveal cancer and may lead to increased complications and hospitalization (3-6)



### **Prostate cancer diagnosis**

500,000 men undergo biopsies annually <sup>(2)</sup>

30% of cancer-negative biopsies are false negatives, meaning these patients actually have cancer (7)



### Prostate cancer risk stratification

288,300 prostate cancers diagnosed annually (8)

69% of new prostate cancer diagnosis are localized Active Surveillance or treatment decision<sup>(8)</sup>

Prostate cancer is the most common cancer and the 2nd deadliest cancer in U.S. men<sup>(1)</sup>

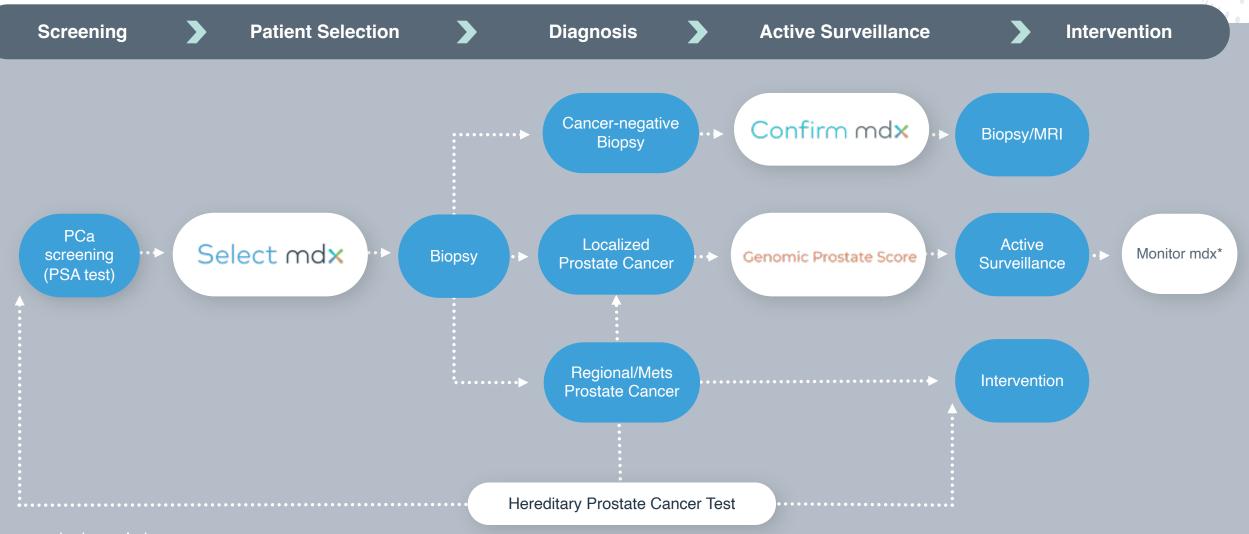
mdxhealth<sup>\*</sup>

CONFIDENTIA

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# Expanding menu in the prostate cancer diagnostic pathway

#### The most comprehensive menu in prostate cancer



#### mdxhealth<sup>®</sup> \*in development

# Select mdx improves patient selection prior to prostate biopsy

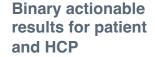
A highly predictive test to identify men at low risk for aggressive prostate cancer

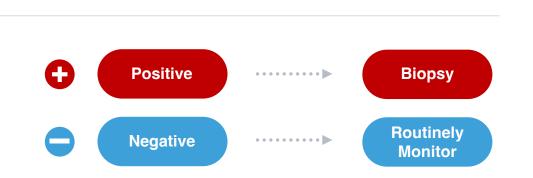
#### **Abnormal PSA/DRE**

#### At risk for aggressive cancer?

95% NPV







- **Non-invasive:** Urine-based "rule-out" test improves the diagnostic disposition of patients by avoiding unnecessary prostate biopsies
- Accurate: 95% negative predictive value <sup>(1)</sup>
- Validated: 12 published studies on genes and technology
- **Cost effective:** Potential to avoid invasive and unnecessary prostate biopsies and save the U.S. healthcare system >\$500 million <sup>(2)</sup> each year
- National guidelines: Included in EAU and NCCN guidelines <sup>(3-4)</sup>

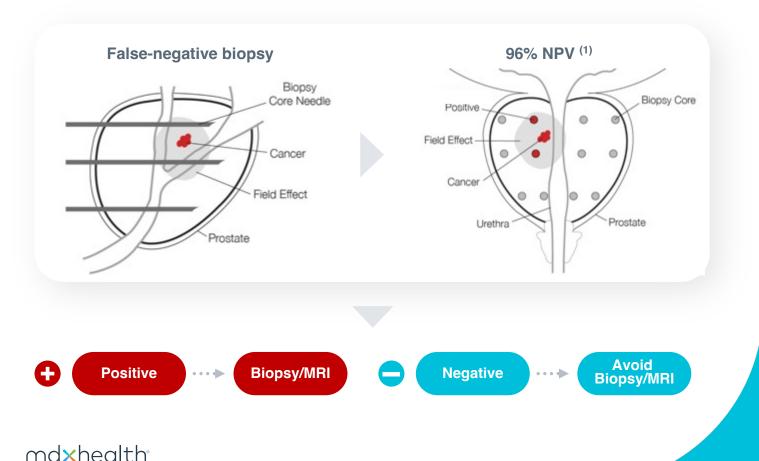
60%

60% of initial biopsies do not reveal cancer <sup>(5-8)</sup>

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# Confirm md× improves diagnostic confidence of biopsy result

The only epigenetic test to identify men at risk for aggressive prostate cancer



- **Non-invasive:** "Rule-out" test performed on previous biopsy tissue
- Accurate: 96% Negative Predictive Value for aggressive prostate cancer<sup>(1)</sup>
- Validated: Over 55 published studies on genes and technology
- Cost effective: Potential annual U.S. health system savings of \$500K per 1M covered patients <sup>(2)</sup>
- National guidelines: Included in EAU and NCCN guidelines <sup>(3-4)</sup>



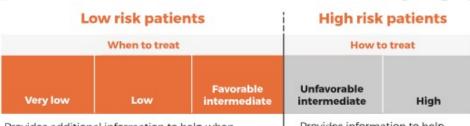
30% of men with a cancer-negative biopsy result actually have cancer <sup>(5)</sup>

# Genomic Prostate Score (GPS) guides treatment decisions for localized prostate cancer

The test analyzes prostate cancer gene activity to predict disease aggressiveness and provide clinically meaningful endpoints <sup>(1-23)</sup>



- Non-invasive: test performed on previous biopsy tissue
- Accurate: Predicts adverse pathology, distant metastasis, prostate cancer mortality and pT3/Extra prostatic extension
- Validated: Predicts adverse pathology in AS candidate cohorts in 7 studies >2,000 patients
- National guidelines: Included in NCCN guidelines (24)



Provides additional information to help when deciding on whether to pursue active surveillance or more agressive treatment options. Provides information to help select treatment intensity.

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### **Hereditary Prostate Cancer Testing**

Prostate cancer remains a leading cause of cancer-related death among men, with an estimated 288,300 new diagnoses and 34,700 deaths annually. Decades of research indicate that prostate cancer has a strong genetic component with implications to ancestry.

- Prostate cancer has the highest heritability of any major cancer in men
- Hereditary Prostate Cancer Testing:
  - is recommended in the National Comprehensive Cancer Network (NCCN) guidelines
  - is critical to identify patients eligible for novel therapies (e.g., PARP inhibitors, immunotherapies, and targeted agents for inherited prostate cancers)
  - is covered by Medicare and many commercial insurance plans, for eligible patients

Hereditary prostate cancer accounts for

# 5-10%

of newly diagnosed patients

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### **Prostate cancer pipeline**

Active surveillance monitoring (Localized prostate cancer)

### **Monitor mdx**

Patients under active surveillance are currently monitored by invasive and costly prostate biopsies Monitor mdx will be a non-invasive alternative that risk-stratifies patients for continued active surveillance vs. intervention, which may also improve patient compliance

# **1.5M**

Est. market size (men annually)



## **Urinary Tract Infection (UTI)** annual market opportunity

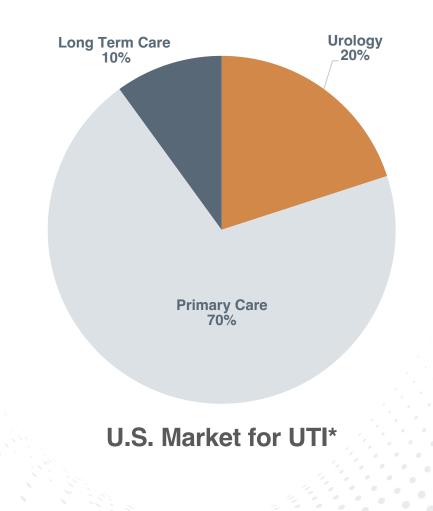
#### UTIs are the most common outpatient infection<sup>(1)</sup>

- 10 million suspected UTI cases present annually<sup>(2)</sup>
- 20% of volume presents to urology\*

#### The current UTI testing market is underserved

- Current standard is based on dated culture methodologies
- Complex molecular methods target both organism and susceptibility markers
- Market conversion comps: Virology and infectious disease
- Reimbursement well characterized (Medicare/commercial)

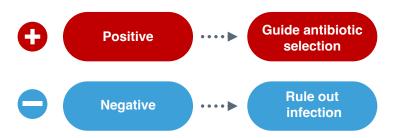
# The addressable market for UTI testing in the urology segment is 2M tests<sup>(2)</sup> annually, or \$1B\*



mdxhealth<sup>®</sup> \*management estimates

## Resolve mdx: Advance molecular urinary tract infection testing

- As many as 33% of urine cultures are polymicrobial, especially in elderly populations, and traditional urine culture may miss up to 67% of recognized uropathogens
- Resolve mdx identifies and quantities uropathogenic bacteria and associated antibiotics susceptibility
- Resolve mdx improves antibiotic stewardship



- **Non-invasive:** Urine-based test that provides personalized antibiotics options for urinary tract infections.
- Accurate: 19 pathogens, 6 classes of resistance genes and susceptibility to guide antibiotic selection
- Turnaround time: Results within 24-48 hours

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### **Selected Financial Data**

Three months ended (unaudited)			Year ended			
USD in thousands	Mar 31, 2024	Mar 31, 2023	% Change	Dec 31, 2023	Dec 31, 2022	% Change
Total revenue	\$19,834	\$14,700	+35%	\$70,193	\$37,054	+89%
Gross profit	\$12,063	\$8,715	+38%	\$43,929	\$19,219	+129%
Gross profit %	60.8%	59.3%	+1.5pp	62.6%	51.9%	+10.7pp
Net loss	(\$8,511)	(\$11,709)	(27%)	(\$43,100)	(\$44,044)	(2%)
EPS <sup>1</sup>	\$(0.31)	\$(0.53)	(42%)	\$(1.66)	\$(2.78)	(40%)

<sup>1</sup> EPS figures have been adjusted to reflect 10-1 reverse stock-split which occurred in November 2023

# Unaudited 1Q24 results and updated 2024 guidance:

• 2024 revenue guidance of \$83-85 million (representing year-over-year revenue growth of approximately 20%)

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# mdxhealth is well-positioned for sustainable growth and value creation

#### Revenue growth

- Multi-billion-dollar addressable market opportunity fortified by acquisition of Oncotype DX GPS from Exact Science
- 2024 guidance of \$79-\$81M

# 02

#### **Gross margin leverage**

- Coverage for Select mdx indication
- Driving additional payer coverage for full menu
- Accretion of (f/k/a Oncotype DX) GPS and UTI tes



#### Experienced and expanded channel into urology

- Field sales team of 70 in the US
- Urinary Tract Infection opportunity taking hold
- · Additional channel opportunities as they present



#### Leadership team and operating discipline

· Focus and execution across all operating disciplines

# Thank you

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#### Slide 6 - Our menu addresses a \$4.9B U.S. market opportunity

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#### Slide 8 – Current challenges with diagnosing prostate cancer in U.S.

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#### Slide 10 – SelectMDx improves patient selection prior to prostate biopsy

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#### Slide 11 – ConfirmMDx improves diagnostic confidence of biopsy result

- 1. Van Neste, et al. (2016) Risk Score Predicts High-Grade Prostate Cancer in DNA-Methylation Positive, Histopathologically Negative Biopsies. J Urology.
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Slide 12 –(f/k/a Oncotype DX) Genomic Prostate Score (GPS) to guide treatment decisions for localized prostate cancer

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#### Slide 16 – U.S. Urinary Tract Infection (UTI) annual market opportunity

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# Appendix



### Select mdx robust clinical evidence

12 published studies on genes and technology



Analytical validity

Clinical validity



Health economics

#### **Pivotal clinical studies**

Analytical validation

Clinically validated for a 95% NPV

Hessels et al., Translational Medicine Communications 2017

Haese et al., Journal of Urology 2019

Significantly impacts prostate biopsy decision making

>\$500M in savings to health care system

Shore et al., Urology Practice 2019

Govers et al., Journal of Urology 2018



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## **Confirm mdx robust clinical evidence**

Over 55 published studies on genes and technology

Analytical Clinical validity	Clinical Health utility conomics
Pivotal clinical studies	
Analytical validation	Van Neste et al., BMC Urology 2013
Validation of high NPV	Partin et al., Journal of Urology 2014.
Meta analysis validating high NPV	Partin et al., Trans. of the Am. Clin. and Clim. Assoc 2016
Risk score development NPV 96% CS PCa	Van Neste et al. The Prostate 2016
Validated in African American men	Waterhouse et al., Urology 2016
Validation of clinical utility/actionability	Wojno., et al 2014
Savings to health care system	Aubry et al., American Health Drug and Benefits 2013

BMC Urology

"THE JOURNAL UROLOGY"

Transactions of the American Clinical and Climatological Association

#### The Prostate



### **GPS robust clinical evidence**

Over 20 published clinical validation and utility studies

Analytical Clinical Validity Clinical Validity Clinical Validity Clinical Validity Clinical Validity Clinical Validity Clinical Validity

#### **Pivotal clinical studies**

Analytical validation

Clinically validated as an independent predictor of adverse pathology

Clinical validated in African American men

Validation of clinical utility

Validation of clinical utility/actionability

Cost savings by decreasing unnecessary immediate treatment

Klein et al., 2014, Cullen et al., 2015, Eeden et al., 2017, Eggner et al., 2019

Cullen et al., 2015, Murphy et al., 2021

#### Badani et al., 2015, D

Knezevic et al., 2013

Badani et al., 2015, Dall'Era et al., 2015, Eure et al., 2017, Lynch et al., 2017, Murphy et al., 2021, Moschovas et al., 2021

Albala et al., 2016





**EUROPEAN** 

UROLOGY



### Select mdx, Confirm mdx and GPS technology

The most comprehensive menu in prostate cancer

	Select mdx <sup>(1)</sup>	Confirm mdx <sup>(2)</sup>	GPS <sup>(3)</sup>
Specimen	Urine	Prostate tissue	Localized PCa tissue
Science	mRNA RT-PCR assay	DNA Methylation Specific PCR assay	Multi gene expression RT-PCR Assay
Biomarkers	DLX1, HOXC6	GSTP1, APC RASSF1	17 genes (AZGP1, FAM13C, KLK2, SRD5A2, FLNC GSN, GSTM2, TPM2, BGN, COL1A1, SFRP4, TPX2, ARF1, ATP5E, CLTC, GPS1, PGK1)
Clinical Model	Clinical model combines mRNA with established clinical risk factors	Clinical model combines DNA Methylation markers with established clinical risk factors	Clinical algorithm aggregates expression of 5 reference genes to normalize the expression of the 12 cancer- related genes
Performance	95% NPV for clinically significant prostate cancer	96% NPV for clinically significant prostate cancer	Predicts adverse pathology, distant metastases, PCa mortality

1. Haese, A, et al. (2019) Multicenter Optimization and Validation of a 2-Gene mRNA Urine Test for Detection of Clinically Significant Prostate Cancer Prior to Initial Prostate Biopsy. J Uro. doi: 10.1097/JU.000000000000293.

2. Van Neste, et al. (2016) Risk Score Predicts High-Grade Prostate Cancer in DNA-Methylation Positive, Histopathologically Negative Biopsies. J Urology.

3. Knezevic et al., (2013) Analytical validation of the Oncotype DX prostate cancer assay – a clinical RT-PCR assay optimized for prostate needle biopsies. BMC Genomics

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### Prostate cancer precision diagnostics: menu and pipeline

Product name	Sample type	Clinical decision	R&D	Validation	Launch	Expanded coverage and utilization
Confirm mdx	Tissue	Post biopsy				•
Select mdx	Urine	Pre biopsy				•
GPS	Tissue	AS or treatment intensity				•
Monitor mdx	TBD	AS Monitoring	•			

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