

# Forward looking statement

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#### **Analyst coverage**

Any opinions, estimates or forecasts made by analysts are theirs alone and do not represent opinions, forecasts or predictions of mdxhealth or its management. Requests for copies of analyst reports should be directed at the respective analyst and institution.



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



Ticker: MDXH



Ticker: MDXH.BR

# 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 lab operation
- Experienced and expanded channel into urology
- Urinary Tract Infection opportunity validated



#### **Potential opportunities**

- Select mdx point of care testing
- Expanded channel outside of urology
- Pipeline: Monitor mdx and business development opportunities



# **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



**Miriam** Reyes

**Executive Vice President Laboratory Operations** 

Joined Mdxhealth in 2011 CombiMatrix Agendia LabCorp



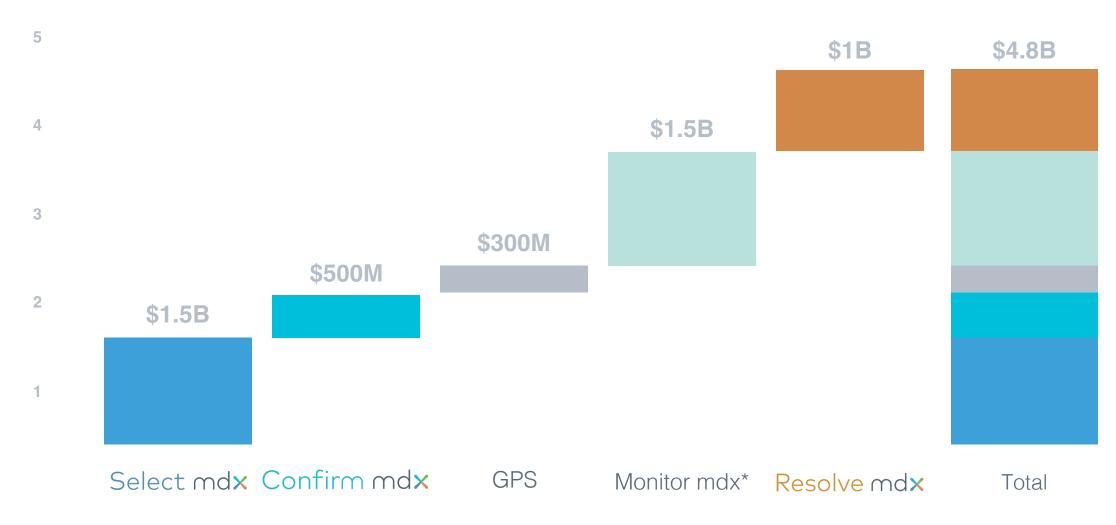
Joseph Sollee

**Executive Vice President** Corp. Dev. General Counsel

Joined mdxhealth in 2008 Triangle Pharmaceuticals TherapyEdge

# Our menu addresses a \$4.8B U.S. market opportunity

Comprehensive Urology Menu



# **Commercial levers to drive growth**

Best-in-class offering into urology with menu of the most accurate clinically-actionable tests for patients and urologists

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**

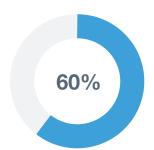
Acquired August 2022



UTI test launched 2021



# **Current challenges with diagnosing prostate cancer**



#### **Prostate cancer screening**

3 million elevated PSA results annually (1-2)

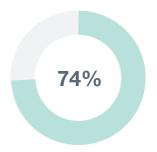
60% of biopsies DO NOT reveal cancer and may lead to increased complications and hospitalization (3-6)



#### **Prostate cancer diagnosis**

500,000 men undergo biopsies annually (2)

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



#### Prostate cancer risk stratification

268,000 prostate cancers diagnosed annually (8)

74% of new prostate cancer diagnosis are localized Active Surveillance or treatment decision (8)

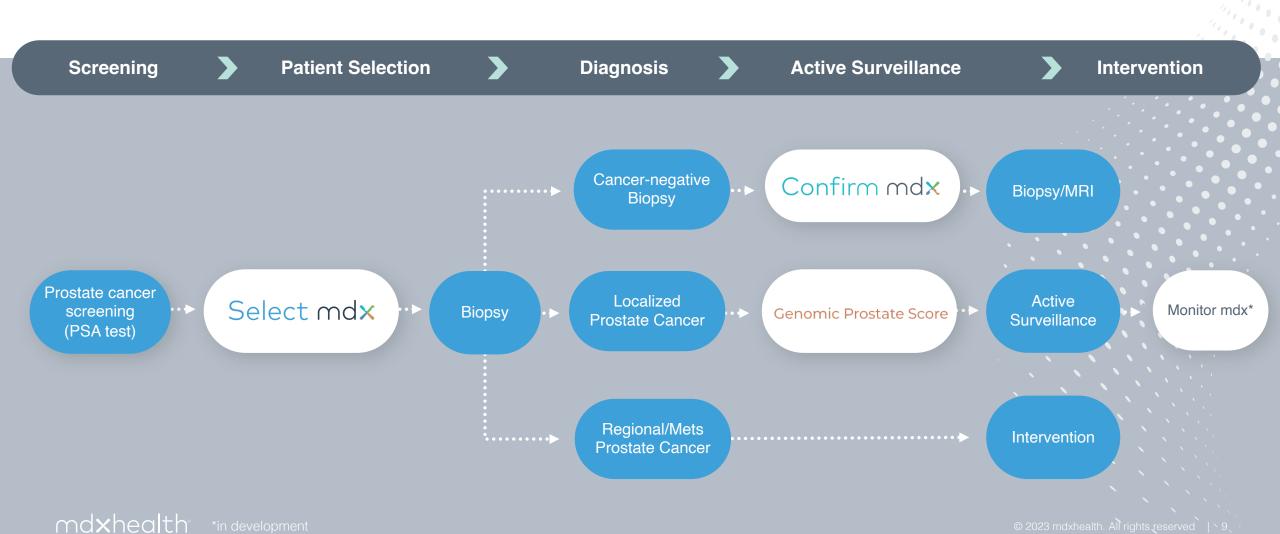
md×health

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



# Expanding menu in the prostate cancer diagnostic pathway

The most comprehensive menu in prostate cancer



# Select mdx improves patient selection prior to prostate biopsy

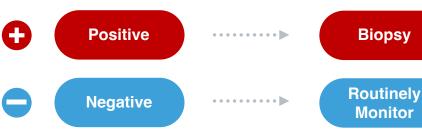
A highly predictive test to identify men at low risk for aggressive prostate cancer

Abnormal PSA/DRE At risk for aggressive cancer?

95% NPV

Select mdx\*

Binary actionable results for patient and HCP



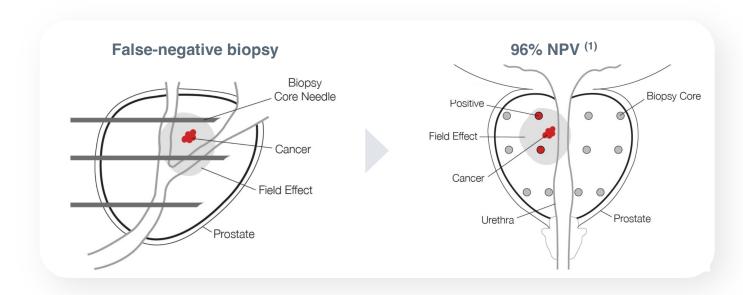
- Non-invasive: Urine-based "rule-out" test improves the diagnostic disposition of patients by avoiding unnecessary prostate biopsies
- **Accurate:** 95% negative predictive value (1)
- Validated: 12 published studies on genes and
- Cost effective: Potential to avoid invasive and unnecessary prostate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



60% of initial biopsies do not reveal cancer (5-8)

# Confirm mdx improves diagnostic confidence of biopsy result

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



 Positive
 Biopsy/MRI

 —
 Negative

 … ▶
 Avoid Biopsy/MRI

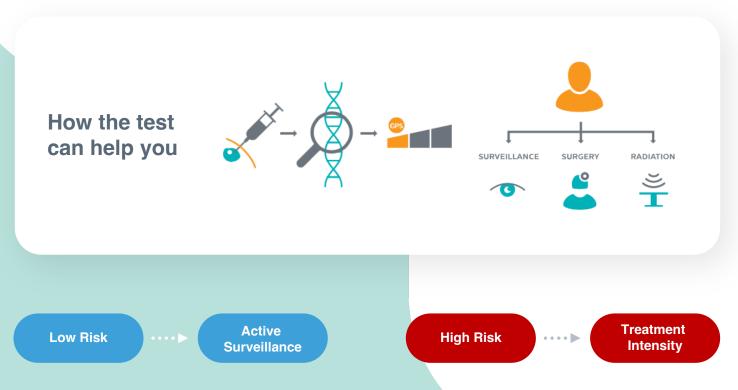
- Non-invasive: "Rule-out" test performed on previous biopsy tissue
- Accurate: 96% Negative Predictive Value for aggressive prostate cancer (1)
- Validated: Over 55 published studies on genes and technology
- Cost effective: Potential annual U.S. health system savings of \$500K per 1M covered patients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



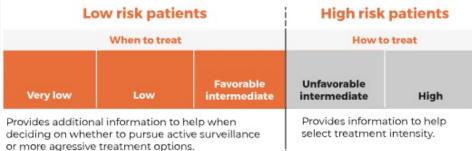
30% of men with a cancer-negative biopsy result actually have cancer (5)

# 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 (1-23)



- 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)



# 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







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

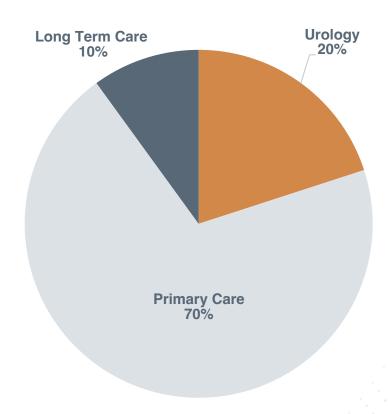
#### UTIs are the most common outpatient infection<sup>(1)</sup>

- 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)

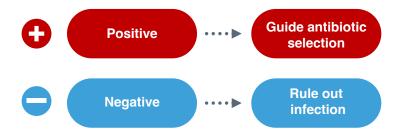
The addressable market for UTI testing in the urology segment is 2M tests<sup>(2)</sup> annually, or \$1B\*



**U.S. Market for UTI\*** 

# 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



# **Selected Financial Data**

Six months ended (unaudited)			Year ended			
USD in thousands	Jun 30, 2023	Jun 30, 2022	% Change	Dec 31, 2022	Dec 31, 2021	% Change
Total revenue	\$31,445	\$13,009	+142%	\$37,054	\$22,239	+67%
Total revenue (excl. GPS)	\$17,419	\$13,009	+34%	\$27,720	\$22,239	+25%
Gross profit	\$18,705	\$5,772	+224%	\$19,219	\$10,564	+82%
Gross profit %	59.5%	44.4%	+15.1%	51.9%	47.5%	+4.4%
Net loss	(\$22,335)	(\$18,104)	23%	(\$44,044)1	(\$29,002)	52%
EPS	\$(0.08)	\$(0.12)	(33%)	\$(0.28)	\$(0.24)	17%

<sup>&</sup>lt;sup>1</sup> Includes one-time GPS transactions costs of approximately \$3.7 million and non-recurring debt restructuring costs of \$1.2 million

**H1-2023 Unaudited Results** & 2022 Audited Results

- \$39.5 million cash as of June 30, 2023
- 2023 revenue guidance of \$65 million to \$70 million, representing growth of 75% to 89% over FY 2022

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

01

#### Revenue growth

- Multi-billion-dollar addressable market opportunity fortified by acquisition of Oncotype DX GPS from Exact Science
- 2023 guidance of \$40-\$42M

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 test

03

#### 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

04

#### Leadership team and operating discipline

· Focus and execution across all operating disciplines

# Thank you

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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

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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







Clinical utility



Health economics

#### **Pivotal clinical studies**

Analytical validation	Hessels et al., Translational Medicine Communications 2017
Clinically validated for a 95% NPV	Haese et al., Journal of Urology 2019
Significantly impacts prostate biopsy decision making	Shore et al., Urology Practice 2019
>\$500M in savings to health care system	Govers et al.,











## Confirm mdx robust clinical evidence

Over 55 published studies on genes and technology









Health economics

#### **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		





Transactions of the American Clinical and Climatological Association

#### The Prostate





## **GPS** robust clinical evidence

Over 20 published clinical validation and utility studies





Clinical validity



Clinical utility



Health economics

#### **Pivotal clinical studies**

Analytical validation	Knezevic et al., 2013		
Clinically validated as an independent predictor of adverse pathology	Klein et al., 2014, Cullen et al., 2015, Eeden et al., 2017, Eggner et al., 2019		
Clinical validated in African American men	Cullen et al., 2015, Murphy et al., 2021		
Validation of clinical utility	Badani et al., 2015, D		
Validation of clinical utility/actionability	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		
Cost savings by decreasing unnecessary immediate treatment	Albala et al., 2016		











# 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

<sup>3.</sup> 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



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

# 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	•			

