



Research Note

MDxHealth

Further validation SelectMDx

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Name:	MDxHealth SA
Country:	Belgium
Price:	EUR 3.55
ISIN Code:	BE0003844611
Reuters Code:	MDXH.BR
Market Cap (EUR m):	160.5
EV (EUR m):	128.8
Cash & cash eq. (EUR m):	31.7
Shares outstanding (m):	45.2
Volume:	105,277
Free float:	73%
52-week Range:	2.80-5.50

	2014A	2015A	2016E
Total Revenues	11.671	17.640	30.000
Net (Loss)/Profit	(15.256)	(14.473)	(12.800)
Net loss per share (cents)	(0.44)	(0.32)	(0.28)
R&D costs	2.376	4.500	3.800
Cash increase/(decrease)	(5.786)	12.783	(18.500)
Cash and marketable sec.	18.897	31.680	13.180



Positive results SelectMDx™ presented at EAU

MDxHealth presented positive results of a multicenter validation study of its liquid biopsy test SelectMDx™ for Prostate Cancer at the Annual European Association of Urology (EAU) Congress in Munich, Germany. Urine samples from two prospective, multicenter studies with 492 men (cohort A) and 371 men (cohort B) respectively were collected after digital rectal examination (DRE) to measure the mRNA expression levels of the two genes included in the SelectMDx test. These results were combined with traditional clinical risk factors, i.e. DRE, PSA, PSA density, age and family history to further improve patient stratification. An algorithm was developed in cohort A, and successfully validated in the independent cohort B. The optimal model was generated to assess the likelihood of detecting high-grade disease upon biopsy for an individual patient.

The SelectMDx urinary molecular biomarker-based risk score resulted in an improved detection of men harboring high-grade PCa, with a negative predictive value (NPV) for significant cancer of 98%

The SelectMDx™ test was designed to address an unmet need in the identification of men at risk for prostate cancer and importantly, the stratification of patients at risk for potentially lethal high-grade prostate cancer compared to those with low-grade cancer. In clinical studies, SelectMDx has been shown to outperform PCA3 in the identification of men at increased risk for aggressive prostate cancer, thereby improving the information available to urologists deciding on the need for a prostate biopsy while also aiding to identify men a sufficiently low risk for prostate cancer who may avoid unnecessary invasive biopsy procedures. See also the table on the next page.

The very high NPV of the test could reduce unnecessary biopsies by approximately 50%, as well as other expensive diagnostic procedures such as MRI scans, and thus could result in significant cost savings for healthcare providers. Prof. Dr. Jack Schalken, original developer of the PCA3 assay, discovered the novel biomarkers that make up SelectMDx™.



Assay Characteristics	SelectMDx [®] for Prostate Cancer	PROGENSA PCA3
Company	MDxHealth	Hologic
Specimen	Urine	Urine
Assay Characteristics	qPCR Assay	mRNA PCR
	2 mRNA Biomarkers	1 Biomarker
	DLX1, HOXC6	PCA3
Regulatory	LDT/CLIA/CE	FDA/CE
PCR Instrument	All open PCR instruments	Only of DTS from Hologic
List price (\$)	\$500	\$500
Assay Performance (AUC)	AUC 0.90	AUC 0.65
Comments	Indicates risk for high grade cancer	Indicates risk for cancer (any grade)

Source: MDxHealth

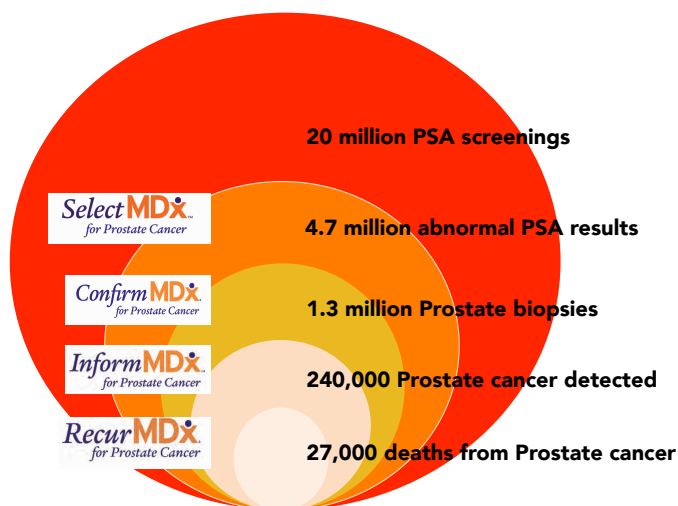
In November 2015, the test was launched as SelectMDx™ for Prostate Cancer in the Benelux region and it will be launched as an IVD kit on the European market in early 2016. MDxHealth also plans to launch SelectMDx™ as a laboratory developed test (LDT) on the US market later in 2016.

Annually, there are approximately 20 million men screened by the PSA test resulting in approximately 4.7 million abnormal PSA test results (>4.0) leading to over 1.3 million biopsy procedures, of which 240,000 are diagnosed with prostate cancer with 27,000 annual deaths.¹ Approximately USD 4.4 billion is spent annually on screening, diagnosing and staging and an additional USD 9.9 billion is spent annually on treatment of these patients, totaling nearly USD

¹Aubry et al; Budget Impact Model-Epigenetic Assay Can Help Avoid Unnecessary Repeated Prostate Biopsies and Reduce Healthcare Spending, American Health and Drug Benefits 2013



15 billion being spent annually on prostate cancer in the US alone. Annually, over USD 4 billion is spent on pharmaceuticals for prostate cancer, which is expected to increase to USD 8.7 billion by 2019.¹



Source: Van Leeuwenhoek, MDxHealth

Over 975,000 American men are diagnosed with a negative prostate biopsy each year; however approximately 25% of those men receive false-negative results.

SelectMDx™ important part of valuation MDxHealth

Using our valuation model and taking into account the future revenues of ConfirmMDx®, SelectMDx™ for Prostate Cancer and AssureMDx™ for Bladder Cancer, we believe the company’s current total value should be EUR 361 million, or EUR 8.00 per share. This represents a substantial upside from the current share price. According to our models, SelectMDx™ can potentially generate revenues of more than USD 150 million.



Sales forecast and valuation SelectMDx™ (USD)

Year	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Price	350	358	367	377	386	365	406	416	426	437
Number of tests	1800	11500	28000	44800	75200	105200	131200	188000	244000	300000
Market share	0.04%	0.2%	0.6%	1.0%	1.6%	2.2%	2.8%	4.0%	5.2%	6.4%
Tests US (million)	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7
Revenues (million)	0.63	4.13	10.30	16.89	29.05	41.66	53.25	78.22	104.05	131.13
Net Margin 35%	0.22	1.44	3.60	5.91	10.17	14.58	18.64	27.38	36.42	45.90
WACC 11%	1.00	0.90	0.81	0.73	0.66	0.59	0.53	0.48	0.43	0.39
NPV (million)	0.22	1.30	2.92	4.32	6.70	8.65	9.96	13.19	15.80	17.94
Total NPV (million)										81
Value per share (EUR)										1.63



Analyst: Marcel Wijma MSc

Marcel Wijma, Chief Research Officer and managing partner, has a longstanding history in financial biotech research. After selling Van Leeuwenhoek Research (VLR) to SNS Securities in 2006, he established an award winning analyst team in biotech/life sciences at SNS Securities. In 2009, Marcel was awarded by Financial Times/Starmine as being one of the Top-3 biotech analysts in Europe. Later that year, Marcel purchased VLR from SNS Securities after which the company was reconstituted. At VLR, he leads the professional VLR research organisation, which is augmented by selected external financial researchers with a specialisation in Life Sciences. Mr. Wijma has a Masters degree in Financial Economics from Erasmus University in Rotterdam.

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