



Research Note

MDxHealth

AssureMDx leaves competition behind

MDxHealth

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Date: 19 January 2015

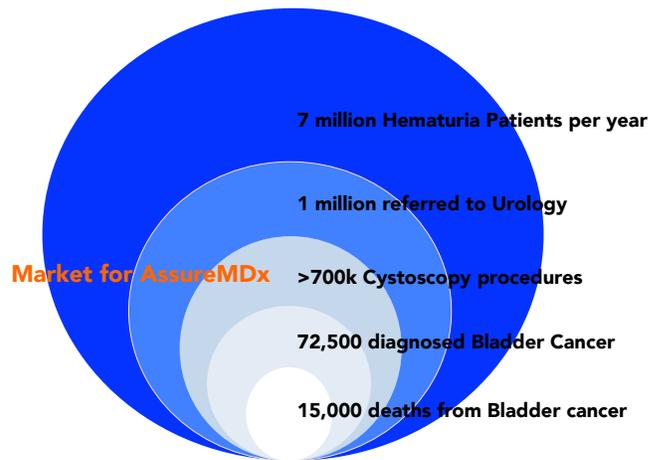
Name:	MDxHealth SA
Country:	Belgium
Price:	EUR 3.83
ISIN Code:	BE0003844611
Reuters Code:	MDXH.BR
Market Cap (EUR m):	168.5
EV (EUR m):	133.4
Cash & cash eq. (EUR m):	35.1
Shares outstanding (m):	45.2
Volume:	105,277
Free float:	73%
52-week Range:	3.21-5.88

	2014A	2015E	2016E
Total Revenues	11.671	18.000	32.000
Net (Loss)/Profit	(15.256)	(14.900)	(12.800)
Net loss per share (cents)	(0.44)	(0.33)	(0.28)
R&D costs	2.376	4.200	3.800
Cash increase/(decrease)	(5.786)	12.000	(18.500)
Cash and marketable sec.	18.897	30.897	12.397



Strong Data on AssureMDx published in The Journal of Urology

The authoritative Journal of Urology published data demonstrating the clinical potential of its urine-based epigenetic bladder cancer test AssureMDx™ to aid urologists in the management of patients presenting with haematuria (blood in the urine). The AssureMDx™ for Bladder Cancer test, which analyses DNA methylation of three genes (*TWIST1*, *ONECUT2* and *OTX1*) in combination with mutation analyses of three others, was used to create an epigenetic profile of 154 urine samples from haematuria patients without (n=80) and with (n=74) bladder cancer. The study demonstrated the test's high negative predictive value (99.2%) for the detection of bladder cancer in this cohort of haematuria patients.¹



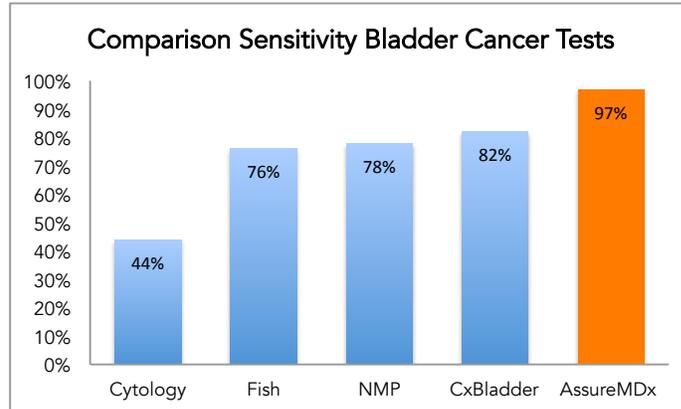
¹ Van Kessel et al; Evaluation of an Epigenetic Profile for the Detection of Bladder Cancer in Patients with Hematuria. The Journal of Urology



The market for hematuria testing and monitoring represents a noteworthy commercial opportunity. In the US, an estimated USD 1 billion is spent investigating hematuria each year, with approximately one million people referred to an urologist annually. For patients treated for early stage bladder cancer, a high recurrence rate means continual monitoring at an estimated extra cost of USD 1-2 billion for those requiring regular follow-on testing.

AssureMDx™ is being validated in a, multi-center, two-arm, prospective randomized clinical trial financed by three organisations, including Erasmus MC. A total 435 patients will be enrolled into this trial (2,000 urine samples). The study is designed to assess the test's ability to safely reduce the number of invasive cystoscopies performed during follow-up of patients with NMIBC with a low/intermediate risk of recurrence or progression. The study will also examine whether the addition of urine tests to follow-up of patients with higher risk of recurrence and progression leads to earlier detection of potentially dangerous recurrences. All urine samples will be tested using AssureMDx™ assay. Earlier in 2015, MDxHealth announced positive topline data on its biopsy test for bladder cancer. In a cohort of 154 patients with hematuria, the company's liquid biopsy urine test for bladder cancer showed a negative predictive value (NPV) of 98.3%. The test will be offered as an LDT service on the US market and a CE-marked IVD kit in Europe.

Van Leeuwenhoek's analysis shows AssureMDx™ comparing favourably against Abbott's Urovysion in separate large-scale clinical trials, each with over 400 patients as well as to Pacific Edge's CxBladder. Urovysion was launched 2001 as an aid in monitoring bladder cancer and in 2005 to aid diagnosis. The test uses Abbott's FISH fluorescence technology to detect chromosomal abnormalities. In a trial conducted by Abbott, Urovysion showed an overall sensitivity of 68.6% and specificity of 77.7% in the detection of bladder cancer in 479 patients presenting with hematuria. CxBladder showed an overall sensitivity of 82% and specificity of 85%. This compared with a sensitivity of 97% and specificity of 91% for AssureMDx™. We note some caution must be used with the comparisons, given tests were not compared head to head.



Source: Company Reports, MDxHealth

MDxHealth considerably undervalued: Value estimated to be EUR 395 million

Based on NPV based valuation, we believe that MDxHealth is substantially undervalued at the current share price of EUR 3.83. Using our valuation model and taking into account the future revenues of ConfirmMDx[®], SelectMDx[™], AssureMDx[™] for Bladder Cancer, and the growing income from royalties derived from its out-licensed products, we believe the company's current total value should be EUR 395 million, or EUR 8.72 per share. This represents a substantial upside from the current share price.



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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