



Research Note

MDxHealth

Strong outlook for 2017

MDxHealth

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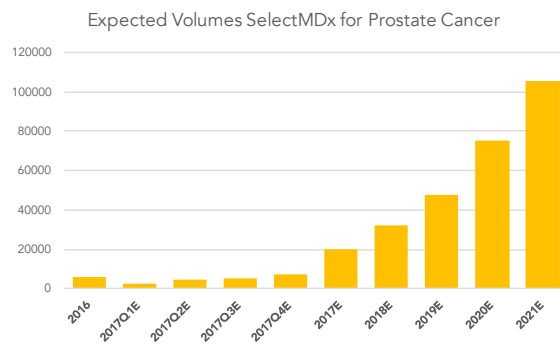
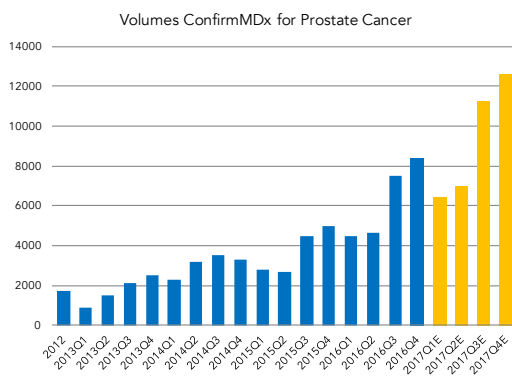
Name:	MDxHealth SA
Country:	Belgium
Price:	EUR 5.38
ISIN Code:	BE0003844611
Reuters Code:	MDXH.BR
Market Cap (EUR m):	267.9
EV (EUR m):	237.1
Cash & cash eq. (EUR m):	30.8
Shares outstanding (m):	49.8
Volume:	189,059
Free float:	73%
52-week Range:	2.80-5.69

	2015A	2016A	2017E
Total Revenues	17.640	29.970	52.000
Net (Loss)/Profit	(14.473)	(13.147)	(11.800)
Net loss per share (cents)	(0.32)	(0.26)	(0.24)
R&D costs	3.257	1.977	2.000
Cash increase/(decrease)	12.783	(0.880)	(15.000)
Cash and marketable sec.	31.680	30.800	15.800



2016FY Figures: Ongoing Strong Revenue Growth: +70%

MDxHealth published its 2016FY figures which were in line with our expectations. Already in January, the company released a preliminary update on the 2016FY results. Total revenues increased 70% to USD 30.0 million (2015FY: USD 17.6 million). Net loss was reduced further to USD 13.2 million (2015: USD 14.5 million) with cash levels amounting to USD 30.8 at the end of 2016 after having successfully raised USD 21.7 million in a private placement. The main growth driver was the ongoing strong growth of ConfirmMDx and the successful launch of SelectMDx. According to the company, the number of SelectMDx test sold since its launch in 2016 were nearly 3.5 times higher compared to the first year for ConfirmMDx in 2012 (according to our models 1700 ConfirmMDx tests were sold in 2012). We estimate that for the whole year MDxHealth sold more than 25,000 tests. Strong growth driver was the inclusion of ConfirmMDx in the US 2016 NCCN guidelines. The NCCN is an alliance of 23 top cancer centers in the US. The guidelines provide recommendations to ensure that patients receive the right diagnostic tests that are proven to get better clinical outcomes. ConfirmMDx for Prostate Cancer is the first epigenetic, and only tissue-based test in the 2016 NCCN Guidelines for early detection of prostate cancer which addresses false negative biopsy concerns.



Source: Van Leeuwenhoek Inc



Boost in Sales Growth ConfirmMDx Expected by Obtaining CPT Code

For the coming quarters we expect a further increase in volumes rising to more than 50,000 ConfirmMDx tests sold in 2018. As of 1 January 2018, the Category I MAAA Current Procedural Terminology (CPT) Code will become effective. The Current Procedural Terminology (CPT) book is a listing of descriptive terms and identifying numeric codes used for reporting medical, surgical, and diagnostic services and procedures. CPT is a widely accepted system of medical nomenclature about health care provided to patients that enables reliable communication among physicians, other health care providers, patients, and third parties. In our view this will boost sales of ConfirmMDx further as the company will be able to recognize a higher percentage of the total net billings. According to company policy, revenue is only recognized when there is reasonable evidence that the test will effectively be reimbursed. Last year, MDxHealth's total net billings were USD 49.3 million, whereas USD 30 million was recognized as revenue (including the royalty payments from Exact Sciences).

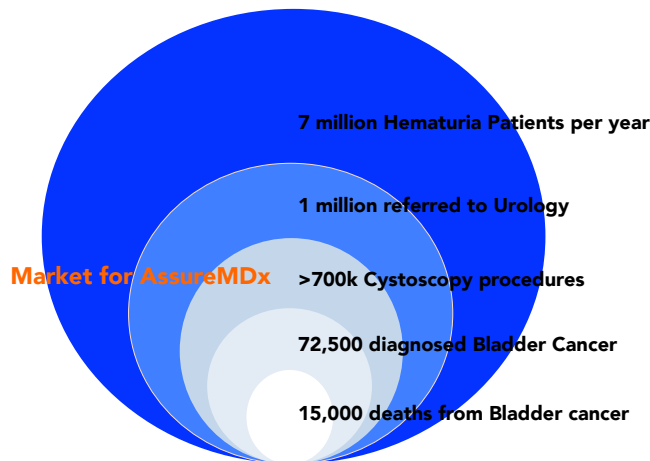
Outlook 2017: Strong Growth in Revenues from Own Liquid Biopsy Tests in Urologic Cancers

For 2017, the company expects revenues to increase between 55-75%, which is excluding royalties and milestone payments. The increase is driven by ongoing growth from its Prostate Cancer tests ConfirmMDx and SelectMDx. It also expects to launch its liquid biopsy test AssureMDx for Bladder Cancer. In 2016, 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

Bladder cancer is the sixth most common cancer worldwide and has the highest per patient medical costs of any cancer. There will be an estimated 75,000 new cases diagnosed in the US and over 300,000 world wide at an incidence rate of approximately 3%. 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.

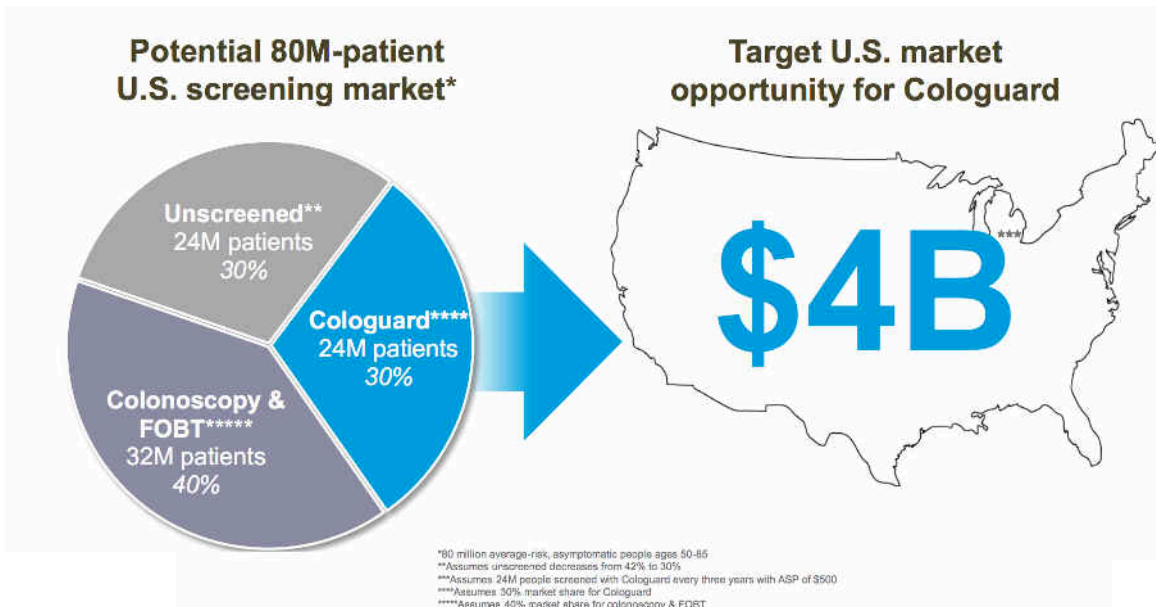


¹ Van Kessel et al; Evaluation of an Epigenetic Profile for the Detection of Bladder Cancer in Patients with Hematuria. The Journal of Urology



Also Strong Sales Figures at License Partner Exact Sciences with Cologuard

This week, MDxHealth’s license partner Exact Sciences also published its 2016FY figures. According to its press release, a total of 244,000 Cologuard tests are sold in 2016 with almost 60,000 ordering physicians. The company anticipates revenue of USD 170-180 million and Cologuard volume of at least 415,000 completed tests during 2017. During 2017Q1, the company expects Cologuard volume of at least 88,000 completed tests. The total addressable market is estimated to be 80 million tests in the US. Exact Sciences has the capacity to process more than 1 million Cologuard tests per year. Exact Sciences has obtained FDA approval and CMS coverage, and launched its Cologuard test in 2014H2. MDxHealth receives a low to mid single digit royalty on sales of Cologuard. For 2017 we estimate royalty income from Cologuard to be USD 4-6 million.



Source: Exact Sciences



MDxHealth considerably undervalued: Increased valuation to EUR 589 million

Based on NPV based valuation, we believe that MDxHealth is substantially undervalued at the current share price of EUR 5.38. Using our valuation model and taking into account the increased outlook for the future revenues of ConfirmMDx[®], SelectMDx[™] and AssureMDx[™], and the growing income from royalties derived from its out-licensed products, we have increased our valuation from EUR 500 million to EUR 589 million, or EUR 11.83 per share (from EUR 10.00). 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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