



Research Note

MDxHealth

Acceleration of payor coverage ConfirmMDx

MDxHealth

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Name:	MDxHealth SA
Country:	Belgium
Price:	EUR 4.63
ISIN Code:	BE0003844611
Reuters Code:	MDXH.BR
Market Cap (EUR m):	209.6
EV (EUR m):	174.5
Cash & cash eq. (EUR m):	35.1 *)
Shares outstanding (m):	45.3
Volume:	176,636
Free float:	73%
52-week Range:	2.80-5.00

*) Following the proceeds of this week's placement

	2014A	2015A	2016E
Total Revenues	11.671	17.640	33.000
Net (Loss)/Profit	(15.256)	(14.473)	(13.500)
Net loss per share (cents)	(0.44)	(0.32)	(0.30)
R&D costs	2.376	4.500	3.800
Cash increase/(decrease)	(5.786)	12.783	(2.680)
Cash and marketable sec.	18.897	31.680	29.000



Acceleration in revenues ConfirmMDx following strong increase in payor coverage

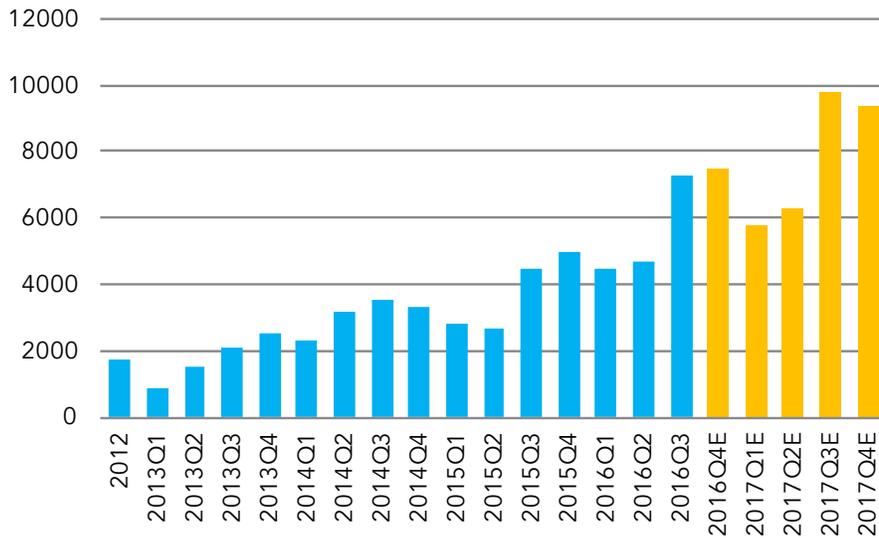
Last week, MDxHealth published its 2016-9M figures, which were better than expected. Total revenues increased with 84% to USD 22 million compared to USD 11.9 million in the first nine months of 2015. The revenue increase was primarily driven by the strong increase of sales of the prostate cancer test ConfirmMDx. Both operating loss and net loss amounted to USD 10.2 million.

The company's cash position was USD 15.1 million as of the end of 2016Q3. The average cash burn in the first nine months of 2016 was USD 1.8 million per month. Separately, the company announced that it planned to raise EUR 15 million via a private placement of up to 4.5 million new shares (10% of the outstanding shares). The same day it became clear that MDxHealth was successful in raising EUR 20 million with the issue of 4.5 million shares at a share price of EUR 4.50. Combined with the increasing sales from ConfirmMDx[®] for Prostate Cancer, increasing royalty income from Cologuard and the near-term revenue potential from its novel non invasive tests SelectMDx[™] for Prostate Cancer and AssureMDx[™] for Bladder Cancer, we believe that the company has enough cash to further increase its sales and marketing efforts, and finance the further development costs of its product portfolio.

Although the Company did not specify sales volume number, we estimate that the company sold 7,000-7,500 ConfirmMDx tests for Prostate cancer. That was much better than we estimated (5,000 tests). For the whole year management reiterated its outlook that revenue growth will be above 60%. The company expects continued revenue growth from increased adoption of ConfirmMDx and SelectMDx for Prostate Cancer tests in the EU and US markets, driven by the investment in sales and managed care representatives. Due to the higher than expected revenue growth, we increase our 2016FY estimate of sales volumes in ConfirmMDx for Prostate Cancer from 21,000 to 23,500. For the next few years we expect an increase to more than 40,000 tests in 2018.



Volumes ConfirmMDx for Prostate Cancer



Source: Van Leeuwenhoek Inc

A strong driver for the acceleration of the number of ConfirmMDx tests sold is unmistakably the surge in the number of health plans that have established positive medical policy for the ConfirmMDx following the inclusion of ConfirmMDx in the US 2016 National Comprehensive Cancer Network (NCCN) guidelines. The NCCN is an alliance of 27 of the world's leading cancer centers 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. Sofar 25 commercial health plans have positive medical policy for ConfirmMDx including Cigna, Highmark BCBS and Independence BC.



Strong start for SelectMDx

Also for MDXH’s liquid biopsy test SelectMDx is showing a strong start since its launch in the US in March. So far more than 2,000 men were tested and nine health plans have contracted to cover SelectMDx. 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 at a sufficiently low risk for prostate cancer who may avoid unnecessary invasive biopsy procedures. See also the table below.

Overview Liquid Biopsy Prostate Cancer tests

Assay Characteristics	Phi	4Kscore	Progenisa PCA3	SelectMDx
Company	Beckman Coulter	Opko	Hologic	MDxHealth
Specimen	Blood	Blood	Urine	Urine
Methodology	Immuno assay 3 Protein biomarkers tPSA and fPSA, proPSA	Immuno assay 4 kalikriens biomarkers PSA, fPSA, Intact PSA, HK-2	qPCR mRNA test, 1 biomarker PCA3	qPCR 2 mRNA biomarkers DLX1, HOXC6
Regulatory	FDA/CE	LDT/CLIA/CE	FDA/CE	LDT/CLIA/CE
List Price (USD)	499	1,900	500	500
Assay Performance (AUC)	AUC 0.73	AUC 0.82	AUC 0.68	AUC 0.89
Comments	Requires Phlebotomist	Requires Phlebotomist & Centrifuge	Urine Sample – In Office Procedure	Urine Sample – In Office Procedure

Source: MDxHealth



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. 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

Also strong sales figures at license partner Exact Sciences with Cologuard

Last week, MDxHealth's license partner Exact Sciences also published its 2016Q3 figures. According to its press release, a total of 68,000 Cologuard tests are sold in 2016Q3 with more than 50,000 ordering physicians, compared to approximately 34,000 tests completed in the same quarter of 2015. The company continues to anticipate completing more than 240,000 Cologuard tests during 2016, generating revenue of USD 90 to USD 100 million. The total addressable market is estimated to be 80 million tests. 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.



MDxHealth considerably undervalued: Value estimated to be EUR 500 million

Based on NPV based valuation, we believe that MDxHealth is substantially undervalued at the current share price of EUR 4.54. 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 500 million, or EUR 11.00 per share. If the recent share increase is taken into account, the value per share is EUR 10.00. This still 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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