



## PRESS RELEASE

# MDxHealth Provides First Quarter 2013 Business Update

## Revenue increases 51% over first quarter 2012

**IRVINE, CA, and LIEGE, BELGIUM** – May 7, 2013 – MDxHealth SA (NYSE Euronext: MDXH), a leading molecular diagnostic company that develops and commercializes epigenetic tests to support cancer treatment, today issued its business update for the quarter ended March 31, 2013.

"In Q1 2013, we recorded considerable growth in the sales of our ConfirmMDx™ for Prostate Cancer test. At the time of this release, we have surpassed a key milestone of 1,500 ConfirmMDx tests sold this year, exceeding the total number of tests sold in 2012. We experienced an increased rate of adoption within the urology community, adding new clients and further establishing a solid base of repeat clients, with nearly 400 urologists ordering ConfirmMDx to date," said Dr. Jan Groen, CEO of MDxHealth. "We are extremely pleased with the growing momentum of our commercialization efforts, augmented by the recent expansion of the sales force and the publication of our clinical validation study in the *Journal of Urology* earlier this year. We believe the increased awareness of ConfirmMDx among urologists will result in continued adoption by the urology community and drive positive coverage decisions by payors."

### Q1 2013 Highlights

During Q1 2013, adoption of the ConfirmMDx™ for Prostate Cancer test, launched in May 2012, continued to grow, as reflected in the significant increase in revenues during the period. Revenues in Q1 2013 increased 51% compared to the same period in 2012, with total revenues of €1.1 million. Reported revenue in Q1 2013 was obtained exclusively from commercial activities. As of March 31, 2013, the company had €9.5 million of cash on hand.

In Q1 2013, MDxHealth published two prostate cancer scientific papers and presented two studies at the February ASCO Genitourinary Cancers symposium in Orlando, Florida, USA. Both the scientific publications and studies demonstrated that the biomarkers in the ConfirmMDx test outperform PSA in a prostate cancer detection algorithm and as an aide to the decision to proceed for a repeat prostate biopsy. The company also published a health economic study in the *Journal of American Health & Drug Benefits*, which demonstrates that a commercial insurance plan would realize approximately \$600 in cost savings per patient within the first year of establishing coverage for the ConfirmMDx for Prostate Cancer test.

During the quarter, Merck KGaA reported that its Phase III clinical study with cilengitide in newly diagnosed glioblastoma did not meet its primary endpoints. As a result the service agreement regarding MGMT testing for this particular project with Merck KGaA ended.

### Events after the Reporting Period

On April 18, 2013, MDxHealth partner Exact Sciences reported top-Line data from the clinical trial of their Cologuard colorectal cancer screening test, a non-invasive, convenient DNA-based screening test for colorectal cancer and pre-cancerous polyps. Data from the 10,000-patient, DeeP-C clinical trial show that all endpoints were achieved, with sensitivity of 92% and specificity of 87% for the detection of colorectal cancer. Exact Sciences is expected to submit data from the DeeP-C study to the U.S. Food and Drug Administration as part of its pre-market approval (PMA) submission. Later this year, Exact Sciences is also expected to submit the study's complete data set for publication in a peer-reviewed journal, for presentation at a major medical meeting, or both. Exact Sciences intends to sell this test through its own CLIA service laboratory in Madison, Wisconsin. MDxHealth will receive milestone payments and royalties from the sale of the Cologuard test.

In April, MDxHealth's Irvine-based CLIA certified and College of American Pathologists (CAP) accredited laboratory also received ISO 9001:2008 certification from DEKRA Certification, Inc., Chalfont, PA.

### Key non-audited financials, as of March 31, 2013

Amounts in Euro's as at or for the **three** months ended

<b><i>Euro thousands</i></b>	<b>March 31, 2013 YTD</b>	<b>March 31, 2012 YTD</b>
Revenues	1,083	719
EBITDA Income (Loss)	(2,838)	(1,842)
EBIT Operating Income (Loss)	(2,906)	(1,953)
Net Profit (Loss)	(2,905)	(1,920)
Cash and cash equivalents	9,467	9,557

Q1 2013 commercial product and service revenue was €1.1 million, growing 51% over Q1 of 2012. None of the revenue was obtained from grants, compared to Q1 2012 which had €137K in revenue from grants. Overall spending in Q1 was €4.0 million, up €1.4 million over the same period last year. The increase in overall expense was primarily due to planned expansion of the company's commercial operations to accelerate the sales of the ConfirmMDx for Prostate Cancer test. First quarter operating loss (EBIT) and net loss were €2.9 million, an increased loss of €953K and €985K, respectively, over the same period in 2012. The Company's cash and cash equivalents as at March 31, 2013 was €9.5 million. The Company's revenue recognition policy at this time is primarily based on cash collections. Because reported revenues generally exclude uncollected outstanding billable cases, the impact of current test sales on reported revenues may be delayed by one or more calendar quarters. However, as billing and reimbursement trends are established with each payor, the Company is transitioning to an accrual-based revenue recognition policy. Additionally, MDxHealth has held claims to Medicare and will pursue payment once Medicare has reviewed and approved the company's medical dossier and finalizes reimbursement for the test, expected in 2013.

### Q2 and FY2013 Outlook

MDxHealth will continue executing its commercialization strategy for the ConfirmMDx for Prostate Cancer test by establishing new sales and marketing agreements within and outside the U.S. Operating expenses are expected to increase primarily from this expansion of our commercial efforts in the U.S. The Company expects total revenue to grow significantly in Q2 over Q1 and to show year-over-year growth for FY2013. This guidance is based on management's assessment of growth, including anticipation of increased sales of the ConfirmMDx for Prostate Cancer test and from new PharmacoMDx opportunities. MDxHealth also expects to receive a license for its CLIA laboratory from the State of New York before the end of Q3, 2013.

## About ConfirmMDx for Prostate Cancer

Over 650,000 American men receive a negative prostate biopsy result each year; though approximately 25% of these men may still harbor occult prostate cancer. This well-documented risk of undetected cancer, often with clinically significant Gleason scores, leads to a high rate of repeat biopsies with over 40% of men receiving at least one repeat prostate biopsy, and many receiving a 3<sup>rd</sup> and 4<sup>th</sup> biopsy. Today's gold standard diagnostic approach is the prostate biopsy procedure, collecting 10-12 needle core biopsy samples, however this sampling represents less than 1% of a man's prostate. ConfirmMDx for Prostate Cancer is an epigenetic assay to help urologists distinguish patients who have a true-negative biopsy from those at risk for occult cancer. The test is able to detect an epigenetic field effect or "halo" associated with the cancerization process at the DNA level. This molecular "halo" around a cancer lesion can be present despite having a normal appearance under the microscope. The test helps urologists rule out prostate cancer-free men from undergoing unnecessary repeat biopsies, and helps rule in high risk patients who may require repeat biopsies and potential treatment.

## About MDxHealth

MDxHealth is a molecular diagnostics company that develops and commercializes advanced epigenetic tests for cancer assessment and the personalized treatment of patients. The company's first commercial product, ConfirmMDx™ for Prostate Cancer, has been shown to help distinguish patients who have a true-negative biopsy from those who may have undetected cancer. MDxHealth helps to address a large and growing unmet medical need for better cancer diagnosis and treatment information. The company has a proprietary platform and a strong epigenetic product pipeline focused on the development of products for prostate, brain and lung cancers. The company is based in Irvine, California with a European headquarters in Liege, Belgium. For more information visit MDxHealth's website at [www.mdxhealth.com](http://www.mdxhealth.com) and follow us on Twitter at: <http://www.twitter.com/mdxhealth>

### For more information:

Dr Jan Groen

Mike Sinclair

Seth Lewis

President and CEO

MDxHealth

Halsin Partners

The Trout Group

US: +1 949 812 6979

UK: +44 20 7318 2955

US: +1 646 378 2952

BE: +32 4 364 20 70

Cell: +44 7968 022075

[info@mdxhealth.com](mailto:info@mdxhealth.com)

[msinclair@halsin.com](mailto:msinclair@halsin.com)

[slewis@troutgroup.com](mailto:slewis@troutgroup.com)

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