

#### **NEWS RELEASE**

#### REGULATED INFORMATION

# MDxHealth Reports Fourth Quarter and Fiscal Year 2012 Results

Revenue of €4.6M (\$6.0M), an increase of 71% versus fiscal year 2011

**IRVINE, CA, and LIEGE, BELGIUM** – 8:00 AM, February 28, 2013 – MDxHealth SA (NYSE Euronext: MDXH), a leading molecular diagnostic company that develops and commercializes epigenetic tests to support cancer treatment, today announced results for the fourth quarter and the fiscal year ended December 31, 2012.

## **Business Highlights**

MDxHealth achieved several major business milestones, including the accreditation of its CLIA laboratory in Irvine, California, the launch of ConfirmMDx<sup>™</sup> for Prostate Cancer and the publication of the multicenter clinical trial of ConfirmMDx for Prostate Cancer in the Journal of Urology. Earlier in July 2012 MDxHealth raised €10 million in gross proceeds through a private placement, to support its ongoing commercial activities and delisted from the NYSE Euronext in Amsterdam, The Netherlands, while maintaining its listing on Euronext Brussels, Belgium. In Q4 2012, the Company established a Center in Pharmaco (Epi)genomics in collaboration with the Ghent University to further advance its strong leadership position in the field of epigenomics. In December 2012, MDxHealth's licensing partner Exact Sciences Corp. (Nasdaq: EXAS) announced that it has submitted the first module of its premarket approval application (PMA) to the U.S. Food and Drug Administration (FDA) for its stool-based DNA colorectal cancer screening test.

In support of commercialization efforts in 2013, MDxHealth presented two prostate cancer studies at the annual ASCO Genitourinary Cancers symposium on February 14-16, 2013 in Florida. The medical dossier for ConfirmMDx supporting clinical validation and utility in the U.S. was submitted to the Centers for Medicare & Medicaid Services (CMS) within the U.S. Department of Health and Human Services.

"MDxHealth's revenues increased by 71% to more than €4.6 million in 2012 versus 2011 and we are poised to build upon this strong momentum in 2013," said Dr. Jan Groen, Chief Executive Officer of MDxHealth. "During the year, we achieved all of our key milestones in support of the commercialization of ConfirmMDx for Prostate Cancer and moving forward, we will continue to execute on our licensed central lab strategy, increasing our market penetration in the urology community and driving the development and commercialization of new ClinicalMDx and PharmacoMDx products and services."

Key Figures (EUR thousands, except number of shares and per share data):

As at or for the year ended December 31	2012	2011
Total revenues	4,602	2,687
Total operating expenses	12,606	9,518
Operating profit (EBIT)	-8,907	-7,097
Net loss	-8,976	-6,947
Earnings per share, basic (€)	-0.35	-0.37
Number of outstanding shares	25,513,440	18,622,327
Cash and cash equivalents	11,714	11,123

#### Revenues

Total revenues for Q4 2012 increased 84% to €1.7 million from €0.9 million during the same period in 2011. The revenue increase was attributable to both the Company's ClinicalMDx and PharmacoMDx products and services. Total revenues for the full year ended December 31, 2012, increased by 71% to €4.6 million, compared to total revenues of €2.7 million for the prior year.

In 2012, the Company began recognizing revenue for its ClinicalMDx products and services, based on the ConfirmMDx for Prostate Cancer test launched in May 2012. The Company initiated billing to U.S. third party private insurance payors in Q3 2012 for tests performed in 2012. 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. The Company's revenue recognition policy at this time is primarily based on cash collections. Uncollected outstanding billable cases have therefore generally been excluded from the Company's 2012 revenues. However, as billing and reimbursement trends are established with each payor, the Company is transitioning to an accrual-based revenue recognition policy.

## **Operating Expenses**

Operating expenses for Q4 2012 were €3.4 million, increasing 53% compared to €2.2 in Q4 2011. This increase is attributable to the build-up of the U.S. operations to support the commercialization of the ConfirmMDx for Prostate Cancer test, as well as potential future tests in the U.S. market. Q4 2012 operating expenses were also higher than in each of the preceding three quarters of 2012 due to the continuing build-up of the U.S. operations through the year. Operating expenses for the year ended December 31, 2012 increased by 32% to €12.6 million from €9.5 million for the prior year.

#### Results

In Q4 2012, the Company reported a net loss of  $\in$ 2.4 million, or ( $\in$ 0.09) a share, compared to a net loss of  $\in$ 1.3 million, or ( $\in$ 0.07) a share, in the same period 2011. The Company's net loss for the year ended December 31, 2012, was  $\in$ 9.0 million, or ( $\in$ 0.35) a share, compared to  $\in$ 6.9 million loss, or ( $\in$ 0.37) a share, for the prior year. This loss is attributed to the expanded development and commercialization efforts.

# **Cash Position**

The Company ended the year with cash and cash equivalents of €11.7 million, compared to €11.1 million on December 31, 2011. The Company raised net proceeds of €9.7 million in a private placement in July 2012. Excluding the proceeds of the 2012 private placement, the Company had a net cash burn of €9.0 million in 2012 compared to a net cash burn of €6.8 million in 2011. This 32% increase in the cash used by the Company resulted from the expansion of its U.S. operations,

commercialization of the ConfirmMDx for Prostate Cancer test, and support of the development PharmacoMDx assays for use in clinical trials.

## **Outlook**

The Company is accelerating the sales efforts of ConfirmMDx for Prostate Cancer. In its Irvine, CA facility, the Company will continue to focus on the development and validation of its own tests to support its ClinicalMDx service offerings through its CLIA laboratory. In 2013 the Company continues with the development of epigenetic assays for it's CLIA Lab. In Belgium, the Company will focus on assay development and service activities for its pharmaceutical partners.

For the fiscal year 2013, the Company expects strong revenue growth, and is expecting the majority of revenues to come from its ClinicalMDx products and services. In the course of 2013 the Company expects to receive Medicare coverage for its ConfirmMDx test. Operating expenses are expected to increase primarily from the expansion of sales and marketing efforts in the U.S. Accordingly, 2013 net loss and cash burn are expected to increase versus 2012, while R&D expenses are expected to be remain at current levels. The projections provided herein should be considered forward looking statements and are subject to the risks summarized in the safe harbor statement at the end of this press release.

## Post closing events

In January 2012, our licensing partner Exact Sciences Corp. (Nasdaq: EXAS) announced that it has submitted the second module of its premarket approval application (PMA) to the U.S. Food and Drug Administration (FDA) for its stool DNA colorectal cancer screening test, Cologuard<sup>TM</sup>, which includes an MDxHealth epigenetic biomarker together with MDxHealth's methylation-specific PCR (MSP) platform.

In February 2012, a pivotal health economics study for the ConfirmMDx for Prostate Cancer test was published in the American Health & Drug Benefits journal. This budget impact analysis demonstrated achievable cost savings of MDxHealth's ConfirmMDx for Prostate Cancer test, which is used by urologists to identify men who may avoid unnecessary repeat prostate biopsies, thereby reducing overall healthcare spending.

Our partner Merck KGaA announced earlier this week that its Phase III clinical study with cilengitide in newly diagnosed glioblastoma did not meet its primary endpoints. MDxHealth has been providing an MGMT (methylguanine-DNA methyltransferase) diagnostic test, PredictMDx for Glioblastoma, that was used in the clinical study to identify and stratify those glioblastoma patients who may be more likely to benefit from cilengitide treatment.

#### **Other Announcements**

In November 2012, the Company appointed Dr. Ming-Chou Lee as Vice President of Product Development, who is based at the Company's U.S. headquarters in Irvine. Dr. Lee has over 25 years of experience in molecular diagnostic product development for CLIA labs and *in vitro* diagnostic companies. In his previous position he was the Senior Director of Assay Development at Roka Biosciences in San Diego. Prior to that he was the Vice President of Assay development at PrimeraDx in Boston. He also held senior R&D positions at Focus Diagnostics and Beckman Coulter. Dr. Lee holds a Ph.D. in Molecular Biology from the University of Alabama in Birmingham and a M.S. in Microbiology from Texas Tech.

#### **Reporting Calendar**

Publication of 2012 FY results: February 28, 2013

Publication Q1 results: May 7, 2013
Publication H1 results: August 22, 2013
Publication Q3 results: November 6, 2013

#### **Financial Statements and Auditors' Opinion**

The Company's 2012 consolidated IFRS financial statements have been audited by its auditors, BDO Réviseurs d'Entreprises. The auditors have issued an unqualified audit opinion.

The condensed Consolidated Statement of Comprehensive Income, Statement of Financial Position, Cash Flow Statement, and Statement of Changes in Shareholders' Equity can be found on the Company's website at <a href="https://www.mdxhealth.com">www.mdxhealth.com</a>. The full Annual Report is expected to be made available to the public via the Company's website during April 2013.

# 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 <a href="https://www.mdxhealth.com">www.mdxhealth.com</a>.

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