

# MDxHealth Provides Third Quarter 2013 Business Update

Commercial Revenues Increase 132% over Q3 2012

**IRVINE, CA, and HERSTAL, BELGIUM, November 6, 2013** – <u>MDxHealth</u> SA (NYSE Euronext: MDXH), a leading molecular diagnostic company that develops and commercializes epigenetic tests to support the diagnosis and treatment of cancer patients, today provides its third quarter 2013 Business Update for the period ended September 30, 2013.

"The growth in sales of our ConfirmMDx® for Prostate Cancer test during the quarter has been exceptional. In Q3 alone we tested over 23,000 prostate biopsies from over 2,100 patients. With expanded access for patients through our recent agreements with insurance companies, we expect continued growth in the coming quarters," said Dr. Jan Groen, CEO of MDxHealth. "We also made strong progress toward equitable Medicare reimbursement during Q3. In an effort to mark a clear path through the growing, industry-wide regulatory hurdles to Medicare coverage, we are working in close collaboration with the Medicare administrator, Palmetto GBA, to participate in the MoIDX program announced at the end of August 2013 that provides an accelerated pathway to coverage. We are grateful for Palmetto's active engagement in this new process and anticipate a positive outcome in 2014."

## **Q3 Business Highlights**

In Q3 2013, MDxHealth made noteworthy progress across its entire commercial operation. Revenues increased to €1.5 million in Q3 2013 versus €0.9 million in Q3 2012. This increase in revenues was primarily driven by a steep increase in ConfirmMDx for Prostate Cancer sales. In the third quarter more than 2,100 patients results were delivered, compared to more than 300 in the same period in 2012. Over the first 9 months, more than 4,500 patients results were delivered, versus over 400 in the same period last year. As of September 30, 2013, the company had €21.1 million cash, compared to €13.9 million at the end of September 2012. The increase in cash resulted primarily from €18 million in new equity funding secured via a private placement in July 2013.

In Q3 2013, MDxHealth received approval for the ConfirmMDx for Prostate Cancer test from the New York State Department of Health (NYSDOH), making the test available across all 50 states. The Company also signed a co-marketing agreement with Bostwick Laboratories, a leading national cancer reference laboratory, providing access to one of the largest urology networks in the U.S. In addition, the Company signed a number of insurance agreements with preferred provider organization (PPO) networks, such as MultiPlan, Three Rivers Provider Network (TRPN) and Stratose, providing expanded availability for the ConfirmMDx for Prostate Cancer test.

Further extending its global footprint, MDxHealth established a collaboration agreement with HistoGeneX to provide pharmaceutical companies, pathologists and oncologists with integrated molecular diagnostic testing services, including the PredictMDx<sup>™</sup> for Glioblastoma test on behalf of MDxHealth's current and future clients. In Q3 2013, the Company also signed a PharmacoMDx marketing partnership agreement with Summit Pharmaceuticals International Corporation (SPI), to gain entrance to the Japanese market.

## **Events after the Reporting Period**

The ConfirmMDx for Prostate Cancer test met all primary endpoints in the recently completed multicenter, blinded DOCUMENT (Detection of Cancer Using Methylated Events in Negative Tissue) clinical validation trial. Preliminary analysis of data verifies the test's high negative predictive value

(NPV) for ruling out the presence of prostate cancer and is a significant, independent predictor of risk for men being considered for repeat biopsy. MDxHealth boosted access to ConfirmMDx for Prostate Cancer to an additional 50 million covered lives by signing agreements with health insurance providers FedMed, Inc. and America's Choice Provider Network, Inc. (ACPN).

The company's PredictMDx for Glioblastoma test, based on the MGMT (O6-methylguanine-DNA methyl transferase) biomarker, which is used to identify patients most likely to respond to targeted therapy, has been included in the 2013 National Comprehensive Cancer Network (NCCN) Guidelines. The NCCN is an alliance of 23 world-leading cancer centers. At the same time, the American Medical Association (AMA) has awarded the PredictMDx for Glioblastoma test with Tier 1 reimbursement code (81287).

On October 29, 2013, MDxHealth partner Exact Sciences reported that they expect the FDA advisory panel hearing for their Cologuard colorectal cancer screening test to occur in Q1 2014. Exact Sciences has also indicated that it has filed for Medicare and that it expects a preliminary coverage determination concurrently with FDA approval of their test. Exact Sciences intends to sell Cologuard through its own CLIA service laboratory in Madison, Wisconsin. MDxHealth will receive milestone payments and royalties from the sale of the Cologuard test.

## Key non-audited financials as of September 30, 2013

Amounts at and for the **three** months ended:

Euro thousands	Sept 30, 2013	Sept 30, 2012
Commercial Revenues*	1,506	644
Total Revenues	1,506	925
EBITDA (Loss)	(2,917)	(2,244)
EBIT Operating Income (Loss)	(2,984)	(2,330)
Net Profit (Loss)	(2,978)	(2,321)
Cash and cash equivalents	21,054	13,899

#### Amounts at and for the **nine** months ended:

Euro thousands	Sept. 30, 2013	Sept 30, 2012
Commercial Revenues*	4,539	2,100
Total Revenues	4,539	2,939
EBITDA Income (Loss)	(8,670)	(6,293)
EBIT Operating Income (Loss)	(8,937)	(6,590)
Net Profit (Loss)	(8,949)	(6,580)
Cash and cash equivalents	21,054	13,899

<sup>\*</sup>Commercial revenue is defined as revenue without government grants and or subsidies, and includes CLIA laboratory diagnostic testing revenue, services to pharmaceutical partners and royalty/licensing income.

## Commercial revenues up 116% for the first 9 months

**Total Revenues** for the first nine months amounted to €4.5 million, a 54% growth. Commercial revenues increased 116% compared to the same period last year (€2.1 million), primarily due to growth from ConfirmMDx for Prostate Cancer test sales.

**Operating Expenses** were €10.9 million in the first nine months, versus €9.2 million in the same period in 2012, as the company continued to invest in the development of its product pipeline, and sales and marketing activities in the U.S.

The **Net Loss** of €9.0 million for the first nine months of 2013 increased €2.4 million compared to the same period last year due to the investment in the US commercial operation and higher cost of sales due to the increasing test volumes for the ConfirmMDx for Prostate Cancer test.

Cash Position as of September 30, 2013, MDxHealth had €21.1 million in cash and equivalents, compared to €13.9 million on September 30, 2012. Average cash burn in the first nine months of 2013 was slightly less than €1.0 million per month.

## Outlook

Based on the growth in Q3 of 2013, we anticipate continued growth in test volumes, our customer base and insurance companies reimbursing the test in the coming quarters.

MDxHealth's reported revenues at this time are primarily based on cash collections, since the company's revenue recognition policy excludes payers with a limited or inconsistent reimbursement history. As a result, reported revenues to date exclude a considerable portion of actual ConfirmMDx test sales (i.e., cases billed but not yet collected). While the number of third party payers who meet the criteria that allows for revenue to be recognized at the time when tests are performed and billed is increasing, presently less than half of the company's billed transactions have met the accrual criteria for revenue recognition. As billing and reimbursement trends are established with additional payers, the Company will continue to transition to an accrual-based revenue recognition policy. We anticipate a continued increase in private third-party reimbursement, as new payers are included.

Additionally, approximately 30% of ConfirmMDx tests sold by MDxHealth are for patients covered by Medicare. The reimbursement climate for Medicare and other government-funded health programs in the U.S. is experiencing a state of unprecedented change. Palmetto GBA, the Medicare administrator overseeing molecular diagnostics (MolDX), has significantly increased the requirements to obtain Medicare coverage, including the successful completion of a prospective, randomized clinical utility study measuring patient outcomes. While MDxHealth believes that, relative to its peers, it is well situated to satisfy these new criteria based on the extensive clinical validation of its ConfirmMDx test, the new standards will likely delay the expected award of Medicare coverage to the second half of 2014. 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. Once Medicare reimbursement is obtained, MDxHealth expects a one time, retrospective billing payment for withheld cases, representing a substantial, one-off, increase in revenue.

## **About MDxHealth**

MDxHealth is a molecular diagnostics company that develops and commercializes advanced epigenetic tests for cancer assessment and the personalized treatment of patients. By applying patented DNA methylation platform and biomarkers, MDxHealth helps to address a large and growing unmet medical need for better cancer diagnosis and treatment information. For more information visit www.mdxhealth.com.

#### For more information:

Dr. Jan Groen, CEO MDxHealth

US: +1 949 812 6979 BE: +32 4 364 20 70

info@mdxhealth.com

Mike Sinclair (Media) Halsin Partners

UK: +44 20 7318 2955 Cell:+44 7968 022075

msinclair@halsin.com

Matt Clawson Allen & Caron, Inc.

US: +1 949 474 4300

matt@allencaron.com

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