

## MDxHealth Provides Third Quarter 2014 Business Update

### *ConfirmMDx® for Prostate Cancer Revenue and Case Volume Continue Rapid Growth*

**IRVINE, CA, and HERSTAL, BELGIUM, November 4, 2014** – [MDxHealth](#) SA (Euronext: MDXH), a leading molecular diagnostic company that develops and commercializes epigenetic tests to improve the diagnosis and treatment of cancer patients, today provided its third quarter Business Update for the period ended September 30, 2014.

“The posting of our final Local Coverage Determination (LCD) for Medicare and confirmation of a \$2,030 reimbursement price for Medicare patients is further validation of the clinical value of ConfirmMDx for Prostate Cancer and will have a material impact on market adoption and product revenues,” stated Dr. Jan Groen, CEO of MDxHealth. “In Q3 2014, ConfirmMDx revenue grew 93% to \$3.1 million, versus the \$1.6 million recorded in Q3 2013, and increased 175% in the first nine months of 2014 to \$7 million, as compared to \$2.5 million in the same period last year. These gains are driven by continuing adoption of the ConfirmMDx test by the U.S. urology community, with over 3,500 patient tests in Q3 2014, and more than 9,000 tests performed year to date.”

Dr. Groen continued: “We are also excited about the FDA approval and Medicare coverage of our licensee Exact Sciences’ Cologuard® test for colon cancer screening and we expect to begin to recognize additional milestone revenue and product royalties in the quarters ahead.”

### **Q3 2014 Highlights**

- Overall revenues increased 78% to \$3.5 million in Q3 2014 versus \$2.0 million in Q3 2013
- ConfirmMDx revenue nearly doubled to \$3.1 million in Q3 2014 from \$1.6 million in Q3 2013
- For the first 9 months of 2014, overall revenues increased significantly to \$8.3 million, compared to \$6.0 million in the same period last year
- ConfirmMDx case volume rose 64% to over 3,500 tests in Q3 2014, compared to 2,100 tests in Q3 2013
- In the first 9 months of 2014, case volume doubled to more than 9,000 patients tested, versus 4,500 tests in the same period last year
- Since ConfirmMDx was launched in May 2012, over 17,000 tests have been ordered by nearly 1,800 urologists
- The final Medicare LCD for coverage of ConfirmMDx became effective November 3, 2014
- A co-marketing agreement for ConfirmMDx was signed with Miraca Life Sciences (MLS)
- Insurance agreements signed with Ancillary Care Services (ACS) and Consilium, LLC
- The results from an important study, published in *The Journal of Urology*® suggests that ConfirmMDx biomarker is associated with the risk of recurrence for early stage prostate cancer patients

### Other Business Activities

- MDxHealth's licensee Exact Sciences launched its FDA-approval Cologuard test, making it the first and only approved stool-based DNA test for the detection of colorectal cancer
- Exact Sciences received its final National Coverage Determination (NCD) for Cologuard from the Centers for Medicare & Medicaid Services (CMS). Based on cross walk analysis, the expected Cologuard reimbursement price is \$502 for Medicare patients

### Events after the Reporting Period

- Publication of the DOCUMENT clinical validation study in the October issue of *The Journal of Urology*® confirmed the performance of the ConfirmMDx test in a U.S. multicenter cohort
- ConfirmMDx® genes were shown to correlate with prostate cancer (PCa) aggressiveness in diagnostic biopsies. The data were presented at the European Association of Urology (October 9-11, 2014)

### Key non-audited financials as of September 30, 2014

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

<i>Dollars thousands</i>	<b>Sept 30, 2014</b>	<b>Sept 30, 2013</b>
Total Revenues	3,496	1,995
EBITDA (Loss)	(3,465)	(3,895)
EBIT Operating Income (Loss)	(3,552)	(3,953)
Net Profit (Loss)	(4,193)	(3,945)
Cash and cash equivalents	7,611	28,433

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

<i>Dollars thousands</i>	<b>Sept. 30, 2014</b>	<b>Sept 30, 2013</b>
Total Revenues	8,299	5,979
EBITDA Income (Loss)	(11,398)	(11,420)
EBIT Operating Income (Loss)	(11,637)	(11,772)
Net Profit (Loss)	(12,237)	(11,787)
Cash and cash equivalents	7,611	28,433

### Commercial revenues up 39% for the first 9 months

**Total Revenues** for the first nine months amounted to \$8.3 million, a 39% growth over the previous year, primarily due to an increase in ConfirmMDx test sales, which grew by 175% during the same period.

**Operating Expenses** were \$15.7 million in the first nine months of 2014, versus \$14.1 million in the same period in 2013, as the company continued to invest in the development of its product pipeline, and sales, marketing, managed care, and clinical study activities in the U.S.

The **Net Loss** of \$12.2 million for the first nine months of 2014 increased by \$0.45 million compared to the same period last year. Continued investment in the US commercial operation and higher cost of sales due to the increasing test volumes for the ConfirmMDx for Prostate Cancer test were offset by higher recognized revenue from its sale.

**Cash Position** as of September 30, 2014 was \$7.6 million in cash and equivalents, compared to \$28 million on September 30, 2013. Average net cash burn in the first nine months of 2014 was slightly less than \$1.9 million per month.

## **Outlook**

We anticipate continued strong growth in ConfirmMDx for Prostate Cancer test volumes and revenue for the rest of 2014 and into 2015 with our current sales force, enabling us to allocate more resources toward reimbursement, billing and collections efforts. Additionally the Centers for Medicare and Medicaid Services (CMS) publication of the final Local Coverage Determination (LCD) for ConfirmMDx for Prostate Cancer, with a Medicare reimbursement rate of \$2,030 and an effective date of November 3<sup>rd</sup>, is also important for the company's managed care strategy with private insurance companies. The LCD validates that ConfirmMDx is deemed reasonable and necessary by Medicare, bolstering the value of the test in the marketplace.

With increasing ConfirmMDx test volumes and the expansion of our reimbursement and collection department, MDxHealth is able to collect more cash and recognize more accrual-based revenue. However, with growing adoption of the test by new prescribing urologists across the U.S., the company expects a growing number of new payors, thus also increasing the group of non-contracted, third party payors. This could lead to continued delays in collections and revenue recognition among those payors specifically. At the end of Q3 2014, the company engaged with over 430 payors from which reimbursements have been obtained from over 280 payors, as compared to 155 payors reported in the first half of this year.

MDxHealth has started enrollment for the prospective clinical utility study, PASCUAL, which will generate additional clinical utility data supporting continued Medicare coverage of the ConfirmMDx for Prostate Cancer test. At the date of the release of our Q3 results over 50% of the number of patients required to complete the interim analysis have been enrolled. The completion of interim analysis of the PASCUAL study, as outlined in the Medicare LCD, is expected in the first half of 2015, potentially triggering expanded Medicare coverage.

With the launch of licensee Exact Sciences' FDA-approval Cologuard test, MDxHealth expects to recognize a milestone fee and deferred license fees in excess of \$0.5 million in the near term. In addition, pursuant to its license agreement with Exact Sciences, MDxHealth is eligible to receive minimum annual maintenance fees of \$100,000 per year, sales milestones of \$300,000 after Cologuard attains net sales of \$10 million, \$750,000 after Cologuard attains net sales of \$50 million, and \$1 million after Cologuard attains net sales of \$50 million in a single calendar year, as well as running royalties in the mid-single digit range. The license agreement is expected to remain in effect until the last of the licensed patents expires in 2028.

## **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](http://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](mailto:info@mdxhealth.com)

Mike Sinclair (media)  
Halsin Partners  
+44 20 7318 2955  
Cell: +44 7968 022075  
[msinclair@halsin.com](mailto:msinclair@halsin.com)

*This press release contains forward-looking statements and estimates with respect to the anticipated future performance of MDxHealth and the market in which it operates. Such statements and estimates are based on assumptions and assessments of known and unknown risks, uncertainties and other factors, which were deemed reasonable but may not prove to be correct. Actual events are difficult to predict, may depend upon factors that are beyond the company's control, and may turn out to be materially different. Past performance should not be relied upon as a predictor of future performance. MDxHealth expressly disclaims any obligation to update any such forward-looking statements in this release to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based unless required by law or regulation. . This press release does not constitute an offer or invitation for the sale or purchase of securities or assets of MDxHealth in any jurisdiction. No securities of MDxHealth may be offered or sold within the United States without registration under the U.S. Securities Act of 1933, as amended, or in compliance with an exemption therefrom, and in accordance with any applicable U.S. securities laws*

*NOTE: The MDxHealth logo, MDxHealth, ConfirmMDx and PredictMDx are trademarks or registered trademarks of MDxHealth SA. All other trademarks and service marks are the property of their respective owners.*