

#### **NEWS RELEASE**

#### REGULATED INFORMATION

# MDxHealth Reports Fourth Quarter and Fiscal Year 2014 Results

ConfirmMDx Full Year Revenue and Case Volume Continue Excellent Growth Trends

**IRVINE, CA, and HERSTAL, BELGIUM** – 8:00 AM, February 26, 2015 – MDxHealth SA (Euronext: MDXH.BR), today announced results for the fourth quarter and the fiscal year ended December 31, 2014.

# **Business Highlights**

## **ConfirmMDx for Prostate Cancer**

- ConfirmMDx revenue increased 152% from \$3.7 million to \$9.4 million in 2014
- ConfirmMDx revenue for Q4 doubled to \$2.4 million compared to \$1.2 million in the same period last year
- Total full year revenue increased to \$11.7 million in 2014 versus \$7.6 million in 2013
- Recorded a 76% increase in annual ConfirmMDx case volume, with 12,300 patients tested in 2014 compared to nearly 7,000 patients tested in 2013
- In Q4, ConfirmMDx case volume increased 46% to more than 3,300 tests, compared to approximately 2,300 tests in Q4 2013
- Published ConfirmMDx clinical utility study in the journal of in American Health and Drug Benefits
- Published ConfirmMDx DOCUMENT validation study in the Journal of Urology
- Signed marketing agreements, with Long Island Pathology, Inc., American Pathology Partners, and Miraca Life Sciences (MLS) to co-promote ConfirmMDx
- Signed exclusive distribution agreement with Teva Pharmaceutical Ltd. for Israel
- Signed reimbursement agreements with PPO providers Prime Health Services, Inc., Galaxy Health Network Ancillary Care Services (ACS), and Consilium, LLC
- Palmetto GBA issued a Medicare coverage determination (LCD) for ConfirmMDx

## **Other Business Activities**

- Raised \$15 million in new equity funding via a private placement in November
- MDxHealth and HistoGeneX N.V. awarded \$1.8 million (€1.3 million) from the Flemish Institute for the Promotion of Innovation by Science and Technology (IWT)
- MDxHealth Licensee Exact Sciences received FDA approval and Medicare coverage for its Cologuard<sup>®</sup> colon cancer screening assay and started commercialization in Q4

# **Events after the Reporting Period**

- MDxHealth received the 2014 Euronext Best BEL Small Company Performer Award
- MDxHealth licensed epigenetic technology to Oncgnostics GmbH for cervical cancer test

Commenting on the excellent progress, Dr. Jan Groen, Chief Executive Officer of MDxHealth, said "In 2014, we experienced sharp growth in ConfirmMDx test volume and revenue driven by continued adoption by the U.S. urology community and positive reimbursement from payors, based on recognition of the substantial positive data supporting the assay's clinical value and utility. This growth led to a narrowing of our reported loss versus 2013." Dr. Groen added "The recent Medicare coverage decision for ConfirmMDx will have a significant positive impact on our business in 2015."

Dr. Groen continued: "We have also continued to make enhancements to our ConfirmMDx for Prostate Cancer test. Based on recent clinical and scientific studies, we developed a risk score for ConfirmMDx methylation-positive men. We believe this score will improve the risk stratification of biopsy-negative men who may be harboring undetected, aggressive prostate cancer, further augmenting the clinical value provided by ConfirmMDx."

Key Figures for the full year (thousands of U.S. dollars, except number of shares and per share data):

As of or for the year ended December 31*	4 <sup>th</sup> Quarter 2014	Full Year 2014	4 <sup>th</sup> Quarter 2013	Full Year 2013
Total revenues	3,372	11,671	1,576	7,554
Total operating expenses	7,077	27,013	5,875	23,625
EBITDA (Loss)	-3,611	-15,009	-4,234	-15,653
Operating profit (EBIT)	-3,705	-15,342	-4,299	-16,071
Net Income (Loss)	-3,019	-15,256	-4,387	-16,175
Earnings per share, basic (\$)	-0.08	-0.40	-0.13	-0.47
Number of outstanding shares	37,676,303		34,251,303	
Cash and cash equivalents	18,897		24,683	

## **Revenue and Income**

Total company revenues for the full year ended December 31, 2014, increased by 54% to \$11.7 million, compared to total revenues of \$7.6 million for the prior year. Revenue from ConfirmMDx for Prostate Cancer represented 70% of total Q4 revenues compared to 76% in the same quarter last year. Total revenues for Q4 2014 were \$3.4 million compared to \$1.6 million during the same period in 2013. The increase in Q4 2014 revenues compared to the prior period was due to increased sales of ConfirmMDx and royalty and milestone payments from Exact Sciences. For the full year, ConfirmMDx for Prostate Cancer accounted for 80% of the company's revenue, compared to only 50% in 2013.

At the end of 2014, MDxHealth received the Local Coverage Determination (LCD) for Medicare reimbursement of ConfirmMDx for Prostate Cancer through Palmetto GBA. The LCD not only sets the reimbursement rate for Medicare patients, but also establishes reimbursement for Medicare Advantage patients covered by private commercial payors. By virtue of the Center for Medicare and Medicaid Services policies, payors contracted to offer Medicare Advantage programs are obliged to honor the LCD and price established. MDxHealth will also pursue direct contracts with these payors to cover ConfirmMDx testing for their non-Medicare patient population under the age of 65 years old. The Medicare coverage decision did not impact 2014 cash collections, given the timing of the approval. However, the company expects the Medicare coverage decision for the ConfirmMDx for Prostate Cancer to improve cash collections going forward. As noted in previous press

releases, the growing adoption of the test by new prescribing urologists across the U.S. will continue to result in 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.

Based on 2014 reported cases and historical average reimbursement amounts, the total estimated value of tests performed in 2014 was \$19.1 million. Of this amount \$9.4 million was recognized as revenue, leaving uncollected outstanding unrecognized revenues of \$9.7 million, consisting of \$7.9 million from Medicare and \$1.2 million from private payors. This uncollected amount has been excluded from the Company's 2014 revenues. While collection efforts continue on these outstanding amounts, the timing and amount of actual collections is uncertain. MDxHealth's revenue recognition policy evaluates the certainty of payment on a payor-by-payor basis, currently resulting in a mixture of accrual based revenue recognition and cash based collections depending on our evaluation of certainty of payment. MDxHealth believes this revenue recognition policy is appropriate at this time. However, the recent Medicare coverage of ConfirmMDx should help to secure more managed care contracts. The Company expects to transition more payors to an accrual accounting basis resulting in increased revenue recognition in 2015.

In Q4 2014, the Company reported a net loss of \$3.0 million, or (\$0.08) a share, compared to a net loss of \$4.4 million, or (\$0.13) a share, in the same period of 2013. The Company's net loss for the year ended December 31, 2014, was \$15.3 million, or (\$0.40) a share, compared to \$16.2 million loss, or (\$0.47) a share, for the prior year. This loss is attributed to the continued investment in commercialization efforts in the U.S. and the delay in recognizing revenues from ConfirmMDx sales.

# **Operating Expenses**

Operating expenses for Q4 2014 were \$7.1 million, an increase of \$1.2 million compared to \$5.9 million in Q4 2013. This increase is attributable to the clinical utility study and other associated costs to meet the requirements of Medicare. Operating expenses for the year ended December 31, 2014 increased by \$3.4 million to \$27.0 million from \$23.6 million for the prior year. The year-over-year increase is due to the continuing build-up of U.S. operations to support the commercialization of the ConfirmMDx for Prostate Cancer test.

# **Cash Position**

The Company ended 2014 with cash and cash equivalents of \$18.9 million, compared to \$24.7 million on December 31, 2013. The Company raised net proceeds of \$14.7 million in a private placement in November 2014. Collections from ConfirmMDx reimbursements were \$4.5 million in 2014 vs. \$2.4 million in 2013. Collections, which are an important variable in net cash burn, are improving, and will be an important factor in strengthening the Company's cash position moving forward. More specifically, the Medicare LCD and its expected positive impact on private third party payor reimbursement decisions will enhance the company's collections going forward. Excluding the proceeds of the 2014 private placement, the Company had a net cash burn of \$20.5 million in 2014 compared to a net cash burn of \$15.3 million in 2013. This 25% increase in cash used by the Company is a result of expanding operating activities supporting the commercialization of the ConfirmMDx for Prostate Cancer test, an increase in accounts receivables and the start of the PASCUAL clinical utility trial.

## **Outlook**

For fiscal year 2015, the Company expects continuing growth in ConfirmMDx test volume and revenue driven by the recent positive Medicare coverage decision (LCD) by Palmetto GBA for the ConfirmMDx for Prostate Cancer test. Anticipated growth in reported case volume and revenue will be supported by the Company's continued focus on obtaining payor contracts, recognition in Clinical Guidelines and increasing reimbursement for the ConfirmMDx test. However, based on seasonality, some quarter-to-quarter fluctuation in reported case volume and revenue is expected. With increasing volume, gross margin on ConfirmMDx revenue for 2015 is anticipated to improve.

The Company is providing the following guidance for 2015:

- ConfirmMDx for Prostate Cancer test volume: 15,000 to 17,000
- Revenue: \$16 million to \$20 million
- Completion of the PASCUAL clinical utility trial
- Scientific publication on ConfirmMDx risk score profile
- Publication of the ConfirmMDx for Bladder Cancer validation study results

This guidance also reflects the Company's plans for continued expansion of its sales and marketing, managed care and billing personnel to drive and manage growth, as well as investment in product development, automation to reduce the cost of tests performed, and facilities.

# 2015 Reporting Calendar

2014 FY results: February 26, 2015

Q1 results: May 5, 2015
H1 results: August 20, 2015
Q3 results: November 3, 2015

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

The Company's 2014 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 may 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 2015.

## **About MDxHealth**

MDxHealth is a multinational healthcare company that provides actionable epigenetic information to personalize the diagnosis and treatment of cancer. The company's tests are based on proprietary gene methylation (epigenetic) technology and assist physicians with the diagnosis of cancer, prognosis of recurrence risk, and prediction of response to a specific therapy. For more information visit mdxhealth.com and follow us on Twitter at: twitter.com/mdxhealth.

### For more information:

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