

## MDxHealth Reports Fourth Quarter and Fiscal Year 2015 Results

*Full Year ConfirmMDx Revenue up 62% Compared to Full Year 2014*

**IRVINE, CA, and HERSTAL, BELGIUM** – 7:00 AM, February 18, 2016 – MDxHealth SA (Euronext: MDXH.BR) today announced its financial results for the fourth quarter and fiscal year ended December 31, 2015.

### Financial Highlights

- ConfirmMDx revenue up 62% to \$15.2 million in 2015 compared to \$9.4 million in 2014
- Total full-year 2015 revenue up 51% to \$17.6 million versus \$11.7 million in 2014
- Q4 2015 revenue more than doubled to \$4.9 million versus \$2.4 million in the same period in 2014, demonstrating the impact of strategic investments made in H2 2015 in our sales force and managed care team
- Full year 2015 ConfirmMDx case volume exceeded 15,000 patients tested, compared to 12,300 in 2014
- Net loss for the full-year 2015 narrowed to \$14.5 million compared to \$15.3 million in 2014
- Cash and cash equivalents of \$31.7 million, at December 31, 2015

### Corporate Highlights

- Strengthened global commercial urologic oncology product offering with the acquisition of NovioGendix, providing MDxHealth with a validated, non-invasive, 'liquid biopsy' test branded SelectMDx for Prostate Cancer, currently available in the EU and soon to be launched in US
- Signed 19 contracts for ConfirmMDx with commercial and/or Medicare Advantage payer organizations (including Aetna, UPMC, Vanderbilt University, Tufts, BCBS of IL, BCBS of MA, SelectHealth and Priority Health), highlighting the impact of our emphasis on gaining broader reimbursement
- Partnered with SouthGenetics Inc. for the commercialization of ConfirmMDx® for Prostate Cancer in 12 countries across Central and South America
- Signed worldwide methylation specific polymerase chain reaction (PCR) out-licensing agreement with German diagnostics company, oncnostics GmbH, for the identification of cervical cancer, underscoring the broad application of our epigenetic approach
- Signed worldwide exclusive license agreement with University Erasmus Medical Center for DNA methylation markers for our non-invasive, urine-based "liquid biopsy" test, AssureMDx for Bladder Cancer
- Strengthened management team and Board with the appointment of Philip J. Ginsburg, M.D. as Chief Medical Officer and Walter Narajowski as an Independent Director

### Research & Development Highlights

- Joined the prospective 4M clinical study evaluating the synergy of MRI and SelectMDx for Prostate Cancer. The 600-patient study is designed to evaluate the effectiveness of emerging technologies for the improved selection of patients for prostate biopsy
- Signed agreement with University Erasmus Medical Center for the inclusion of AssureMDx for Bladder Cancer in a prospective clinical study to validate for recurrence monitoring of patients treated for non-muscle invasive bladder cancer (NMIBC)
- Presented data at the American Urological Association (AUA) 2015 Annual Meeting demonstrating the potential prognostic value of the ConfirmMDx test genes and their ability to aid in the detection of clinically significant prostate cancer. MDxHealth hopes to be able to introduce and promote this aspect of the test in 2016

- Presented data at the 11th World Congress on Urological Research in September demonstrating that the mRNA biomarkers that comprise the SelectMDx for Prostate Cancer test can improve patient stratification for risk of low and high-grade prostate cancer, and the need for prostate biopsy
- Reported data validating the clinical performance of the AssureMDx for Bladder Cancer test at the 11th World Congress on Urological Research, demonstrating its high negative predictive value and supporting the use of AssureMDx for avoidance of unnecessary invasive procedures

### Post 2015 Events

- Published data in *The Journal of Urology* demonstrating that AssureMDx for Bladder Cancer delivers a high negative predictive value of 99.2% supporting the clinical potential of the Company's urine-based epigenetic bladder cancer test to aid urologists in the management of patients presenting with haematuria (i.e., blood in urine)
- Presented data at the American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium demonstrating that ConfirmMDx genes can aid in the detection of clinically significant prostate cancer, as well as difficult to detect anterior cancers, further validating the product's clinical utility for patients who may benefit from early detection and treatment
- Received the 2016 Frost & Sullivan Global Prostate Cancer Diagnostics Technology Innovation Award

**Dr. Jan Groen, CEO of MDxHealth commented:** “It is my pleasure to provide an update on our strong progress in 2015. Our stated aims were to focus on strengthening our position in the urologic oncology molecular diagnostics market and to increase the market share of ConfirmMDx in the US. The strategic investments we made in our sales force and managed care teams in the second half of 2015 were effective as evidenced by the sharp increase in revenue.

During the year we substantially expanded adoption of ConfirmMDx within the US urology community, with over 15,000 patients tested in 2015, an increase of 22%. As a result, we saw a strong rise in annual revenue, with year-on-year growth of 51%. In Q4 alone, traditionally a slower sales period due to the holiday season, reported revenues doubled compared to the previous year. We expect to carry this positive momentum into 2016, driven by growing adoption of ConfirmMDx for Prostate Cancer among US urologists.

In the coming year, an important strategic focus for the Company will be expanding our product pipeline and test indications to address further unmet medical needs for cancer patients. With the strategic acquisition of NovioGen, we now offer SelectMDx™ for Prostate Cancer, a non-invasive, liquid biopsy test which is currently available as a laboratory testing service in Europe, with plans to launch in the US and elsewhere internationally in the first half of 2016. In addition we expect to launch our second liquid biopsy test, AssureMDx™ for Bladder Cancer, later in 2016.

Our mission remains to improve patient outcomes by delivering molecular diagnostic solutions for urologic cancers. To that end, I am confident that our dedicated efforts and investment in our urologic oncology portfolio, commercialization activities and operations has positioned us to capture market share and increase shareholder value.”

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

<i>As of or for the year ended December 31</i>	<b>4<sup>th</sup> Quarter 2015</b>	<b>Full Year 2015</b>	<b>4<sup>th</sup> Quarter 2014</b>	<b>Full Year 2014</b>
Total revenues	5,692	17,640	3,372	11,671
Total operating expenses	9,772	32,022	7,077	27,013
EBITDA (Loss)	-3,649	-13,634	-3,611	-15,009
Operating profit (EBIT)	-4,080	-14,382	-3,705	-15,342
Net Income (Loss)	-4,149	-14,473	-3,019	-15,256
Earnings per share, basic (\$)	-0.09	-0.32	-0.08	-0.40
Number of outstanding shares	45,153,633		37,676,303	
Cash and cash equivalents	31,680		18,897	

### **Revenue and Income**

Total company revenues for the full year ended December 31, 2015 increased 51% to \$17.6 million, compared to total revenues of \$11.7 million for the prior year. For the full year, ConfirmMDx for Prostate Cancer accounted for 86% of the Company's revenue, compared to 80% in 2014. Total revenues for Q4 2015 increased to \$5.7 million compared to \$3.4 million during the same period in 2014. Revenue from ConfirmMDx for Prostate Cancer represented 86% of total Q4 revenues compared to 70% in the same quarter last year. The increase in Q4 2015 revenues compared to the prior period was due to increased sales of ConfirmMDx and royalty and milestone payments from Exact Sciences.

Based on 2015 reported cases and historical average reimbursement amounts, the total estimated value of tests performed in 2015 was \$36 million. Of this amount \$15.2 million was recognized as revenue, leaving uncollected outstanding unrecognized revenues of \$20.8 million, consisting of \$1.7 million from Medicare and \$19.1 million from private payors. This uncollected amount has been excluded from the Company's 2015 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 has already resulted in an increased number of contracts with private payors as well as managed care contracts. The Company continues to expect to transition more payors to an accrual accounting basis resulting in increased revenue recognition in 2016.

The Company's net loss for the year ended December 31, 2015, was \$14.5 million, or (\$0.32) a share, compared to \$15.3 million loss, or (\$0.40) a share, for the prior year. In Q4 2015, the Company reported a net loss of \$4.1 million, or (\$0.09) a share, compared to a net loss of \$3.0 million, or (\$0.08) a share, in the same period of 2014. The increased loss in Q4 2015 is attributable to the costs associated with the acquisition of NovioGendix in Nijmegen, The Netherlands, the continued investment in commercialization efforts in the US and our evolving revenue recognition policies for ConfirmMDx sales.

### **Operating Expenses**

Operating expenses for the year ended December 31, 2015 increased by \$5.0 million to \$32.0 million from \$27.0 million for the prior year. The year-over-year increase is due to R&D spending on new products and the continuing build-up of US operations to support the commercialization of the ConfirmMDx for Prostate Cancer test and preparation for new uro-oncological products. Operating expenses including Cost of Sales for Q4 2015 were \$9.8 million, an increase of \$2.7 million compared to \$7.1 million in Q4 2014. This increase is attributable to R&D spending, continued costs related to the clinical utility study for ConfirmMDx, and additions to staff in sales, managed care, information technology and medical affairs. Q4 2015 Cost of Sales remained flat

compared to same period last year despite higher volumes, due to laboratory efficiencies gained from automation.

### **Cash Position**

The Company ended 2015 with cash and cash equivalents of \$31.7 million, compared to \$18.9 million on December 31, 2014. The Company raised net proceeds of \$29.5 million in a private placement in June 2015. Collections from ConfirmMDx reimbursements were \$12.2 million in 2015 vs. \$4.5 million in 2014. Collections, which are an important variable in net cash burn, are improving, and will continue to be an important factor in strengthening the Company's cash position moving forward. The Medicare coverage determination (LCD) has had a positive impact on private third party payor reimbursement decisions and this will continue to enhance the company's collections going forward.

### **Outlook**

For the 2016 fiscal year, the Company expects to see continued growth in revenue driven by the increase in sales representatives, new payor contracts, increased adoption of ConfirmMDx and introduction of the SelectMDx for Prostate Cancer test on the EU and US market. However, based on seasonality, some quarter-to-quarter fluctuation in reported case volume and revenue is expected. With increasing product offerings, test volumes and expanding coverage with payor contracts, both revenue and cash collections for 2016 are anticipated to improve. Importantly, increasing payor coverage is expected to reduce days sales outstanding (DSO) for receivables. In addition, following issuance of the Medicare coverage determination (LCD) for ConfirmMDx in November 2014, the Company continues to work collaboratively with the MoIDX Program, administered by Palmetto GBA, to generate clinical study data and collect registry data under Coverage with Data Development (CDD) to support a transition to unrestricted coverage for our ConfirmMDx test.

The Company is providing the following guidance for 2016:

- Revenue growth between 30% to 50%
- Improved EBITDA compared to 2015
- Publication of SelectMDx validation study
- Launch SelectMDx on US market in H1
- Launch AssureMDx on US market in H2

### **2016 Reporting Calendar**

- 2015 FY results: February 18, 2016
- Q1 results: May 3, 2016
- H1 results: August 18, 2016
- Q3 results: November 3, 2016

### **Financial Statements and Auditors' Review**

The Company's statutory auditor, BDO Bedrijfsrevisoren Burg. Ven. CBVA, has confirmed that its audit procedures with respect to the Company's consolidated financial statements, prepared in accordance with the International Financial Reporting Standards as adopted in the European Union, have been substantially completed, that these procedures have not revealed any material adjustments that would have to be made to the accounting information derived from the Company's consolidated financial information that is included in this press release, and that it intends to issue an unqualified opinion.

The condensed Consolidated Statement of Comprehensive Income may be found on the Company's website at [www.mdxhealth.com](http://www.mdxhealth.com). The full Annual Report is expected to be made available to the public via the Company's website in April 2016.

[About MDxHealth](#)

MDxHealth is a multinational healthcare company that provides actionable molecular diagnostic information to personalize the diagnosis and treatment of cancer. The company's tests are based on proprietary genetic, epigenetic (methylation) and other molecular technologies and assist physicians with the diagnosis of urologic cancers, prognosis of recurrence risk, and prediction of response to a specific therapy. The Company's European headquarters are in Herstal, Belgium, with laboratory operations in Nijmegen, The Netherlands, and US headquarters and laboratory operations based in Irvine, California. For more information visit [mdxhealth.com](http://mdxhealth.com) and follow us on Twitter at: [twitter.com/mdxhealth](https://twitter.com/mdxhealth).

**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)

Consilium Strategic Communications (IR & PR)  
Amber Fennell, Chris Welsh & Hendrik Thys  
UK: +44 20 3709 5701  
[mdxhealth@consilium-comms.com](mailto:mdxhealth@consilium-comms.com)

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