

## MDxHealth Reports Financial Year 2016 Results

*Record revenue of \$30 million, up 70% from 2015  
Total test volume up 57% over 2015*

**Conference call for analysts and investors today at 15:00 CET / 09:00 EST, details below**

**IRVINE, CA, and HERSTAL, BELGIUM** – 7:00 AM, February 23, 2017 – MDxHealth SA (Euronext: MDXH.BR), or the “Company”, today announced its financial results for the financial year ended December 31, 2016.

### KEY HIGHLIGHTS

#### **Financial**

- Total revenue of \$30.0 million up 70% from \$17.6 million in 2015 driven by strong growth of ConfirmMDx<sup>®</sup> and successful launch of SelectMDx<sup>™</sup>
- US revenue was \$24.4 million, up 60% from \$15.2 million in 2015. Non-US revenue was \$5.6 million, up 133% or \$2.4 million compared to 2015
- EBITDA of \$(11.1) million improved by \$2.5 million from 2015
- Cash and cash equivalents of \$30.9 million, at December 31, 2016 following successful capital raise of €20.4 million (\$21.7 million)
- Nearly 24,000 patients tested worldwide across all MDxHealth products in 2016, with SelectMDx representing approximately 17% of the total

#### **Corporate**

- Strong growth of ConfirmMDx driven by wide market adoption and continued expansion of reimbursement coverage
  - ConfirmMDx included in the US National Comprehensive Cancer Network (NCCN) Clinical Guidelines
  - 19 new payor agreements added and 28 payor issued positive medical policies on ConfirmMDx in US
  - Obtained unique Category I MAAA Current Procedural Terminology (CPT) code effective January 2018
- Successful US commercial launch of SelectMDx including coverage from 11 US payors and 7 distribution agreements in Europe, Asia, Latin America and Israel
- Continued strong body of evidence demonstrating the clinical significance of MDxHealth tests with 10 clinical papers and abstracts published, including 7 for ConfirmMDx, 2 for SelectMDx and 1 for AssureMDx<sup>™</sup> (for bladder cancer)
- ISO Certification granted for MDxHealth’s laboratory in The Netherlands, an important step in the Company’s in vitro diagnostic commercial strategy in Europe and other international markets

#### **Post-Period End**

- US Government Services Administration (GSA) contract awarded for ConfirmMDx
- Positive coverage policy on ConfirmMDx for Horizon Blue Cross Blue Shield of New Jersey
- Non-exclusive distribution agreement with Istituto Diagnostico Varelli to offer SelectMDx throughout central and southern Italy

**Dr. Jan Groen, Chief Executive Officer of MDxHealth commented:** “The strong progress made in 2016 with the accelerated adoption of ConfirmMDx and the successful launch of our first liquid biopsy test, SelectMDx, demonstrates the significant potential of MDxHealth’s world leading urological oncology franchise.”

“With the ongoing roll out of SelectMDx, together with the planned launch of our second liquid biopsy test AssureMDx for Bladder Cancer this year, the Company continues to make rapid and meaningful progress in the expansion of its portfolio of products that address unmet medical needs for cancer patients, while leveraging the commercial infrastructure we have built over the last several years. We are pleased with our progress in 2016 and believe MDxHealth is well positioned to build strong, sustainable growth in 2017 and beyond.”

## **BUSINESS AND STRATEGIC REVIEW**

### ***Strong growth of ConfirmMDx driven by wide market adoption and continued expansion of reimbursement coverage***

NCCN Guideline inclusion and increasing adoption has enabled MDxHealth to secure 19 reimbursement contracts, while 28 payors issued positive medical coverage policies. The test is now also covered under the California Medical Assistance Program (Medi-Cal), the single largest state-run public health program in the US with nearly 12 million enrollees. This positive trend will continue in 2017 with Horizon Blue Cross Blue Shield recently issuing positive policy coverage for more than 3.8 million members. The recently obtained unique ConfirmMDx CPT code, effective January 2018, is expected to further streamline the Company’s reimbursement efforts and significantly reduce collection periods.

Further to the period end, MDxHealth was awarded a US Government Services Administration (GSA) contract. This contract is critical to making ConfirmMDx widely accessible to authorized government customers.

The Company’s continued investments in demonstrating clinical utility and improved patient care from use of ConfirmMDx has resulted in publication in 10 clinical scientific publications and presentations, including in the journal *The Prostate*. Scientific data were also presented at several urology conferences across the US, including the Annual Meeting of the American Urology Association (AUA) in San Diego, and the Symposium of the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) in San Francisco.

### ***Successful global commercial launch of first liquid biopsy test SelectMDx. Second liquid biopsy test AssureMDx for Bladder Cancer set for 2017 full commercial launch***

Following the European launch in late 2015, the Company’s proprietary liquid biopsy test SelectMDx was commercially launched in the US in March 2016. This non-invasive urine-based test identifies men at risk for clinically significant prostate cancer who may benefit from an initial prostate biopsy or magnetic resonance imaging (MRI). The validation study published in *European Urology* confirms the superior performance compared to other commonly used biomarker tests and risk calculators. The enrollment of the prospective 4M clinical study on 600 subjects evaluating the synergy of MRI and SelectMDx is complete and results are expected to be published in the course of 2017.

In the US, SelectMDx is marketed as a Laboratory Developed Test (LDT) through MDxHealth’s sales force. Outside the US, the Company pursues a direct sales strategy in the Benelux, Germany and Italy, complemented by European and global distributors and commercial lab partners. The Company concluded several agreements for the distribution of SelectMDx, covering various countries in Europe, Central and Latin America, Israel and most recently Hong Kong and Macao China. Outside the US, the test is currently performed at the Company’s ISO 13485:2016 certified lab in Nijmegen, The Netherlands.

Volumes for SelectMDx since its US launch in 2016 were nearly 3.5 times higher compared to the first year for ConfirmMDx, representing 17% of the total test volume for 2016. The fast uptake of this test by urologists and their patients has already resulted in 11 payor contracts in the first year.

In the last quarter of 2016, the Company beta launched its second liquid biopsy test, AssureMDx for Bladder Cancer. The launch followed the publication of two clinical validation studies underscoring the test's clinical validity. AssureMDx has a very high negative predictive value of 99% and may significantly reduce unnecessary invasive and costly cystoscopy procedures. With 700,000 cystoscopy procedures performed in the US every year, AssureMDx addresses a potential \$300 million market in the US, and is scheduled for commercial launch in the US as an LDT by the end of the first half of 2017.

### ***Leveraging our cutting-edge technology for licensing opportunities***

MDxHealth has built a robust portfolio of proprietary biomarkers for molecular assays for areas such as colorectal, lung and brain cancers. In addition to its proprietary offering in uro-oncology, the Company leverages this non-core portfolio of biomarkers and technologies through various licensing agreements. In 2016, MDxHealth granted a non-exclusive worldwide license for its methylation-specific PSR (MSP) technology to QIAGEN for use in its diagnostic cervical cancer assay, QIASure.

## **FINANCIAL REVIEW**

Key unaudited consolidated figures for the financial year ended December 31, 2016 (thousands of US dollars, except number of shares and per share data):

<i>As of or for the year ended December 31</i>	<b>2016</b>	<b>2015</b>	<b>Change</b>	<b>Change as a %</b>
Revenues	29,970	17,640	12,330	69.9%
Gross Profit	19,867	10,735	9,132	85.1%
Operating expenses	32,713	25,117	7,596	30.2%
EBITDA (Loss)	(11,126)	(13,634)	2,508	(18.4)%
Operating profit (EBIT)	(12,846)	(14,382)	1,536	(10.7)%
Net Income (Loss)	(13,174)	(14,473)	1,299	(9.0)%
Earnings per share, basic (\$)	(0.26)	(0.32)	0.06	(18.7)%

### ***Revenue and Gross Profit***

Total revenues for the year ended December 31, 2016 amounted to \$30 million, an increase of 70% compared to total revenues of \$17.6 million a year earlier and included \$25 million of product and service income. The strong growth in the US contributed \$24.4 million or 82% of total revenue. Non-US revenues included initial sales of SelectMDx, milestone payments and royalties from license deals, and came in at \$5.5 million, up 133% or \$2.4 million compared to 2015.

Total net billings for 2016 amounted to \$49.3 million. However, the Company only recognizes revenue when there is reasonable evidence that the test will effectively be reimbursed. As a result, a significant portion of the revenue is only recognized when the payment is collected, leaving a significant portion of invoiced amounts unrecognized in 2016. The deferral of part of the revenue gradually decreases as the Company concludes firm agreements for reimbursement with a growing number of payors.

Cost of goods sold for 2016 came in at \$10.1 million, compared to \$6.9 million in 2015. Increased revenues resulted in a gross profit of \$19.9 million, while a sustained focus on operational

efficiencies yielded an improvement of the gross profit margin from 60.9% in 2015 to 66.3% in 2016.

### ***Operating Expenses***

Operating expenses for the year ended December 31, 2016 amounted to \$32.7 million, an increase of \$7.6 million or 30.2%. The year-on-year increase is mainly attributable to the acquisition of NovioGendix (renamed to MDxHealth BV), which was only included for one quarter in 2015. Furthermore, MDxHealth invested in the build-out of the organisation to support the global commercial launch of SelectMDx. MDxHealth adopts a direct sales strategy for SelectMDx in Benelux, Germany and Italy, supported by European and global distributors and commercial lab partners. The Company appointed a global commercial team to cover business development and direct sales. Finally, the Company continued to validate the clinical utility of its expanded offering through clinical trials and publications. R&D spending remained level with last year despite the increased pace of newly developed product launches.

EBITDA for the year improved by \$2.5 million as the loss was reduced from \$13.6 million in 2015 to \$11.1 million. This improvement was partly offset by increased amortization charges, bringing the Company's net loss for 2016 to \$13.2 million, \$1.3 million better than in 2015. The increased amortization resulted from scheduled amortization of intangible assets associated with the acquisition of NovioGendix in 2015.

### ***Cash Position***

Cash and cash equivalents stood at \$30.8 million at the end of 2016 after having successfully raised \$21.7 million (€20.4 million) in a private placement of 4,526,962 new shares at €4.50 (\$4.99) per share. The number of outstanding shares at December 31 was 49,796,595.

Increased private payor adoption and a sustained focus on reimbursement has helped to improve working capital throughout 2016. Cash used by operations amounted to \$16.6 million, compared to \$14.4 million in 2015, and included cash collections of \$19.7 million, a 61% increase year-on-year. The award of a unique CPT code by the AMA, which will become effective January 1, 2018, is expected to significantly shorten collection periods from both Medicare and private payors.

## **OUTLOOK**

MDxHealth is committed to maintaining its focus on its strategic priorities during 2017. These include:

- Growth between 55% to 75% on product and service income, excluding royalties and milestone payments, with the high-end of the range being driven by sustained growth of SelectMDx in the US and Europe and early commercial success of AssureMDx in the US
- Increasing utilization of its products in and outside the US, contributing to a continuing reduction in operating losses
- Increasing private payor adoption and securing favourable reimbursement rates for ConfirmMDx and SelectMDx in the US, which is expected to improve collectability and to reduce working capital requirements
- Continue to expand its product and services offering and leverage its established commercial presence through the launch of AssureMDx for Bladder Cancer
- Continuing to demonstrate the clinical utility of its product portfolio through peer-review articles, including:
  - Publishing a prospective clinical study for SelectMDx
  - Publishing SelectMDx health economic data
  - Launch of the SelectMDx CE-marked in vitro diagnostic (IVD) kit

## WEBCAST AND PRESENTATION

MDxHealth will host a conference call today at 15:00 CET / 14:00 GMT / 09:00 EST / 06:00 PT to discuss its Financial Year 2016 results. To access the conference call, please dial one of the appropriate numbers below quoting the conference ID 69886101.

Belgium:	+32 (0)81 70 00 61
The Netherlands	+31 (0)8000 235 091
UK:	+44 (0)1452 55 55 66
US:	+1 (866) 966-9439

The call will be conducted in English and a replay will be available for 30 days.

The presentation will be made available on the investors section of the MDxHealth website shortly before the call and can be accessed at: <http://mdxhealth.com/investors>.

## 2017 REPORTING CALENDAR

- Q1 results: May 8, 2017
- H1 results: August 31, 2017
- Q3 results: November 2, 2017
- Preliminary update of top line 2017 FY results: January 5, 2018

## FINANCIAL STATEMENTS AND AUDITOR 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 2017.

### [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. MDxHealth'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).

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