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MDxHealth_FY_Results EN

NEWS RELEASE INFORMATION **REGULATED ANNUAL FINANCIAL REPORT**

MDxHealth Reports Financial Year 2017 Results

Product revenue of $28 million up 13% and total revenue of $40 million up 35% with continued strong volume growth

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

IRVINE, CA, and HERSTAL, BELGIUM - 07:00 CEST, February 22, 2018 - MDxHealth SA ("MDxHealth, or the "Company"), (Euronext: MDXH.BR), today announced financial results for the financial year ended December 31, 2017 and provided an update on its strategic outlook.

2017 was an important year for the continuing development of MDxHealth into the world's leading urological molecular diagnostic company. While the Company encountered some challenges in the latter part of the year relating to short term revenue, revenue and patient test volumes continued to grow. The Company made good operational progress in 2017, aligning its commercial organization and management structure. The Board believes that MDxHealth is well placed to continue driving its innovative urological franchise, increasing market share and realising the market potential of its commercial stage tests across global markets.

The Company has a clear focus for MDxHealth's growth in 2018 and beyond. This is centred around four key pillars:

- Driving adoption of the Company's commercial tests with urologists and payors in the US and Europe
- Expanding the clinical indications for SelectMDx
- Expanding usability of MDxHealth tests by porting them onto IVD sample-to-answer platforms
- Working with pharmaceutical partners to create precision diagnostics

"We remain confident in the potential of ConfirmMDx, which we expect to continue driving momentum in the mid-term and for which we have a renewed approach aimed at capturing additional market share. In the longer term, we expect SelectMDx to continue driving growth with numerous value driving inflection points in the coming years. We are positive about the outlook for the current year," said **Dr. Jan Groen, Chief Executive Officer of MDxHealth.** *"We believe MDxHealth can achieve a higher level of Product and Services revenue growth*

than in 2017. It is too early in the financial year to predict the exact level of growth, but we will provide an update in due course."

Financial Highlights

- Product and services revenue of $28.2 million, up 13% from $24.9 million in 2016
- Total revenue of $40.5 million up 35% from $30.0 million in 2016, driven in part by $12.1 million net revenue from the one-time payment by Exact Sciences for MDxHealth patents for the Cologuard testOperating loss of $12.3 million compared to an operating loss of $12.8 million in 2016
- EBITDA of $-10.4 million compared to $-11.1 million in 2016
- Cash collections on products and services of $23.1 million, up 17% from $19.7 million in 2016
- Cash and cash equivalents of $16.8 million as of December 31, 2017

Operational Highlights

Good progress in test volume, with over 33,100 patients tested with SelectMDx and ConfirmMDx products worldwide in 2017, up 39% from nearly 24,000 patients tested in 2016. US-based testing represented 91% of total volume at 30,000, with total volume for Europe at 3,100. Further highlights include:

ConfirmMDx®

- Total US test volume grew to 21,400 in 2017 from 20,400 in 2016
- Q4 total test volume grew 14% to 6,400 in 2017 from 5,600 in 2016, reflecting the initial momentum from an increase in the sales team from 33 to 50
- Action taken in Q4 to optimize the Company's commercial structure towards a more targeted sales approach
- 20 new US payor contracts for ConfirmMDx including US General Services Administration allowing ConfirmMDx to be available to federal, state and local government buyers, Kaiser Southern California Permanent Medical Group which serves 4.4 million members, 10 out of 36 Blue Cross Blue Shield Association® affiliated plans, Medicaid programs and commercial payors, bringing the total number of contracted payors to 62
- Four new US positive coverage policies for ConfirmMDx

SelectMDx®

- Strong growth for SelectMDx with total global test volume of 11,700 in 2017 versus 4,000 in 2016

- EU SelectMDx test volume up more than 300% to over 3,100 patients tested compared to 800 in 2016

- SelectMDx IVD PCR Kit launch* and adoption by the first large medical laboratory, MVZ Dr. Stein & Kollegen, a subsidiary of the Limbach Gruppe SE in Germany
- Four new US payor contracts for SelectMDx, now totalling 15 payors

- Nine SelectMDx distribution agreements signed in 2017 in seven countries across Europe

AssureMDx

- Initial commercial rollout of MDxHealth's third commercial test in the US, AssureMDx(TM) for Bladder Cancer, a liquid biopsy laboratory developed test (LDT) to assess the risk of bladder cancer for patients diagnosed with haematuria

- Strengthening data set for AssureMDx to support its data package for future reimbursement coverage with a prospective multi-center validation study of AssureMDx for Bladder cancer in over 1,000 patients with haematuria (Published in Urologic Oncology)

Corporate Review

- Expansion of executive functions with the appointments of Jean-Marc Roelandt as Chief Financial Officer, Michael K. Brawer, MD as Chief Medical Officer, and Paul Marr as Executive Vice President of Sales for North America
- Lieve Verplancke MD was nominated as an Independent Non-Executive Director at the Company's Annual General Shareholders Meeting held on 26 May 2017. On October 27, 2017, the Board of Directors elected Mrs. Hilde Windels as an Independent Executive Director. On October 19, 2017, Mark Shaffar, Chairman of the Board of Directors (represented by Shaffar LLC), retired from the Board. The Board of Directors has elected Mr. Wally Narajowski to be the new Chairman

Post period highlights

- In January 2018, MDxHealth announced promising research results published in peer-reviewed journal *The Prostate*, with a new liquid biopsy test in development to help guide personalized treatment of castration-resistant prostate cancer (CRPC) patients
- Data from this study is indicative of MDxHealth's strategy to bring new high precision liquid biopsy tests to market and to support pharmaceutical companies in the development of personalized therapeutics based on significant clinical data

2017 Business Review

MDxHealth's world leading uro-oncology focused molecular diagnostic platform is positioned to capitalize on two critical global trends in healthcare currently: the ever growing incidence of cancer and the demand for fast, actionable, cost-effective cancer diagnosis and patient monitoring. MDxHealth's suite of commercial products and its innovative liquid biopsy pipeline

seek to meet these needs in a market which is estimated to be worth $ 4.2 billion and to grow by 7% to 4.6 billion in 2022.

ConfirmMDx
Our lead product ConfirmMDx for prostate cancer helps urologists identify low-risk men who may forego an unnecessary repeat biopsy and high-risk men who may benefit from intervention. ConfirmMDx is the first epigenetic tissue-based test in the NCCN Guidelines for early detection of prostate cancer and that addresses false negative biopsy concerns. ConfirmMDx has qualified for Medicare reimbursement and covered by numerous private health insurance plans.

During 2017, MDxHealth has been focused on increasing adoption and acceptance of ConfirmMDx in the US with a focus on private payors. Throughout 2017 an additional 20 new US payor contracts for ConfirmMDx were signed. Payors reimbursing the tests now include the US Government Services Administration, 10 of 36 Blue Cross Blue Shield Association® affiliated plans, Medicaid programs and commercial payors, bringing the total number of contracted payors to 62.

The Company increased its sales force in the US from 33 to 50 and in the fourth quarter reorganized it to tailor commercial efforts to key customer channels. 42 sales reps and 8 strategic account managers will cover redesigned geographies and strategic accounts incorporating over 12,000 urologists, 80% of whom are involved in the diagnosis of prostate cancer including those within the following customer groups:

- Large Urology Group Practices (LUGPA) with 152 centers responsible for approximately 30% of all the biopsy procedures
- Integrated Health Networks including to Kaiser Permanente and the VA
- Community based urologists

ConfirmMDx patient volumes continued to grow in the year despite some challenges. Initial revenue expectations included initial volumes from a healthcare services contract with Kaiser Permanente Southern California and volumes from a large multi-center study aimed at supporting on-going Medicare coverage for ConfirmMDx. These programs are central to securing ongoing Medicare coverage by providing required on-going clinical utility data, extensive education and training and supporting the consistent use of ConfirmMDx in the every-day workflow of urologists, both during and after the completion of the studies.

Delivery of the projected number of billable cases failed to materialize due to unforeseen operating issues. The Company expects a portion of the cases to roll over into 2018.

ConfirmMDx currently occupies an estimated 8% market share and the Company believes that there is a substantial opportunity for this to continue to grow in the mid-term.

SelectMDx
MDxHealth's focus during 2017 was to drive further market penetration, both in the US and Europe, as a result of the on-going roll out of SelectMDx. SelectMDx is MDxHealth's first liquid biopsy test which helps to identify men at increased risk of harboring aggressive, potentially lethal, prostate cancer who may benefit most from a prostate biopsy and earlier detection.

MDxHealth has signed nine new contracts with European and Middle-East distributors, which combined with the international launch of the CE-marked SelectMDx IVD-kit, enabled the Company to leverage the commercial infrastructure built over the last several years and make rapid and meaningful progress in the expansion of this product.

In October, the Company added to its commercial and R&D infrastructure through the opening of a new service and research laboratory at the Novio Tech Campus in Nijmegen, the Netherlands. This state-of-the-art laboratory has expanded the Company's capacity to perform SelectMDx tests in Europe and support on-going research, development and commercial activities.

SelectMDx is currently indicated in the US and Europe for use in testing men with elevated PSA levels of 3-10 ng/ml before biopsy. However, the Company sees significant opportunity for SelectMDx to extend its use beyond the current validated pre-biopsy indication through active monitoring of 300,000 patients annually in the US and through use by general practitioners in the primary care setting for patients with lower levels of elevated PSA. The Company believes that these initiatives can quadruple the market opportunity for SelectMDx to more than 2 million patients annually in the US and a similar number for Europe.

In 2017, the Company initiated and completed two US clinical validation studies for SelectMDx in an active surveillance population with the John Hopkins University and the Canary Foundation. Data from these studies is expected in 2018.

In addition, 2017 saw the publication of cost-effectiveness studies conducted in the the Netherlands and published in the *British Journal of Urology.* In addition, five cost-effectiveness studies were completed in Spain, Italy, Germany, France and the US. These studies demonstrated that SelectMDx improves patient outcomes while significantly reducing healthcare costs by foregoing unnecessary invasive procedures, including biopsies and multiparametric MRI (mpMRi). In April, publication of an analytical validation study in *Translational Medicine Communications*, demonstrated the robustness, reproducibility and interlaboratory performance of the SelectMDx test.

In addition, SelectMDx was evaluated in the following studies:

- Data from a retrospective study, conducted by the Radboud Medical Center and published in *The Prostate*, demonstrated that SelectMDx correlated with multipara metric MRI (mpMRI) and outperformed the PCA3 test
- SelectMDx adopted by the Michigan Medicine Prostate Cancer Risk Clinic at US University of Michigan hospital as a pre-biopsy diagnostic tool to monitor men with previously diagnosed genetic mutations
- A US and European cost-effectiveness studies demonstrated that SelectMDx improved patient outcomes while significantly reducing healthcare costs by preventing over-diagnosis and overtreatment of men with clinically insignificant prostate cancer

AssureMDx

- AssureMDx for Bladder Cancer is a proprietary urine-based, molecular diagnostic test that offers a non-invasive 'liquid biopsy' method to improve the identification of patients at increased risk for bladder cancer who will benefit from further clinical evaluation. The test delivers a negative predictive value (NPV) of 99% for bladder cancer, helping to reduce the need for unnecessary invasive cystoscopy procedures by up to 77%, thereby reducing healthcare costs
- Initial commercial rollout of AssureMDx for Bladder Cancer commenced in 2017 in the US

2017 Financial Review

Key unaudited consolidated figures for the financial year ended December 31, 2017 (thousands of US dollars, except per share data):

As of or for the year ended December 31	**2017**	**2016**	***Change***	***Change as a %***
Revenue	40,508	29,970	*10,538*	*35.2%*
Gross Profit	30,305	19,867	*10,438*	*52.5%*
Operating expenses	(42,579)	(32,713)	*(9,866)*	*(30.2) %*
EBITDA (Profit/(Loss))	(10,388)	(11,124)	*736*	*6.6%*
Operating profit/(loss) (EBIT)	(12,274)	(12,846)	*572*	*4.5%*
Net Income/(Loss)	(12,288)	(13,174)	*886*	*6.7%*
Earnings per share, basic ($)	(0.25)	(0.26)	*0.01*	*6.9%*

Revenue and income

Total revenue for the year ended December 31, 2017, increased by 35% to $40.5 million, compared to $30 million a year earlier. Revenue included the sale of the Company's patents directed towards colorectal cancer to Exact Sciences. Excluding revenue from Exact Sciences for both periods, total products and services revenue increased by approximately 13% to $28.2 million during 2017. While its growth was hampered by delays encountered during the fourth quarter in obtaining billable cases from contracted customers and from a large post-marketing study, ConfirmMDx remained the lead product and accounted for 91% of product and services revenue. The reduction of ConfirmMDx's contribution from 97% in 2017 to 91% in 2017, also results from continued strong growth of SelectMDx, both in the US and in Europe. Test volumes for SelectMDx grew by more than 250%, and accounted for 35% of total volumes. The lower price point of SelectMDx compared to ConfirmMDx and the early stage of payor adoption however limited the revenue for SelectMDx to approximately $1.8 million, an increase of 257% year-on-year.

Revenue recognized on the sales of ConfirmMDx and SelectMDx represented just over 51% of total gross billings, a slight increase compared to 2016 and to the first half of 2017, with a marginal improvement in the revenue recognition rate for ConfirmMDx being offset by the lower rate applicable to the fast-growing test volumes of SelectMDx.

The gross profit margin on products and services improved from 60% in 2016 to 64% as a result of continued efficiency improvements and increasing volumes for SelectMDx.

Operating expenses for 2017 of $42.6 million increased by $9.9 million compared to 2016, mainly as a result of the accelerated expansion of the sales force and the management team in the US to address the mounting market opportunity for its robust portfolio of molecular diagnostic tests for urology. Also reflected in the increase is the full year impact of investments made during 2016, such as the build-out of the European operations including commercial and laboratory staff. Total headcount stood at 232 at the end of 2017 compared to 162 a year earlier, an increase designed to expand our US footprint and to accommodate the resulting increase in testing volumes.

Cash position

Cash and cash equivalents stood at $16.8 million at December 31, 2017, compared to $30.8 million at December 31, 2016. The gross proceeds from the sale of patents to Exact Sciences of $15.0 million, net new financing of $0.6 million and $1.9 million of favorable foreign exchange translation effects were offset by an operational cash burn of $25.5 million, the non-recurring payment of royalties and milestones of $1.1 million and investments in tangible and intangible assets of $4.9 million. Cash collections from ConfirmMDx and SelectMDx amounted to $23.1 million, 17% more than a year earlier. The unique ConfirmMDx CPT code, effective January

2018, is expected to further streamline the Company's reimbursement efforts and significantly reduce collection periods.

Strategic Update and Outlook
The Company's strategy to grow the business is focused on four key pillars: 1) driving adoption and acceptance of our commercial tests with urologists and payors in the significant markets of the US and Europe; 2) increasing the clinical utility of our SelectMDx tests to encompass both primary care and the active and recurrence monitoring of patients; 3) expanding usability and access to our tests by porting them onto IVD sample-to-answer platforms; and 4) working with pharmaceutical partners to create precision diagnostics.

The Company remains confident in the potential of ConfirmMDx, which it expects to continue driving momentum in the mid-term and increasing market share. In the longer term, the Company expects SelectMDx to continue driving growth with numerous value driving inflection points in the coming years. The Company is positive about the outlook for the current year and believes it can achieve a higher level of Product and Services revenue growth than in 2017.

Growth in 2018 and beyond will be driven by:

- Increase in private payor coverage in the US for ConfirmMDx and SelectMDx
- Formal application expected in 2018 for Medicare coverage through a Local Coverage Determination (LCD) for SelectMDx. Clinical utility studies and budget impact studies will also drive the Company's effort to secure contracts with an increasing number of private payors for SelectMDx
- The results of the prospective 4M study, using SelectMDx with mpMRI and histopathology, are expected to be released in the course of H1 2018. These data are key to inclusion in the respective clinical guidelines in the US and in Europe
- Expanded market opportunity for SelectMDx in active monitoring and primary care settings expected to quadruple the market opportunity for SelectMDx in the mid-term to more than 2 million patients annually in the US and a similar number for Europe. Data validating this approach from two large scale studies conducted alongside John Hopkins University and the Canary Foundation are expected in 2018
- In addition, MDxHealth plans to expand its IVD strategy by porting some of its products onto commercially established IVD platforms tuned towards sample to answer technology, an increasingly important capability in the field of molecular diagnostics
- MDxHealth will continue to leverage its biomarker portfolio and expand its capabilities towards the pharmaceutical industry. The Company will further develop its new diagnostic companion blood test to guide the personalized treatment of castration resistant prostate cancer patients, building on the very encouraging results of the study published in *The Prostate* on January 12, 2018

2018 Reporting Calender
- First interim trading update: April 24, 2018
- Annual General Meeting of Shareholders: May 31, 2018
- H1 results: August 30, 2018
- Second interim trading update: October 23, 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. 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. The full Annual Report is expected to be made available to the public via the Company's website in April 2018.

Conference Call Details
Dr. Jan Groen, Chief Executive Officer and Jean-Marc Roelandt, Chief Financial Officer, will host a conference call on the day of the results at 15:00 CET / 14:00 GMT / 06:00 PT. The call will be conducted in English and a replay will be available for 30 days.

To access the conference call, please dial one of the appropriate numbers below quoting the conference ID 9294798.

UK:	08003767922
Belgium:	024009874
The Netherlands:	0207143545
US:	18669661396

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.

To ensure a timely connection, it is recommended that users register at least 10 minutes prior to the scheduled start timing.

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 and follow us on social media at: twitter.com/mdxhealth, facebook.com/mdxhealth and linkedin.com/company/mdxhealth.

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**The SelectMDx IVD PCR kit is not available in all geographies and/or may not be approved for all uses discussed in this press release. It is currently not available for use in the United States.*

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. 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.