

## MDxHealth Provides First Quarter 2018 Business Update

IRVINE, CA, and HERSTAL, BELGIUM – 07:00 CEST, April 24, 2018 – MDxHealth SA ("MDxHealth, or the "Company"), (Euronext: MDXH.BR), today issued its business update for the first quarter ended March 31, 2018.

**Dr. Jan Groen, Chief Executive Officer of MDxHealth, commented:** "In the first quarter of 2018, we delivered strong growth in both patient test volumes and revenues. In particular, we are very pleased with the 50% growth of ConfirmMDx volumes compared to Q1 2017. In line with our growth strategy we are also seeing strong volume growth for our liquid biopsy test SelectMDx, with volumes nearly tripling in Europe. Going forward we expect the recent inclusion of this product in the European Association of Urology (EAU) clinical guidelines to contribute to continued growth and adoption of the test in Europe.

"Despite a strong first quarter, we do not yet have full visibility on revenue projections going forward, however we remain confident in the positive outlook for the year and achieving higher levels of testing volume and product revenue compared to 2017. We will continue to keep the market updated as the year progresses."

### Financial highlights

- Total revenue of \$9.7 million, up 50% from \$6.5 million in Q1 2017
- Product revenue of \$7.9 million, up 60% from \$4.9 million in Q1 2017
- Operating loss of \$6.7 million compared to \$5.8 million in Q1 2017
- Raised \$44 million in new equity funding via a private placement in March
- Cash and cash equivalents of \$51.3 million as of March 31, 2018

### Operational highlights

- Total global patient test volume of 9,300, up 55% from 6,000 in Q1 2017
- Six new payor contracts, four for ConfirmMDx and two for SelectMDx
- Existing Brain Cancer Biomarker license with LabCorp expanded globally

### Summary by product

#### *ConfirmMDx®*

- Total global patient test volume grew to almost 5,800 in the first three months of 2018 from 3,800 in the same period last year, up more than 50%, including 640 tests associated with clinical studies initiated in 2017
- Four new US payor contracts for ConfirmMDx, including two with Blue Cross Blue Shield Association® licensees.
- ConfirmMDx evaluation study for Predicting Repeat Prostate Biopsy Outcome in African American Men presented at the 28<sup>th</sup> IPCU meeting 24-28 January in Vail, Colorado, US <https://grandroundsinurology.com/ipcu-2018/>

#### *SelectMDx®*

- Strong growth for SelectMDx with total global commercial test volume of 3,500 in the first three months of 2018 versus 2,100 in the same period last year, representing an increase of 62%, excluding an additional 1,000 non-billable study cases
- SelectMDx US patient test volume up 47% to over 2,700 compared to nearly 1,900 in 2017
- In March, SelectMDx was included in the 2018 EAU guidelines which assist clinicians in

making informed treatment decisions, taking into account the available scientific data. The inclusion of SelectMDx in the EAU guidelines will enable faster adoption of the test in EU member states specific guidelines and contribute to drive payor adoption

- EU SelectMDx commercial test volume almost tripled to 720 patients tested compared to 270 in 2017. The total EU lab testing throughput in Q1 was 1,720 cases including 1,000 non-billable tests related to reimbursement and registration studies
- Two new US military hospitals payor contracts for SelectMDx
- Commercial service agreement signed with Fondazione Luigi Maria Monti - Istituto Dermopatico dell' Immacolata (IDI), a leading research Hospital in Rome, to provide SelectMDx® for Prostate Cancer as a service test

### Summary of patient test volume by product

Product by territory	Q1 2018	Q1 2017	Change as a %
ConfirmMDx US	5,794	3,848	51%
SelectMDx US	2,749	1,872	47%
SelectMDx EU	720	270	167%
Total	9,263	5,990	55%

### Other business highlights

- MDxHealth has broadened its existing license with LabCorp for rights to certain patents owned and controlled by MDxHealth relating to the MGMT biomarker for use in oncology, including testing for patients with brain cancer, such as Glioblastoma (GBM). LabCorp's rights are exclusive, subject to certain limited exceptions. Under the terms of the expanded license agreement, which previously covered the US and Canada only, but is now worldwide, MDxHealth is entitled to receive an upfront payment and royalties on sales and may be entitled to receive additional license fees, subject to certain conditions.
- Development of a liquid biopsy test to guide treatment-decision for castration-resistant prostate cancer (CRPC) patients (*The Prostate*, vol, no, 2018)
- Presentation of AssureMDx for Bladder Cancer multicenter hematuria study at the EAU conference in Copenhagen on 16-22 March, 2018

### Post Period Events

- The SelectMDx® CE marked test is now part of the Dutch Diagnosis Related Groups (DRG) reimbursement system and may be used under the DRG system for the diagnosis of prostate cancer.

### Key non-audited financial information as of March 31, 2018

Amounts in USD as at, and for the three months ended March 31, 2018:

('000 USD)	March 31, 2018	March 31, 2017	Change	Change as a %
Revenues	9,741	6,478	3,263	50.4%
EBITDA Income (Loss)	(6,234)	(5,401)	(833)	-15.4%
EBIT Operating Income (Loss)	(6,715)	(5,847)	(868)	-14.8%
Net Profit (Loss)	(6,713)	(5,837)	(876)	-15%
Cash and cash equivalents	51,325	22,478	28,847	128.3%

**Total revenue** for the first quarter was \$9.7 million compared to \$6.5 million during the same period in 2017. Included in the total revenue for the first quarter is a license fee payment of \$0.5 million. Product revenue from ConfirmMDx and SelectMDx amounted to \$7.9 million and increased 60% from \$4.9 million a year earlier. Revenue from ConfirmMDx represented 91% of product revenue.

**Operating expenses** in the first quarter were \$13 million, up \$3.3 million over the same period last year. The increase in operating costs can be primarily attributed to expansion of the Company's commercial operations to accelerate sales of the ConfirmMDx and support the launch of SelectMDx for Prostate Cancer, including the building out of a global sales force.

**Operating loss (EBIT)** and net loss for the first quarter were \$6.7 million, an increase over the same period in 2017 reflecting primarily further investment in commercialization.

**Cash and cash equivalents** as of March 31, 2018 were \$51.3 million. In March 2018, the Company raised \$44 million (€36 million) in gross proceeds by means of a private placement of 9,989,881 new shares at an issue price of EUR 3.60 per share through an accelerated book building

## **Q2 and 2018 Outlook**

The Company remains confident that ConfirmMDx will continue to drive momentum in the mid-term and increase market share. In the longer term, the Company expects SelectMDx to increasingly contribute to overall growth alongside numerous value creating inflection points due 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. The Company will continue to update the market as the year progresses.

The Company has a clear growth strategy for 2018 and beyond. This is centred around four key pillars:

- Driving adoption of the Company's commercial tests with urologists and payors
- Expanding the clinical indications for SelectMDx
- Porting MDxHealth tests onto IVD sample-to-answer platforms to increase usability
- Leveraging our product offering through partnering with pharmaceutical companies

This will be driven by:

- Increase in private payor coverage in the US for ConfirmMDx and SelectMDx
- Submission of SelectMDx clinical data package in 2018 in consideration for Medicare coverage through a Local Coverage Determination (LCD).
- Publication of clinical utility studies and budget impact studies to secure more contracts with private payors for SelectMDx
- Releasing the results of the prospective 4M study, comparing SelectMDx with the *PHi* test, combined with mpMRI and histopathology in the course of H1 2018. These data are key to inclusion in US clinical guidelines and driving payor adoption
- 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
- 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, MonitorMDx for Prostate Cancer 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

## 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 social media at: [twitter.com/mdxhealth](https://twitter.com/mdxhealth), [facebook.com/mdxhealth](https://facebook.com/mdxhealth) and [linkedin.com/company/mdxhealth](https://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.*

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