

MDxHealth Reports Half Year 2018 Results

Good Operational Progress and Healthy Double-Digit Growth of Clinical Testing Volumes

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

IRVINE, CA, and HERSTAL, BELGIUM – 07:00 CEST, August 30, 2018 – MDxHealth SA (Euronext: MDXH.BR), today announced financial results for the half year ended June 30, 2018 and provided an update on its strategic outlook.

First half highlights and recent developments

- Product and service revenue of \$16.6 million, up 39% from \$12.0 million in H1 2017. Total revenue of \$17.2 million, compared to normalized total revenue of \$12.2 million during H1 2017. Including the one-time \$12.1 million revenue from the sale of patents, H1 2017 revenue amounted to a total of \$24.3 million
- ConfirmMDx remains the key revenue driver and grew 28% to \$14.2 million driven by increased reimbursement, expanded Medicare coverage and overall improved cash collection
- SelectMDx is now included in the 2018 European Association of Urology (EAU) guidelines. Total SelectMDx revenue grew 46% from \$0.8 million in H1 2017 to \$1.1 million
- Expanding product portfolio through a licensing agreement with Royal Philips N.V. to finalize the development of InformMDx (a tissue-based test to stratify patients according to their risk of disease progression) in the course of 2019, and completion of a clinical validation study for MonitorMDx (a liquid biopsy test designed to guide the personalised treatment of castration resistant prostate cancer patients)

"We have made good operational progress during the first half of 2018, and are pleased with the healthy double-digit growth of overall clinical testing volumes," said **Dr. Jan Groen, Chief Executive Officer of MDxHealth**. "Throughout the period, we continued to deliver on our stated four strategic objectives.

"We continue to be confident in our ability to achieve a higher level of product and services revenue growth than in 2017. We look forward to keeping the market updated as the year progresses."

Financial Highlights

- Product and service revenue of \$16.6 million, up 39% from \$12.0 million in H1 2017
- Total revenue of \$17.2 million, compared to normalized total revenue of \$12.2 million during H1 2017. Including the one-time \$12.1 million revenue from the sale of patents, H1 2017 revenue amounted to a total of \$24.3 million
- SelectMDx total revenue grew 46% from \$0.8 million in H1 2017 to \$1.1 million
- ConfirmMDx revenue grew by 28% from \$11.1 million in H1 2017 to \$14.2 million
- Gross profit (excluding royalties) of \$10.0 million improved by 42% year over year
- Operating loss of \$15 million in H1 2018 compared to an operating profit of \$0.6 million in H1 2017 (affected by additional H1 2017 revenue from sale of patents to Exact Sciences)

- EBITDA of \$(13.5) million compared to \$1.4 million in 2017
- Cash collections on products of \$14.7 million, up 35% from \$10.8 million in H1 2017
- Cash and cash equivalents of \$40.9 million as of June 30, 2018 following successful completion of \$44 million (€36M) fundraise in March 2018

Operational highlights (including post-period)

ConfirmMDx®

- Patient test volume for ConfirmMDx up 11%, to 11,139 in H1 versus 10,041 in H1 2017
- Positive final local coverage decision (LCD, July 2018) providing nationwide access to ConfirmMDx for all men covered by Medicare
- Nine new US payor contracts in first half of 2018, bringing total number to 71.
- 58% of ConfirmMDx testing performed in H1 2018 was covered by payor contracts
- ConfirmMDx included in the 2018 European Association of Urology (EAU) guidelines
- Multicenter validation study demonstrating the utility of ConfirmMDx in African American men published in the leading peer-reviewed scientific journal *Urology*
- A study demonstrating that the combined use of ConfirmMDx and SelectMDx may improve the detection of high-grade prostate cancer was presented at the AUA Annual Meeting in San Francisco, CA, May 18-21, 2018

SelectMDx®

- Global SelectMDx volume of 8,980 tests, increasing 67% year over year
- US SelectMDx volume of 5,731 tests up 36% compared to 4,220 in H1 2017
- EU SelectMDx volume of 3,249 tests up 179% compared to 1,165 in H1 2017, including tests for clinical experience and payor adoption
- SelectMDx included in reimbursement system in the Netherlands
- Eight new payor contracts signed for SelectMDx in H1 2018, now totalling 23 US payors
- SelectMDx included in the 2018 European Association of Urology (EAU) guidelines
- Presentation of two SelectMDx studies at the Global Congress on Prostate Cancer (PROSCA) in Frankfurt, Germany:
 - A positive clinical utility study demonstrating the value of SelectMDx in patient management and in guiding biopsy decisions in real-world clinical practice
 - A study combining SelectMDx with transrectal ultrasonography to identify patients with low risk to avoid an unnecessary mpMRI procedure
- One US and four EU cost-effectiveness studies of SelectMDx, modelling the impact of utilising the test prior to prostate biopsy on health outcomes and healthcare costs:
 - US study published in *The Journal of Urology, 2018*
 - EU study is accepted by the peer-reviewed medical journal *Prostate Cancer and Prostatic Diseases, 2018*, published by Nature Publishing Group

Summary of patient test volume by product

Territory	Products	H1 2018		H1 2017		H1 YoY
		Volume	% billable	Volume	% billable	% Change
U.S.	ConfirmMDx	11,139	98%	10,041	97%	11%
	SelectMDx	5,731	94%	4,220	96%	36%
EU	SelectMDx	3,249	39%	1,165	43%	179%
U.S. + EU	Grand total	20,119		15,426		30%

Other business highlights and corporate developments

Continued development of new products

- Worldwide licencing agreement with Royal Philips N.V. for the use of the rights to manufacture and market prognostic biomarker PDE47, enabling the finalization of development of InformMDx®, a tissue-based test to stratify patients according to risk of disease progression
- Continued development of MonitorMDx, a liquid biopsy test designed to guide clinical decision-making for castration-resistant prostate cancer (CRPC) patients following publication of data in *The Prostate*

Leveraging and validation of existing products and assets

- Broadened existing license with LabCorp for rights to 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
- Presentation of multicenter haematuria study of AssureMDx for Bladder Cancer, MDxHealth's third commercial stage test, at the EAU conference in Copenhagen, Denmark

Corporate developments

- Koen Hoffman nominated as an Independent Non-Executive Director at the Company's Annual General Shareholders Meeting held on 26 May 2018 in Brussels, Belgium. After his nomination the Board of Directors elected Mr. Hoffman as Chairman
- Mr. Narajowski, who served as Interim Chairman following the resignation of Mark Shaffar from the Board last year, will remain on the Company's Board as an Independent Director
- Mrs. Ruth Devenyns, Non-Executive Independent Director, will be stepping down from the Board with effect from 31 August 2018 to focus on other pursuits

First half financial review

Key unaudited consolidated figures for the six months ended June 30, 2018 (thousands of US dollars, except per share data):

	2018	2017	Change	% Change
Product and services revenue	16,638	12,004	4,634	38.6%
Royalties and patent income	562	12,256	(11,694)	-95.4%
Total Revenue ¹	17,200	24,260	(7,060)	-29.1%
Gross Profit	10,526	19,261	(8,735)	-45.4%
Operating expenses	(25,478)	(18,709)	(6,769)	-36.2%
EBITDA (Profit/(Loss))	(13,472)	1,433	(14,905)	
Operating profit/(loss) (EBIT)	(14,952)	552	(15,504)	
Net Income/(Loss)	(15,113)	538	(15,651)	
Earnings per share, basic (\$)	(0.27)	0.01	(0.28)	

¹ H1 2017 included \$12.1 million one-time revenue from the sale of patents to Exact Sciences

Total revenue for the first half was \$17.2 million compared to normalized total revenue of \$12.2 million during the same period in 2017. Including the one-time \$12.1 million revenue from the sale of patents to Exact Sciences, H1 2017 total revenue amounted to \$24.3 million. Product and services revenue of \$16.6 million compared to \$12.0 million in the same period last year. Revenue from ConfirmMDx and SelectMDx amounted to \$15.3 million and increased 29% from \$11.9 million a year earlier.

Revenue from ConfirmMDx represented 92% of product revenue. Product revenue from SelectMDx grew 46% from \$0.8 million in H1 2017 to \$1.1 million in H1 2018.

Revenue recognized on the sales of ConfirmMDx and SelectMDx represented just over 51% of total gross billings, a slight increase from 50% in 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.

Operating expenses in the first half were \$25.5 million, up \$6.8 million over the same period last year, largely related to the expansion of the Company's commercial operations, including the build-out of the US sales force, and increased amortization charges on internally developed intangible assets.

Operating loss (EBIT) and net loss for the first half were \$15 million and \$15.1 million, an increase of \$15.5 million and \$15.7 million, respectively, over the same period in 2017. Excluding royalties, the gross profit on products and services improved by \$3 million to \$10 million and was offset by the increased operating costs reflecting primarily further investment in commercialization.

Cash and cash equivalents as of June 30, 2018 were \$40.9 million. In March 2018, the Company raised \$44 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. Cash collections from ConfirmMDx and SelectMDx amounted to \$14.7 million, an increase of 35% compared to last year. The operational cash burn of \$15 million was compounded by \$1.3 million investments in tangible and intangible assets and adverse unrealized foreign exchange translation differences of \$1.7 million.

Outlook

The Company maintains its view that the year-over-year growth of product-and services revenue will be higher than in 2017. The Company will continue to update the market as the year progresses. With SelectMDx and ConfirmMDx being the drivers of testing volume growth, the Company predicts that both solutions will continue to increase market share in the mid-to-longer term. Management expects SelectMDx to increasingly contribute to overall growth, once numerous value creating inflection points anticipated in the coming years, have come to fruition.

As previously outlined, MDxHealth has a clear growth strategy for the remainder of 2018 and beyond. This strategy is centered around four key pillars:

- Driving adoption of the Company's commercial tests with urologists and payors, through:
 - Submission for publication, expected in H2, of the 4M prospective clinical study which was completed in H1 2018 by an independent entity. The study is designed to evaluate the mpMRI and SelectMDx, for the improved selection of patients at risk for high grade disease
 - Completion of medical data package for SelectMDx US guideline inclusion and Medicare coverage in near future
 - Validation and finalization of development of InformMDx test for prostate cancer, expected to be completed in 2019
- Expanding the clinical indications for SelectMDx, through:
 - Expansion of market opportunity for SelectMDx into active monitoring and primary care settings, expected to quadruple the market opportunity for SelectMDx in the mid-term to more than two million patients annually in the US and a similar number for Europe
 - Developing and executing a direct-to-consumer marketing strategy for SelectMDx in the US
 - Accelerating product awareness among urologists and patients through a newly developed digital marketing campaign

- Porting MDxHealth tests onto in vitro diagnostic (IVD) sample-to-answer platforms to increase usability, by:
 - Working with IVD partners to port part of our current product portfolio onto sample-to-answer platform(s)
- Leveraging our product offering through partnering with pharmaceutical companies, through:
 - Continued development of MonitorMDx for Prostate Cancer, building on the encouraging results of the study published in The Prostate on January 12, 2018
 - Pursuing additional deals to leverage patents owned and controlled by MDxHealth relating to biomarkers for use in non-urological oncology

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 BST / 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 7458739.

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 time.

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.

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