

## MDxHealth Reports Second Quarter and First Half 2016 Results

- **Q2 ConfirmMDx revenues up 79%; total revenues up 63%**
- **Eight new and expanded ConfirmMDx® insurance agreements in Q2**
- **Six new insurance agreements for SelectMDx in Q2**
- **Mark Shaffar appointed as Chairman of the board**

**IRVINE, CA, and HERSTAL, BELGIUM** – August 18, 2016 – MDxHealth SA (Euronext: MDXH.BR) today announced its financial results for the second quarter and first half year ended June 30, 2016.

### Q2 Financial Highlights

- Q2 total revenues increased 63% to \$6.3 million (Q2 2015: \$3.9 million)
- ConfirmMDx® revenues up 79% to \$5.6 million (Q2 2015: \$3.1 million)
- Q2 net loss of \$4.2 million (Q2 2015: \$3.0 million)
- Basic and diluted net loss per share of \$0.09

### H1 Financial Highlights

- H1 2016 total revenues increased 65% to \$13 million (H1 2015: \$7.9 million)
- ConfirmMDx revenues up 56% to \$10.8 million (H1 2015: \$6.9 million)
- H1 net loss of \$7.6 million (H1 2015: \$5.5 million)
- Basic and diluted net loss per share of \$0.17
- Cash and cash equivalents at June 30, 2016 of \$20.1 million

“Inclusion of our ConfirmMDx test in the US National Comprehensive Cancer Network (NCCN) Clinical Guidelines in Q1 enabled us to effectively execute on key growth drivers, supporting further clinical adoption, facilitating contract negotiations with new payors and resulting in a sharp increase in revenues,” commented Dr. Jan Groen, CEO of MDxHealth. “In the first half of 2016, we negotiated ten new or expanded payor agreements for ConfirmMDx, and as of today more than 57% of the male population considered at risk of prostate cancer in the US is covered. To date over 3,000 urologists have ordered ConfirmMDx in a clinical setting on more than 45,000 men at risk for prostate cancer.

“The successful launch of SelectMDx® in the US and the publication of pivotal SelectMDx validation study results in the leading journal *European Urology* during H1 led to six new payor agreements for the test and growing clinical adoption by the urology community,” continued Dr. Groen. “Since the introduction of SelectMDx, more than 1,000 people have already been tested.”

### H1 Business Highlights

- **ConfirmMDx for Prostate Cancer**
  - ConfirmMDx included in the US 2016 National Comprehensive Cancer Network (NCCN) Guidelines for Prostate Cancer Early Detection

- Clinical validation of ConfirmMDx Risk Profile for aggressive prostate cancer published in *The Prostate*
- New and expanded payor agreements signed for commercial and Medicare Advantage plans for coverage of ConfirmMDx with Gilsbar 360, USA MCO, Fortified Provider Network, Vanderbilt, JVHL, Blue Cross Blue Shield of Alaska, Fallon Community Health Plan, Three Rivers, Prime Health Services and Equian
- **SelectMDx for Prostate Cancer**
  - Global commercial team appointed to drive adoption of SelectMDx internationally
  - SelectMDx launched in the US in Q1 2016
  - Multicenter, prospective clinical validation study for SelectMDx published in *European Urology*
  - Established coverage agreements for coverage of SelectMDx with US payors, including MultiPlan, Interwest Health, Midland's Choice, Intergroup Network Services, Fortified Provider Network, and Equian
- **Other business**
  - Analytical Validation Study on AssureMDx for Bladder Cancer Published in *The Journal of Urology*
  - Worldwide, non-exclusive license granted to QIAGEN on MSP technology for use in cervical cancer

## **Post Q2 Events**

In August MDxHealth announced that it had received a positive medical coverage policy decision for ConfirmMDx<sup>®</sup> for Prostate Cancer test by Cigna, one of the top five largest health insurers in the US. Cigna's positive policy on ConfirmMDx will provide access to their 15 million global medical members.

In July, MDxHealth signed a collaboration agreement with Cerba HealthCare Belgium to commercialize SelectMDx in France, Belgium and Luxembourg. Cerba is a leading healthcare provider specializing in the delivery of advanced diagnostic assays through its 5,000 customers worldwide, serving 15,000 patients per day.

MDxHealth is also pleased to announce that the Board of Directors elected Shaffar LLC, represented by Mr. Mark Shaffar, as its Chairman. Mr. Shaffar, a former Abbott Diagnostics executive who joined MDxHealth's Board of Directors in June 2016, has nearly 40 years of experience in the biotechnology sector, having held numerous positions at Abbott Laboratories, including divisional vice-president of acquisition and licensing for 12 years, director of technology acquisition and licensing for seven years, and manager of licensing and acquisitions for five years. He holds a Master of Management with a major in management policy, finance, from the Northwestern University Kellogg Graduate School of Management, and a Bachelor of Science degree in biochemistry from the University of Wisconsin-Madison. Mr. Shaffar also serves, through Shaffar LLC, as an independent director on the boards of Biocartis Group NV and MyCartis NV.

"On behalf of the Company and our shareholders, we would like to welcome Mark to our Board as Chairman, and thank Edward Erickson (acting through Greenlands Consulting LLC), who retired as Director as well as Chairman of the Board on June 30, 2016, for his leadership, diligence, and hard work for the Company over the last six years," Dr. Jan Groen said.

## **Financial Review**

Key figures for Q2 2016 and the first half of 2016 (thousands of US dollars, except number of shares and per share data):

<i>As of June 30, 2016</i>	<b>Q2 2016</b>	<b>First half year 2016</b>	<b>Q2 2015</b>	<b>First half year 2015</b>
Total revenues	6,278	12,945	3,851	7,860
Total operating expenses	8,042	15,985	5,435	10,499
EBITDA (Loss)	-3,405	-6,699	-2,635	-5,277
Operating profit (EBIT)	-4,112	-7,528	-2,717	-5,475
Net loss	-4,195	-7,618	-2,976	-5,484
Earnings per share, basic (\$)	-0.09	-0.17	-0.07	-0.12
Number of outstanding shares	45,269,633		43,998,490	
Cash and cash equivalents	20,114		40,444	

## **Revenue and Income**

Total company revenues for the first six months ended June 30, 2016, increased 65% to \$12.9 million, compared to total revenues of \$7.9 million for the prior year. ConfirmMDx for Prostate Cancer accounted for 83% of the Company's revenue in H1 2016, compared to 88% in H1 2015. Total revenues for Q2 2016 increased to \$6.3 million compared to \$3.9 million during the same period in 2015. Revenue from ConfirmMDx represented 88% of total Q2 revenues compared to 81% in the same quarter last year. The growth in Q2 2016 revenues compared to the prior period was principally driven by increased sales of ConfirmMDx as well as royalty and milestone payments from Exact Sciences. The SelectMDx for Prostate Cancer assay, still in the early stages of commercialization, contributed less than 1% of total revenue.

The Company's net loss for the first six months ended June 30, 2016, was \$7.6 million, or (\$0.17) a share, compared to a loss of \$5.5 million loss, or (\$0.12) a share, for the prior year. The \$2.1 million increase in net loss compared to the same period last year is due to the anticipated initial losses of the newly acquired Dutch entity NovioGendix, laboratory investments related to the new SelectMDx for Prostate Cancer assay, and non-recurring corporate development spending in the first half.

## **Operating Expenses**

Operating expenses for the first six months ended June 30, 2016 increased by \$5.5 million to \$16.0 million from \$10.5 million for the prior year. The year-over-year increase is attributed to increased material costs related to growing ConfirmMDx test volume, expanded laboratory operations, investment in capital equipment and infrastructure to augment increasing ConfirmMDx sales, EU operations, and spending related to the build-up for US and European commercialization of the SelectMDx test, as well as the manufacturing set-up for the SelectMDx CE-marked IVD kit and one-off corporate development projects. During H1, investment in the European and US commercial infrastructure, including laboratory equipment and operations, information technology and expansion of managed care, billing and collections staff, contributed to increased operating

expenses. The investment in commercial operations was made to support anticipated volume growth and to support reimbursement efforts.

### **Cash Position**

The Company's cash and cash equivalents were \$20.1 million on June 30, 2016, compared to \$40.4 million on June 30, 2015. Collections from ConfirmMDx reimbursements were \$8.2 million in 2016 vs. \$5.3 million in the first half of 2015. Average net cash burn in the first six months of 2016 was approximately \$1.9 million per month.

### **Q3 and FY2016 Outlook**

The Company maintains its guidance for the full year ending December 31, 2016, and expects continued revenue growth predominantly from product and service revenue in the US and international markets, driven by the inclusion of the ConfirmMDx test in the NCCN guidelines in the US, additional coverage agreements with major payors, for both ConfirmMDx and SelectMDx, and growing adoption of MDxHealth products among the urology community. The continued infrastructure investments over the last twelve months, particularly in the sales force, managed care, and billing and collections are expected to further improve volume, collections, EBITDA and revenue recognition in the second half.

2016 guidance:

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

Reporting Calendar

- Q3 results; November 3, 2016
- Top-line 2016 results: January 9, 2017

### **About MDxHealth**

MDxHealth is a multinational healthcare company that provides actionable epigenetic information to personalize the diagnosis and treatment of cancer. The company's tests are based on proprietary gene methylation (epigenetic) technology and assist physicians with the diagnosis of cancer, prognosis of recurrence risk, and prediction of response to a specific therapy. For more information visit [mdxhealth.com](http://mdxhealth.com) and follow us on Twitter at: [twitter.com/mdxhealth](https://twitter.com/mdxhealth).

### **Statutory Auditor's Limited Review Report:**

We have reviewed the accompanying interim consolidated statement of financial position of MDxHealth SA as of 30 June 2016 and the related interim consolidated statements of comprehensive income, cash flows and changes in equity for the six-month period then ended, as well as the explanatory notes. The Board of Directors is responsible for the preparation and presentation of this consolidated interim financial information in accordance with IAS 34 "Interim Financial Reporting", as adopted by the European Union. Our responsibility is to express a conclusion on this consolidated interim financial information based on our review.

We conducted our review in accordance with International Standard on Review Engagements 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Based on our review, nothing has come to our attention that causes us to believe that the accompanying consolidated interim financial information is not prepared, in all material respects, in accordance with IAS 34 "Interim Financial Reporting", as adopted by the European Union.

Zaventem, August 17, 2016

BDO Bedrijfsrevisoren Burg. Ven. CBVA / BDO Réviseurs d'Entreprises Soc. Civ. SCRL  
Statutory auditor  
Represented by Gert Claes

Complete Financial Statements: To download the 2016 interim report, go to:  
<http://www.mdxhealth.com/investors/financials>

**For more information:**

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