

# **MDxHealth Nine Month Trading Update**

Patient test volume for the first nine months up 43% SelectMDx test volume in Europe increased nearly 400%

**IRVINE, CA, and HERSTAL, BELGIUM** – 07:00 CET, November 2, 2017 – MDxHealth SA (Euronext: MDXH.BR) today issued its interim trading update summarizing commercial, R&D and financial highlights for the nine months ended September 30, 2017.

# Financial highlights for the nine months ended September 30, 2017

- Total revenue of \$30.5 million, up 38% from the same period in 2016, in part driven by \$12.1 million net revenue from a one-time buy-out of the Company's patents directed towards colorectal cancer to Exact Sciences;
- Product revenue of \$18.2 million, up 3% from \$17.6 million last year, adversely affected by the impact of hurricanes;
- EBITDA improved by 34.1% from \$-6.2 million compared to \$-9.1 million in 2016;
- Cash and cash equivalents on September 30, 2017 of \$22.9 million;
- Over 23,000 patients tested, an increase of 43% compared to the same period in 2016, with SelectMDx® representing approximately 36% of total;
- EU SelectMDx test volume up nearly 400% to over 2,000 patients tested compared to 400 in the same period in 2016.

"Hurricanes Harvey and Irma depressed industry-wide laboratory Q3 testing volumes and reduced ConfirmMDx test volumes in the affected states by an estimated 50%," **said Dr. Jan Groen, Chief Executive Officer of MDxHealth.** "However, overall growth of patient test volume remains strong. After nine months, we tested nearly as many patients as for the full year in 2016. Our expanded sales force has been fully deployed since early September and is expected to fuel growth in the fourth quarter and beyond."

#### Business highlights for the three months ended September 30, 2017

# Commercial achievements, clinical and business development

- Expanded access to portfolio of prostate cancer tests:
  - Blue Cross Blue Shield plans of Arizona and Idaho added to payors under contract for ConfirmMDx<sup>®</sup> for Prostate Cancer test, now totaling 62 payors;

- Healthcare services agreement signed with Southern California Permanente Medical Group to assess the performance of the ConfirmMDx;
- US payor contract for SelectMDx signed with Lakehead Airforce Base, bringing the total number of SelectMDx contracted payors to 15;
- Distribution agreements signed with IDI Hospital in Rome, Italy; MicroDiagnostics in Thessaloniki, Greece and IPS Genomix in the Middle East;
- MVZ Dr. Stein & Kollegen medical laboratory in Mönchengladbach Germany, one
  of the laboratories within the Limbach Gruppe SE, will perform SelectMDx service
  testing. To offer this service through its network, the laboratory will purchase
  SelectMDx CE-marked IVD kits from MDxHealth.
- Data from a retrospective study, conducted by the Radboud Medical Center and published in *The Prostate*, demonstrated that SelectMDx correlated with multiparametric MRI (mpMRI) and outperformed the PCA3 test;
- A US cost-effectiveness study demonstrated that SelectMDx improved patient outcomes while significantly reducing healthcare costs by preventing over-diagnosis and overtreatment of men with clinically insignificant prostate cancer;
- Opening of a new service and research laboratory at the Novio Tech Campus in Nijmegen, the Netherlands, expanding the capacity to perform SelectMDx and support ongoing research, development and commercial activities;
- Continued expansion of executive functions with the appointments of Michael K. Brawer, MD as Chief Medical Officer and Paul Marr as Executive Vice President of Sales for North America in conjunction with the expansion of its US sales force to 50 representatives.

#### Post-Period Development

- Signed three distribution agreements for SelectMDx with Unilabs, in Geneva, Switzerland; Omgen in Istanbul, Turkey and TH Servive in Sofia, Bulgaria;
- Two new US positive coverage policies for ConfirmMDx issued by Blue Cross Blue Shield Idaho and Geisinger Health Plan, bringing the total to 33;
- The Board of Directors elected Mrs. Hilde Windels, as independent director. Mrs. Windels is an executive director of Biocartis, has 20 years of experience in the biotechnology sector with a track record of building and structuring organizations, fundraising, M&A, public capital markets and corporate strategies. At Biocartis, she was CEO ad interim and Deputy CEO from September 2015 until September 2017 and CFO from 2011 until September 2015. Previously, Mrs. Windels worked as independent CFO for several private biotech companies and from 1999 to 2008 she was CFO of Devgen. Currently, Mrs. Windels also serves as a board member at EryTech, Ablynx and BioCartis. In the past, she also served on the boards of Devgen.

MDxHealth and FlandersBio. Mrs. Windels holds a Masters in Economics from the University of Leuven, Belgium;

 On October 19<sup>th</sup> Mark Shaffar, chairman of the board of directors (represented by Shaffar LLC), has informed the Company of his decision to retire from the board of directors. The board of directors has elected Mr. Wally Narajowski to be the new chairman.

As a result of the aforementioned changes, the MDxHealth Board now consists of:

- Lab Dx L.L.C., represented by Mr. Wally Narajowski, Chairman of the Board of Directors and Independent Director
- Dr. Jan Groen, Chief Executive Officer and Executive Director
- Hasselberg BVBA, represented Mrs. Ruth Devenyns, Independent Director
- Hilde Windels BVBA, represented by Mrs. Hilde Windels, Independent Director
- Qaly-Co BVBA, represented by Mrs. Lieve Verplancke MD, Independent Director
- Gengest BVBA, represented by Mr. Rudi Mariën, Non-Executive Director
- Valiance Advisors LLP, represented by Mr. Jan Pensaert, Non-Executive Director

"On behalf of the Company and our shareholders, we would like to welcome Mrs. Hilde Windels to our board, and thank Mark Shaffar, who retired as Director as well as Chairman of the Board, for his leadership, diligence, and hard work for the Company," said **Dr. Jan Groen CEO of MDxHealth**. "Also, with Hilde joining our board of directors, the company is now gender compliant."

## **Key non-audited consolidated financial information:**

As of or for the nine months ended September 30,

| In \$ '000                    | 2017       | 2016       | Change    | Change as a % |
|-------------------------------|------------|------------|-----------|---------------|
| Revenue                       | 30,469     | 22,025     | 8,444     | 38.3%         |
| Gross profit                  | 23,049     | 14,634     | 8,415     | 57.5%         |
| Operating expenses            | (30,471)   | (24,835)   | (5,636)   | (22.7)%       |
| EBITDA (profit/(loss)         | (6,242)    | (9,099)    | 2,857     | 31.4%         |
| Net loss                      | (7,426)    | (10,310)   | 2,884     | 28.0%         |
| Number of outstanding shares  | 49,949,408 | 45,269,633 | 4,679,775 | 10.3%         |
| Earnings per share basic (\$) | (0.15)     | (0.23)     | 0.08      | 34.8%         |
| Cash and cash equivalents     | 22,969     | 15,151     | 7,818     | 51.6%         |

Total revenue for the first nine months ended September 30, 2017, increased by 38% to \$30.5 million, compared to \$22.0 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 revenue increased by approximately 3% to \$18.4 million during the first nine months of 2017.

Sales growth was hampered by the impact of hurricanes Harvey and Irma. Volumes from Texas and Florida, which traditionally contribute significantly to order volumes, fell and depressed revenue in September. Moreover, a larger number of orders than usual were received during the last days of September. The patient test results for these orders were not reported by quarter-end and therefore not included in the revenue for the nine months ended September 30, 2017. Including revenue from these orders and excluding the estimated impact of the multiple hurricanes, pro forma revenue growth for the first nine months of 2017 would have been 11% year-on-year.

Initial sales of SelectMDx IVD kits in Europe and continuously growing order volumes have increased the contribution of SelectMDx to 7% of global product revenue, with ConfirmMDx accounting for 90%, compared to 97% in the same period in 2016.

#### 2017 outlook

The Company is confident that is well-positioned to create long-term shareholder value by delivering continued revenue growth from increased adoption of its leading diagnostic offering in both the US and European markets. The volume shortfall resulting from the hurricanes in the third quarter, improved visibility on the ramp-up of the recently added sales representatives, and lower than expected initial contributions from the GSA contract, leads the Company to target the lower end of its 55%-75% product and service revenue growth guidance for 2017. Certain US payors have recently introduced pre-authorization requirements for molecular testing, which could delay the processing of ordered tests and adversely affect the Company's revenue growth projections. Should such delays materialize, the products and services revenue growth is estimated to be in the range of 45%-55%. Accordingly, total revenue is expected to grow by approximately 60%-70%, to \$48-\$51 million. The Company further expects to maintain a balance of cash and cash equivalents of approximately \$15 million at the end of 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. 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 Twitter at: twitter.com/mdxhealth.

#### For more information:

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