

#### **NEWS RELEASE**

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# MDxHealth Provides Third Quarter 2016 Business Update

Revenue for the first nine months up 84% to \$22 million

Continued strong growth attributed to increased payor coverage

**IRVINE, CA, and HERSTAL, BELGIUM** – November 2, 2016 – MDxHealth SA (Euronext: MDXH.BR), today announced its third quarter 2016 Business Update for the period ended September 30, 2016.

**Dr. Jan Groen, Chief Executive Officer of MDxHealth, commented:** "The sharp revenue growth has been driven by the strong increase in payor coverage for our lead product ConfirmMDx in the key U.S. market. We anticipate continuing acceleration in the adoption of ConfirmMDx among payors and physicians, broadening availability to patients and preventing thousands of unnecessary and often painful biopsies. In doing so we expect our strong Q3 performance to continue into Q4 and maintain our recently upgraded guidance for the full year."

"Since the launch of our SelectMDx 'liquid biopsy' test early 2016, we have tested more than 2,000 men, clearly showing the value of the test for both urologists and their patients," **continued Dr. Groen**. "This is further supported by the rapid adoption by the payor community, with nine insurance companies in the U.S. already covering the SelectMDx test."

### **Q3 Financial Highlights**

- Q3 total revenues increased 122% to \$9.1 million (Q3 2015: \$4.1 million); up 45% from Q2 2016 (\$6.3 million)
- Q3 net loss declined 46% to \$2.7million (Q3 2015: \$4.8million)

# Year to date (first nine months) Financial Highlights

- YTD 2016 total revenues increased 84% to \$22 million (YTD 2015: \$11.9 million)
- YTD net loss of \$10.3 million (YTD 2015: \$10.3 million)
- Cash and cash equivalents at September 30, 2016, of \$15.1 million

# YTD (first nine months) Business Highlights

### **ConfirmMDx Highlights**

- Twenty-five commercial health plans established positive medical policy for ConfirmMDx, including major payors such as Cigna, Highmark BCBS, Independence BC and others.
- ConfirmMDx covered under California Medical Assistance Program (Medi-Cal).
- Commercial agreement for ConfirmMDx signed with The European Health Centre Innovation in Poland and South Genetics in Central/South America.

 ConfirmMDx included in the 2016 NCCN Guidelines for Prostate Cancer Early Detection. The NCCN is an alliance of 26 world-leading cancer centers from across the U.S.

## SelectMDx Highlights

- Nine health plans have contracted to cover SelectMDx, including Multiplan, America's Choice Provider Network, Fortified Provider Network, Galaxy Health Network and others.
- Five distribution agreements signed for SelectMDx, including with Cerba Healthcare in Benelux Region and France, Teva Pharmaceuticals in Israel, The European Health Centre Innovation, HIFU Clinic Prostate Cancer Centre in Poland and South Genetics in Central/South America.
- Prospective, multicenter SelectMDx validation study published in the prestigious journal *European Urology*.

# **Post-Period Highlights**

- Health Care Services Corporation (BCBS of Texas, BCBS of Illinois, BCBS of Oklahoma, BCBS of New Mexico and BCBS of Montana), which serves more than 15 million members across the United States, issued positive medical policy on the ConfirmMDx® for Prostate Cancer test.
- ConfirmMDx for Prostate Cancer has been awarded a unique Current Procedural Terminology (CPT) code by the American Medical Association. The Category I MAAA code will facilitate reimbursement from U.S. government programs such as Medicare and Medicaid as well as commercial health insurance plans. The CPT code will be effective as of January 2018.

# Key non-audited financials as of September 30, 2016

Amounts at and for the **three** and **nine** months ended:

As of September 30, 2016	Q3 2016	First nine months 2016	Q3 2015	First nine months 2015
Total revenues	9,080	22,025	4,088	11,948
EBITDA (Loss)	(2,456)	(9,099)	(4,708)	(9,985)
Operating profit (EBIT)	(2,673)	(10,201)	(4,827)	(10,302)
Net loss	(2,692)	(10,310)	(4,840)	(10,324)
Number of outstanding shares	45,269,633		43,998,490	
Cash and cash equivalents	15,151		35,111	

Except for Outstanding Shares, amounts are in thousands of dollars

# Commercial revenues up 84% for the first 9 months

**Total Revenues** for the first nine months of 2016 amounted to \$22.0 million, representing 84% growth over the same period a year earlier, primarily due to an increase in ConfirmMDx test sales in the U.S.

**Operating Expenses** were \$24.8 million in the first nine months of 2016, versus \$17.6 million in the same period in 2015, with the increase attributable to our continued investment in product development, sales, marketing and the managed care sales team.

**Net Loss** of \$10.3 million for the first nine months of 2016 is unchanged compared to the same period in 2015. Continued investment in U.S. commercial operations and a higher cost of sales due to increasing volumes of ConfirmMDx were offset by higher recognized sales revenues.

**Cash Position** as of September 30, 2016, was \$15.1 million in cash and equivalents, compared to \$35.1 million on September 30, 2015. Average net cash burn in the first nine months of 2016 was approximately \$1.8 million per month.

### Q4 and H1 2017 Outlook

The Company maintains its upgraded guidance for projected 2016 revenues, which are expected to increase by more than 60% over 2015. This sharp growth can be attributed to accelerated adoption of the ConfirmMDx for Prostate Cancer test by urologists in the U.S. The test's inclusion in the U.S. National Comprehensive Cancer Network (NCCN) Clinical Guidelines in Q1 2016 has facilitated successful contract negotiations with a number of new payors, leading to a significant increase in revenues. In addition, the Company believes that the recent award of a unique Category I CPT code for ConfirmMDx from the American Medical Association will streamline reimbursement from government and commercial payors, further accelerating adoption among payors and physicians.

For the acceleration of the second prostate cancer product SelectMDx, the Company has completed a health economic study for the Netherlands and data have been submitted for publication. The Company also completed a study comparing the SelectMDx test with MRI scan outcome data and intends to presents and publish these data. In preparation for the launch of MDxHealth's third product AssureMDx for bladder cancer, a multi-center clinical validation study has been completed and submitted for publication. Publication of these data is important to support a successful introduction and launch of the AssureMDx test.

MDxHealth maintains its guidance that underlying Earnings Before Interest, Taxes, Depreciation and Amortization (EBIDTA) for the year ended 2016 are expected to improve compared to 2015.

The Company continues to work towards broadening its portfolio and continues to make progress on the development of tests for the diagnosis of other indications, including kidney cancer, with the aim of providing a full suite of products for the diagnosis of urological cancers.

#### **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 gene methylation (epigenetic) and other molecular technologies 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 and follow us on Twitter at: twitter.com/mdxhealth.

#### For more information:

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