



## MDxHealth Reports 2013 First-Half Results

*Over 80% Increase in ConfirmMDx™ for Prostate Cancer Test Volume  
From Q1 to Q2 2013*

**IRVINE, CA, and LIEGE, BELGIUM, August 22, 2013** – [MDxHealth](#) SA (NYSE Euronext: MDXH), a leading molecular diagnostic company that develops and commercializes epigenetic tests to support the diagnosis and treatment of cancer patients, today announced its 2013 first half results.

### **Business Highlights**

In the first half of 2013, MDxHealth continued to deliver on its commercialization plan for ConfirmMDx for Prostate Cancer in the U.S. That plan includes increasing the penetration of the test at an expanding number of urology practices, while advancing the clinical and economic impact studies necessary to secure reimbursement in line with the test's health economic benefits. During the first half of 2013, test volumes ramped up significantly, with 67 million lives added to the total number of patients who can obtain reimbursement for the test. More than 90 different third-party insurance payers have reimbursed the ConfirmMDx test.

Data supporting the ConfirmMDx test were published in peer-reviewed journals and presented at major scientific conferences. The data demonstrated that the biomarkers in the ConfirmMDx test outperform prostate specific antigen testing (PSA) and other traditional risk factors in prostate cancer detection, representing a powerful new tool for urologists assessing the need for a repeat prostate biopsy. Additionally, investigators from the University of California at San Francisco and Thomas Jefferson University published a health economic study in the journal *American Health & Drug Benefits* (2013;6(1):15-24), which demonstrated that health insurance plans establishing coverage for the ConfirmMDx for Prostate Cancer test would realize approximately \$600 in cost savings per patient managed, generating significant economic benefits within the first year.

MDxHealth reported commercial and total revenues of €3.0 million in the first half of 2013, a 51% increase versus the same period in 2012. Commercial revenues grew by 108% over the first half of 2012. There were no grant or subsidy revenues during the first half of 2013. The company's cash position was significantly improved through an €18 million private placement which closed on June 25, 2013.

On June 7<sup>th</sup> MDxHealth partner Exact Sciences (NASDAQ: EXAS) submitted the final module of the premarket approval (PMA) application for Cologuard™, the company's molecular stool-based colorectal cancer screening test to the U.S. Food and Drug Administration. Pending FDA approval Exact Sciences is now preparing for the commercial launch of their test. MDxHealth expects to receive milestone payments and royalties from the sale of the Cologuard test.

"Adoption of our ConfirmMDx for Prostate Cancer test in the U.S. continues to accelerate. Year to date we have tested more than 42,000 prostate biopsies from over 3,500 patients. This represents a sequential increase of 82% in volume in Q2 over Q1 2013," said Dr. Jan Groen, CEO of MDxHealth. "We continue to build our commercialization structure in the U.S. to support this growth through the remainder of 2013 and beyond. Together with our partners, we now have more than 70 sales representatives in the U.S. promoting our ConfirmMDx test for Prostate Cancer test, and the penetration rates are being aided further by the growing number of payers that have recognized the clinical and economic value of the test and are reimbursing its use."

Commenting on the financial results, Dr. Groen continued: “We are pleased with the significant growth in commercial revenue thus far in 2013, derived from both diagnostic test and services sales. At this point more than 90 insurance companies have recognized the clinical utility and economic value and are reimbursing the ConfirmMDx for Prostate Cancer test. Our managed care efforts are focused on increasing coverage through contracts with third-party payors and networks. Reimbursement codes at these insurers and other third-party payors allow MDxHealth to secure appropriate payment, increase the percentage of revenue recognized, and expedite collections, while providing economic benefit to payers and the entire healthcare system.”

### **Key limited audited financials, as of June 30, 2013**

Amounts as at and for the six months ended

<b><i>Euro thousands</i></b>	<b>June 30, 2013</b>	<b>June 30, 2012</b>
Commercial Revenues*	3,033	1,456
Total Revenues	3,033	2,014
EBITDA (Loss)	(5,754)	(4,049)
EBIT Operating Income (Loss)	(5,953)	(4,260)
Net Profit (Loss)	(5,971)	(4,259)
Cash and cash equivalents	24,677	6,551

\*Commercial revenue is defined as revenue without government grants and or subsidies, and includes CLIA laboratory diagnostic testing revenue, services to pharmaceutical partners and royalty/licensing income.

### **Revenues**

Commercial revenue in H1 2013 amounted to €3.0 million compared to €1.5 million in H1 2012, representing an increase of 108%. No revenues were derived from government grants as the company continued to focus on growing its commercial revenue sources.

Test volumes for ConfirmMDx for Prostate Cancer continued to increase, with more than 4,500 tests sold to date since launch. A steady increase in reimbursement from private third-party payers was recorded during the period, with more than 90 insurers now paying for the test. This is expected to increase further through the agreements with Multiplan and Three Rivers, which plans have combined access to 67 million covered lives.

### **Operating Expenses**

Operating expenses for 1H 2013 were €7.6 million, increasing 24% compared to €6.1 in 1H 2012. As previously noted, this increase was attributable to the build-up of the U.S. operations in support of ConfirmMDx for Prostate Cancer test commercialization, as well as R&D investment in our pipeline of new diagnostic tests.

Non-operational and one-time restructuring costs, not expected to continue in future periods, amounted to €302K for the period.

### **Results**

As expected, 1H 2013 loss increased over the same period in 2012 due to costs associated with growing commercial infrastructure to support U.S. sales and marketing and new product R&D investment. The company's operating loss (EBIT) increased by 39.7%, and the net loss increased by 40.2% in H1 2013.



### **Cash Position**

MDxHealth ended the first half of 2013 with cash and cash equivalents of €24.7 million compared to €6.6 million on June 30, 2012. The increase in cash was supported in part by the €18 million gross private placement closed on June 25, 2013.

### **Outlook**

Based on the growth in the first two quarters of 2013 we anticipate continued growth in test volumes, our customer base and payer reimbursement in coming quarters.

The central histopathology review of the company's second multicenter validation study for ConfirmMDx for Prostate Cancer has completed. The study involved five major cancer centers in the U.S. with Prof. Dr. Alan Partin from Johns Hopkins University serving as principle investigator. Testing included 3,687 archived prostate biopsy cores from 350 men in a blinded fashion. In the coming weeks the database will be unlocked and data will be analyzed and submitted for an oral presentation at a major urology conference and publication in a leading urology journal.

The development of MDxHealth's second prostate cancer product (InformMDx) is on target. This test will provide prognostic assessment to distinguish between aggressive and non-aggressive prostate cancer. In Q1 2014 the company will start validation studies for the test.

The reimbursement climate in the U.S. is still evolving. Along with our peers in the industry, MDxHealth is closely monitoring the Centers for Medicare and Medicaid Services' (CMS) changes to the Medicare Clinical Laboratory Fee Schedule. These fee schedule changes, coupled with the changing reimbursement landscape, pose challenges for all diagnostic companies. While we believe the lack of clarity is a temporary situation, we have elected to take a conservative view and will likely adjust our per test revenue projections downward to reflect the uncertainties. Once payment histories under the new codes are well established, we will reevaluate our revenue recognition policy to determine if upward revision is appropriate.

The Company's revenue recognition policy at this time is primarily based on cash collections. Because reported revenues generally exclude uncollected outstanding billable cases, the impact of current test sales on reported revenues may be delayed by one or more calendar quarters. However, as billing and reimbursement trends are established with each payer, the Company is transitioning to an accrual-based revenue recognition policy. Additionally, MDxHealth has held claims to Medicare and will pursue payment once Medicare has reviewed and approved the company's medical dossier and finalizes reimbursement for the test, expected in 2013. Once Medicare reimbursement is obtained, the company expects a one time, retrospective billing payment for cases dating back to 2012, representing a significant, one off, increase in revenue. We anticipate a continued increase in private third-party reimbursement as new payers are included. Currently, 70% of all MDxHealth ConfirmMDx cases are non-Medicare.

Total operating costs in the second half are expected to increase in a carefully controlled manner in line with ramping up of the commercialization activities associated with the ConfirmMDx for Prostate Cancer test.

### **Post-closing events**

MDxHealth signed a partnership agreement with Bostwick Laboratories, a full-service laboratory specializing in anatomic and clinical pathology, with a focus on uropathology, providing MDxHealth with access to one of the largest urology networks in the U.S.

In addition and as noted above, agreements were signed with MultiPlan and Three Rivers Provider Network (TRPN) to provide expanded access for the ConfirmMDx for Prostate Cancer test. These



preferred provider organizations (PPO's) contract with healthcare providers typically on a discounted fee-for service basis in circumstances where the financial risk for changes in utilization of medical services appears limited based on actuarial assumptions. PPOs and third party administrators (TPA's) contract with health maintenance organizations (HMO's), self funded employers, and other payers to provide expanded choice, and services for patients, at discounted rates, with seamless claims processing and claims optimization efficiencies.

The New York State Department of Health (NYSDOH) also certified and granted approval for the ConfirmMDx for Prostate Cancer test, completing MDxHealth's list of state licensures, opening access to one of the largest markets in the U.S.

In the PharmacoMDx business area, MDxHealth established a service collaboration with HistoGeneX to provide pharmaceutical companies and oncologists with integrated molecular diagnostic testing services. HistoGeneX's laboratory in Belgium will also perform MGMT service testing on behalf of MDxHealth's current and future clients.

In early July, MDxHealth signed a marketing partnership was signed with Summit Pharmaceuticals International Corporation (SPI), a subsidiary of Sumitomo Corporation, to gain access to the Japanese market with MDxHealth's PharmacoMDx services, including *Next Generation* sequencing (NGS) and epigenetic technologies and assays.

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

We have reviewed the accompanying interim consolidated statement of financial position of MDxHealth SA as of 30 June 2013 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 22, 2013

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



### **Complete Financial Statements:**

To download the 2013 interim report, go to: <http://www.mdxhealth.com/investors/financials>

### **About MDxHealth**

MDxHealth is a molecular diagnostics company that develops and commercializes advanced epigenetic tests for cancer assessment and the personalized treatment of patients. By applying patented DNA methylation platform and biomarkers, MDxHealth helps to address a large and growing unmet medical need for better cancer diagnosis and treatment information. For more information visit [www.mdxhealth.com](http://www.mdxhealth.com).

### **For more information:**

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