

MDxHealth Reports First Half Year 2014 Results

Strong market adoption leads to more than doubling of ConfirmMDx case volume

IRVINE, CA, and HERSTAL, BELGIUM – August 21, 2014 – MDxHealth SA (NYSE Euronext: MDXH), a leading molecular diagnostic company that develops and commercializes epigenetic tests to improve the diagnosis and treatment of cancer patients, today announced results of the first-half year ended June 30, 2014.

“During the first half of 2014, adoption of ConfirmMDx[®] for Prostate Cancer continued to grow rapidly, with 5,500 patient cases tested, compared to approximately 2,400 cases in the first half of 2013. ConfirmMDx revenue increased sharply to \$3.9 million in H1 2014, rising from \$0.9 million in the first half 2013. The fast growth of revenue was due to a combination of factors including test volume growth and increased recognition of revenue based on broader non-Medicare insurance coverage and improving payment and collection trends,” reported Dr. Jan Groen, CEO of MDxHealth. “We also achieved a significant milestone in the Medicare coverage process during this reporting period. The Local Coverage Determination (LCD) for ConfirmMDx has been posted for public comment, signaling that the test has passed the technical assessment. Following the notification period, we anticipate that the LCD should be effective before the end of 2014.”

Business Highlights

ConfirmMDx for Prostate Cancer

- Revenue increased 317% to \$3.9 million in H1 2014 over \$0.9 million in H1 2013
- Case volume increased 129%, with 5,500 patients tested in H1 2014 compared to 2,400 patients tested in H1 2013
- Published clinical utility study in the journal *American Health and Drug Benefits*
- DOCUMENT validation study published in the *Journal of Urology*
- Presented data regarding the prognostic value of the ConfirmMDx test genes at the 2014 ASCO Genitourinary (GU) Seminar
- Signed co-marketing agreements with Long Island Pathology and American Pathology Partners
- Signed an exclusive agreement with Teva Pharmaceutical Ltd. for distribution of ConfirmMDx for Prostate Cancer in Israel
- Signed insurance agreements with additional PPO providers Prime Health Services and Galaxy Health Network, adding nearly 10 million covered lives
- The Centers for Medicare and Medicaid Services (CMS) posted the draft Local Coverage Determination (LCD) for the ConfirmMDx for Prostate Cancer test on its website

Other Business Activities

- MDxHealth and HistoGeneX N.V. were awarded \$1.8 million from the Flemish Institute for the Promotion of Innovation by Science and Technology to fund the development of companion diagnostics for cancer immunotherapy

- MDxHealth licensee Exact Sciences published the positive results of its 10,000 patient DeeP-C pivotal clinical study for its Cologuard test in the *New England Journal of Medicine*
- Data confirming the clinical utility of PredictMDx[®] for Glioblastoma test published in the *New England Journal of Medicine*
- MDxHealth received approval from the Belgium tax authority for patent income deductions (PID), which allows for an 80% deduction of qualifying gross patent income. PID treatment is granted to Belgian companies who support investments in technical innovation which stimulate ownership of patents and promotes business based on these patents. PID reduces the effective tax rate from 34% to 6.8% for the qualifying income.

Events After the Reporting Period

- Validation Study demonstrating the prognostic value of ConfirmMDx biomarker published in *The Journal of Urology*[®]
- CMS initiated National Coverage Analysis for screening for colorectal cancer using Exact Sciences Cologuard test, and posted the related Proposed Decision Memorandum on its website.
- MDxHealth licensee Exact Sciences received FDA approval for its Cologuard colon cancer screening assay
- Signed two insurance agreements with Ancillary Care Services (ACS), and separately, with Consilium, LLC.
- Signed a co-marketing agreement with Miraca Life Sciences, the largest independent anatomic pathology lab in the U.S., to promote ConfirmMDx.

Financials

Key Figures for the first half (thousands of U.S. dollars, except number of shares and per share data):

<i>As of June 30, 2014</i>	<i>First half year 2014</i>	<i>First half year 2013</i>
Total revenues	4,804	3,984
Total operating expenses	10,434	10,022
EBITDA (Loss)	-7,932	-7,525
Operating profit (EBIT)	-8,086	-7,820
Net loss	-8,043	-7,843
Earnings per share, basic (\$)	-0.23	-0.23
Number of outstanding shares	34,251,303	34,251,303
Cash and cash equivalents	12,709	32,253

Revenues

Total revenues grew 21% to \$4.8 million in H1 2014, compared to \$4.0 million in H1 2013. Revenue from ConfirmMDx sales increased 317%, with \$3.9 million in H1 2014 compared to \$0.9 million in H1 2013. ConfirmMDx represents 81% of the overall revenue mix in H1 2014, as compared to 23% in the same period last year. In H1 2013 50% of MDxHealth's revenue was related to the Merck Cilengitide companion diagnostic project. The Merck agreement was terminated after Merck's Phase III clinical study did not meet its primary endpoints.

Operating Expenses

Operating expenses for H1 2014 were \$10.4 million, increasing 4% compared to \$10.0 million in H1 2013. This increase was attributable to the continued build-up of the U.S. commercial operations in support of ConfirmMDx for Prostate Cancer test.

Results

As expected, H1 2014 loss increased slightly over the same period in 2013 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 3.4%, and the net loss increased by 2.6% in H1 2014.

Cash Position: MDxHealth ended the first half of 2014 with cash and cash equivalents of \$12.7 million compared to \$32.3 million on June 30, 2013.

Q3 and FY2014 Outlook

In Q3 2014, MDxHealth will begin enrollment in its 600 patient, prospective clinical utility study, PASCUAL, which will generate additional clinical utility data supporting Medicare coverage of the ConfirmMDx for Prostate Cancer test. MDxHealth anticipates that the final LCD for Medicare coverage of ConfirmMDx with data development will be effective in Q4 2014. An interim analysis of the PASCUAL study, as outlined in the Medicare LCD, is expected in the first half of 2015, potentially triggering expanded coverage.

A steady increase in reimbursement from third-party payors was achieved during the period, with more than 155 insurers now paying for the test. With increasing ConfirmMDx test volumes and collections, MDxHealth is able to recognize more accrual-based revenue. However, with growing adoption of the test by new prescribing urologists across the U.S., the company expects a growing number of new payors, thus also increasing the group of non-contracted, third party payors. This could lead to continued delays in collections and revenue recognition among those payors. Any projections provided herein should be considered forward looking statements and are subject to the risks summarized in the safe harbor statement at the end of this press release.

MDxHealth licensee Exact Sciences recently reported on the successful completion of their FDA preapproval inspection (PAI). CMS initiated National Coverage Analysis for screening for colorectal cancer using Cologuard, and posted the related Proposed Decision Memorandum on the CMS website. Exact Sciences reported that it is preparing for commercialization of its Cologuard test, most recently completing the training of an eighty-person direct sales force. In August, Cologuard received FDA approval and the product launch is expected before the end of 2014. MDxHealth is entitled to receive milestone payments and royalties from the sale of the test under the terms of its licensing agreement.

About MDxHealth

MDxHealth is a leading molecular diagnostic company that develops and commercializes epigenetic tests to support cancer treatment. The company's tests are based on proprietary gene methylation (epigenetics) 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 and follow us on Twitter at 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 2014 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 21, 2014

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

Complete Financial Statements: To download the 2014 interim report, go to:
<http://www.mdxhealth.com/investors/financials>

For more information:

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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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