MDxHealth

# 2012 INTERIM REPORT

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*This Interim Report 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 MDxHealth's control, and may turn out to be materially different. MDxHealth expressly disclaims any obligation to update any such forward-looking statements in this Interim Report 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.*

# I. INTERIM MANAGEMENT REPORT

## Highlights

In the first half of 2012, MDxHealth made significant progress in both its ClinicalMDx and PharmacoMDx businesses.

In H1 2012, MDxHealth presented positive clinical trial data on the ConfirmMDx™ for Prostate Cancer at the American Urology Association (AUA) annual meeting, signed a co-marketing agreement for this test with PLUS Diagnostics, built out its own sales and marketing organization and launched the ConfirmMDx test in May. In the same period, MDxHealth licensing partner Predictive Biosciences launched its CertNDx™ bladder cancer test. The company also signed a worldwide development and commercialization agreement for the company's PredictMDx™ test as a companion diagnostic to Merck KGaA's drug candidate cilengitide, a treatment for glioblastoma currently in Phase III clinical trials.

The company received its CLIA (Clinical Laboratory Improvement Amendments) certification, CAP (College of American Pathologists) certification, and licenses from California, Maryland and Florida for its reference laboratory in Irvine, CA. Additionally, the company received the Frost & Sullivan European award for technology leadership in oncology molecular diagnostics

"In the first half of 2012, we accomplished many milestones to support the commercialization of our ConfirmMDx™ product for prostate cancer in the U.S. market" said Dr. Jan Groen, CEO of MDxHealth. Commenting further, he went on to say, "To date, the test has been well received by urologists and sales are on track with our forecast. We saw double-digit growth of revenue in both our ClinicalMDx and PharmacoMDx businesses compared to the first half of 2011," and we expect full-year 2012 revenues to exceed 2011 levels as second half revenues continue to increase".

## Key non-audited financials, as of June 30, 2012

Amounts as at and for the six months ended

| *Euro thousands* | June 30, 2012 | June 30, 2011 |
|---|---|---|
| Commercial Revenues | 1,456 | 819 |
| Total Revenues | 2,014 | 1,407 |
| EBITDA (Loss) | (4,049) | (3,685) |
| EBIT Operating Income (Loss) | (4,260) | (3,851) |
| Net Profit (Loss) | (4,259) | (3,813) |
| Cash and cash equivalents | 6,551* | 14,646 |

*does not include gross proceeds of €10 million from the private placement on July 4, 2012

## Revenues

Commercial revenues in H1 2012 increased by 78% to €1.5 million over the comparable period in 2011. Revenues are derived from both our PharmacoMDx business and our ClinicalMDx business. As noted earlier, PharmacoMDx revenues grew 54% to €908K while ClinicalMDx revenues grew 122% to €413K. Income from government grants and other sources declined by 5% as the company continues to focus on growing its commercial revenue sources. However, due to the strong overall commercial revenue growth achieved by the company, total revenue grew by 43% to €2.0 million in H1 2012.

**Operating Expenses**

The company's operating loss (EBIT) increased by 11%, and the net loss increased by 12% in H1 2012 due to the anticipated cost increases associated with the scale up of U.S. sales and marketing and CLIA reference laboratory operating expenses. This was partially offset by cost reductions implemented in the previous year that benefited Q1 2012 spending levels.

**Cash Position**

MDxHealth ended the first half of 2012 with cash and cash equivalents of €6.6 million compared to €14.6 on June 30, 2011, €787K lower than the same period last year after adjusting for the April 2011 capital increase. The higher cash utilization is attributed to the scale up of U.S. sales and marketing and CLIA laboratory operating costs. Consistent with our commercialization plan, cash used in operations for the 6 months ended June 30, 2012increased by 11% as compared to a year earlier, again due to the U.S. commercial expansion.

**Outlook**

For 2012, the company expects overall revenues to exceed 2011 levels as second half revenues continue to increase. The PharmacoMDx business group is expected to continue to have strong performance as projects with Merck KGaA, GSK, and other partners continue. Revenues from the ClinicalMDx business are expected to be bolstered by revenues from the ConfirmMDx for Prostate cancer test in the second half of 2012 as the company continues to focus on building its commercial revenue, while revenues from grants is expected to decline compared to 2011.

Total operating costs in the second half are expected to increase due to higher sales and marketing and other operating activities to expand the sales of ConfirmMDx. As testing volumes increase, variable laboratory costs will increase proportionally along with some administrative costs related to billing and collection activities. Reimbursement support and information technology costs are also expected to increase in the second half. As a result, EBIT is expected to be at planned levels, but will be lower than 2011.

**Post-closing events**

On July 4, 2012, MDxHealth listed 6,891,113 new shares on the Brussels NYSE Euronext exchange resulting from successfully raising €10 million in gross proceeds through a private placement with investors in various countries. The average subscription price was €1.45. Biovest Comm. VA, an existing investor, purchased 1,996,008 of the new shares at €1.50, while the remaining 4,895,105 shares were purchased by other existing and new shareholders at €1.43. ING Belgium NV/SA was the global coordinator, and both ING Belgium NV/SA and Petercam jointly performed the role of book runners.

The funds from the private placement along with the existing cash reserves allows for the continued scale up of U.S. sales and marketing efforts for the company's ClinicalMDx business and the expansion of operations of the U.S. CLIA reference laboratory.

In Q3 2012, the company recognized its first revenues from sales of the ConfirmMDx for Prostate Cancer test. Although the company initiated billing to third party payors for tests performed in Q2 2012, the process to setup accounts and establish reimbursement rates with payors typically takes months.

**Other Announcements**

In March, Prof. Dr. Wim van Criekinge became MDxhealth's Chief Scientific Officer. In this role, Prof van Criekinge is guiding the future of MDxHealth's epigenetic product development strategy and scientific projects and providing scientific support for both our ClinicalMDx and PharmacoMDx businesses. In March, Mr. Francis Ota was appointed as Vice President of Finance. He is based at the company's U.S. headquarters in Irvine, CA. Mr. Ota brings valuable CLIA reference laboratory and medical device experience to MDxHealth, having served as a senior finance executive with a number of leading healthcare companies in the U.S.

**Related party transactions**

In the first six months of 2012, ING Bank Belgium, which is a significant shareholder of the company and a Board member of the company at the time, was part of the consortium of banks that assisted the company in its private placement of June 2012. There were no changes to related party transactions disclosed in the Annual Financial Report 2011 that potentially had a material impact to the financials of the first six months of 2012.

**Principal risks related to the business activities**

The principal risks related to the MDxHealth's business activities have been outlined in the 2011 Registration Document, which is available on the internet at www.mdxhealth.com/investors/financials.htm. The risks have not materially changed from those laid out in the 2011 Registration Document.

**Declaration of responsible persons**

The Board of Directors of MDxHealth SA, represented by all its members, declares that, as far as it is aware, the financial statements in this Interim Report, made up according to the applicable standards for financial statements, give a true and fair view of the equity, financial position and the results of the company and its consolidated companies. The Board of Directors of MDxHealth SA, represented by all its members, further declares that this Interim Report gives a true and fair view on the information that has to be contained herein. The condensed consolidated interim financial statements have been prepared in accordance with International Accounting Standard (IAS) 34 (Interim Financial Reporting) as adopted by the European Union.

## II. CONDENSED UNAUDITED CONSOLIDATED STATEMENT OF FINANCIAL POSITION
## at June 30 2012 compared to December 31 2011

*In thousands of EUR*
*According to IFRS*

| | as at June 30, 2012 | as at Dec 31, 2011 |
|---|---|---|
| **ASSETS** | | |
| Intangible assets | 42 | 44 |
| Property, plant and equipment | 930 | 727 |
| Grants receivable (> 1 year) | 0 | 0 |
| **Non-current assets** | **972** | **771** |
| Grants receivable (< 1 year) | 814 | 827 |
| Trade receivables | 1,402 | 1,267 |
| Prepaid expenses and other current assets | 791 | 704 |
| Cash and cash equivalents | 6,551 | 11,123 |
| **Current assets** | **9,558** | **13,921** |
| **Total assets** | **10,530** | **14,692** |
| | | |
| **EQUITY AND LIABILITIES** | | |
| Share capital | 14,008 | 14,008 |
| Issuance premium | 14,700 | 14,700 |
| Accumulated profit/(loss) | -19,772 | -12,825 |
| Result of the year | -4,259 | -6,947 |
| Share-based compensation | 2,476 | 2,385 |
| Translation reserves | -71 | -1 |
| **Equity attributable to equity holders** | **7,082** | **11,320** |
| **Total equity** | **7,082** | **11,320** |
| Advance on royalties | 82 | 120 |
| Long-term liabilities | 44 | 160 |
| Long-term lease debt | 0 | 0 |
| **Non-current liabilities** | **126** | **280** |
| Current portion of lease debt | 1 | 0 |
| Trade payables | 2,035 | 2,024 |
| Grants payable (< 1 year) | 338 | 403 |
| Other current liabilities | 948 | 665 |
| **Current liabilities** | **3,322** | **3,092** |
| **Total equity and liabilities** | **10,530** | **14,692** |

## III. CONDENSED UNAUDITED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME
## For six months ended June 30 2012 and 2011

*In thousands of EUR (except per share amounts)*
*According to IFRS*

| | For six months ended | |
|---|---|---|
| Continuing Operations | **June 30, 2012** | **June 30, 2011** |
| Product and service income | 1,456 | 819 |
| Government grant income | 558 | 588 |
| **Revenues** | **2,014** | **1,407** |
| Cost of goods and services sold | 128 | 139 |
| **Gross Profit** | **1,886** | **1,268** |
| Research and development costs | 2,467 | 2,935 |
| Selling, general and administrative expenses | 3,703 | 2,256 |
| Other operating income | 28 | 72 |
| Other operating expenses | 4 | 0 |
| **Total operating charges** | **6,146** | **5,119** |
| **EBIT** | **-4,260** | **-3,851** |
| Financial income | 153 | 92 |
| Financial expenses | 152 | 54 |
| **Profit/(loss) before taxes** | **-4,259** | **-3,813** |
| Income taxes | 0 | 0 |
| **Net Profit/(loss) for the period from continuing operations** | **-4,259** | **-3,813** |
| Profit/(loss) for the period from discontinued operations | 0 | 0 |
| **Profit/(loss) for the period from continuing operations [1]** | **-4,259** | **-3,813** |
| **Other comprehensive income** | | |
| Exchange differences arising on translation of foreign operations | -70 | -2 |
| Net gain (loss) on available for sale financial assets | 0 | 0 |
| Effective gains (losses) on cashflow hedges | 0 | 0 |
| Net gain (loss) on hedge of net investment in foreign operations | 0 | 0 |
| Income tax relating to components of other comprehensive income | 0 | 0 |
| Other comprehensive income for the period (net of tax) | -70 | -2 |
| **Total comprehensive profit/(loss) for the period (net of tax) [1]** | **-4,329** | **-3,815** |
| | | |
| **Net profit/(loss) per share – basic & diluted** | -0.23 | -0.20 |
| Shares used in computing per share amount – basic (number outstanding shares) | 18.622.327 | 18.622.327 |

[1]: All amounts are attributable to equity holders of MDxHealth SA since there are no minority interests

## IV. UNAUDITED CONSOLIDATED STATEMENT OF CASH FLOWS
## For six months ended June 30 2012 and 2011

*In thousands of EUR*
*According to IFRS*

| | for six months ended | |
|---|---|---|
| | **June 30, 2012** | **June 30, 2011** |
| **CASH FLOWS FROM OPERATING ACTIVITIES** | | |
| Operating Profit/(Loss) | -4,260 | -3,851 |
| Depreciation, amortization and impairment results | 211 | 166 |
| Share-based compensation | 91 | 159 |
| Interest paid | -6 | -7 |
| (Increase)/decrease in accounts receivable (1) | -209 | 496 |
| Increase/(decrease) in accounts payable (2) | 76 | -199 |
| Total adjustments | 163 | 615 |
| **Net cash provided by/(used in) operating activities** | **-4,097** | **-3,236** |
| | | |
| **CASH FLOWS FROM INVESTING ACTIVITIES** | | |
| Interest received | 48 | 31 |
| Gain/(Loss) on disposal of fixed assets | 3 | 0 |
| Other financial profit/(loss) | -41 | -32 |
| Disposal/(Acquisition) of financial assets | 0 | 0 |
| Investment in intangible assets | -6 | -6 |
| Purchase of property, plant and equipment | -406 | -10 |
| **Net cash provided by/(used in) investing activities** | **-402** | **-17** |
| | | |
| **CASH FLOWS FROM FINANCING ACTIVITIES** | | |
| Proceeds from issuance of shares (net of issue costs) | 0 | 7,308 |
| **Net cash provided by/(used in) financing activities** | **0** | **7,308** |
| | | |
| **Net increase/(decrease) in cash and cash equivalents** | **-4,499** | **4,055** |
| **Cash and cash equivalents at beginning of year** | **11,123** | **10,593** |
| Effect of exchange rates | -73 | -2 |
| **Cash and cash equivalents at end of period** | **6,551** | **14,646** |

(1) = long term grants receivable + short term grants receivable + trade receivables + prepaid expenses & other current assets
(2) = long term grants payable + trade payables + other current liabilities

## V. UNAUDITED CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY

*In thousands of EUR (except share amounts)*
*According to IFRS*

| | Number of shares | Share capital | Issuance Premium | Retained earnings | Share-based compensation | Translation reserves | Total Equity |
|---|---|---|---|---|---|---|---|
| **Balance at 31 December 2010** | **13,185,614** | **10,518** | **10,882** | **-12,825** | **2,151** | **-3** | **10,723** |
| Net Profit/(Loss) for the period | | | | -3,813 | | | -3,813 |
| Income and expenses directly allocated to equity | | | | | | -2 | -2 |
| **Total comprehensive income** | | | | **-3,813** | | **-2** | **-3,815** |
| Capital increase | 5.436.713 | 4,337 | 3,818 | | | | 8,155 |
| SPO costs against capital | | -847 | | | | | -847 |
| Share-based compensation | | | | | 159 | | 159 |
| **Balance at 31 December 2011** | **18.622.327** | **14,008** | **14,700** | **-19,772** | **2,385** | **-1** | **11,320** |

| | Number of shares | Share capital | Issuance Premium | Retained earnings | Share-based compensation | Translation reserves | Total Equity |
|---|---|---|---|---|---|---|---|
| **Balance at 31 December 2011** | **18.622.327** | **14,008** | **14,700** | **-19,772** | **2,385** | **-1** | **11,320** |
| Net Profit/(Loss) for the period | | | | -4,259 | | | -4,259 |
| Income and expenses directly allocated to equity | | | | | | -70 | -70 |
| **Total comprehensive income** | | | | **-4,259** | | **-70** | **-4,329** |
| Share-based compensation | | | | | 91 | | 91 |
| **Balance at 30 June 2012** | **18.622.327** | **14,008** | **14,700** | **-24,031** | **2,476** | **-71** | **7,082** |

## VI. EXPLANATORY NOTES

### Accounting policies

### 1. Basis of preparation

The condensed consolidated interim financial statements have been prepared in accordance with International Accounting Standard (IAS) 34 (Interim Financial Reporting) as adopted by the European Union.

These interim consolidated financial statements do not include all the information required for full annual financial statements and should be read in conjunction with the consolidated financial statements of the Company as at and for the year ended 31 December 2011.

The preparation of the condensed consolidated interim financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated interim financial statements and the reported amounts of revenue and expenses during the reporting period. If in the future such estimates and assumptions, which are based on management's best estimates and judgment, deviate from the actual circumstances, the original estimates and assumptions will be modified and the effects of the revisions will be reflected in the period in which the circumstances change.

Notwithstanding the losses sustained during the Company's existence, the Company has, to date, ended each year with cash. The company expects to continue to incur losses during the financial year 2012. Based on the current cash availability, the board of directors however believes that the future research programs and the Company activities can be continued for more than one year. Consequently the accounts have been prepared on a going concern basis.

Where necessary, the comparatives have been reclassified in order to enhance inter-period comparability of information presented in current and prior years. The consolidated financial statements are presented in Euros and all values are rounded to the nearest thousand except when otherwise indicated.

### 2. Significant accounting policies

The same accounting policies, presentation and methods of computation have been followed in these condensed financial statements as were applied in the preparation of the Group's financial statements for the year ended 31 December 2011, except for the impact of the adoption of the Standards and Interpretations described below.

#### New Standards, Interpretations and Amendments adopted by the Group

During the current financial year, the Group has adopted all the new and revised Standards and Interpretations issued by the International Accounting Standards Board (IASB) and the International Financial Reporting Interpretations Committee (IFRIC) of the IASB, that are relevant to its operations and effective for the accounting period starting on January 1, 2012.

The Group has not applied any new IFRS requirements that are not yet effective as per June 30, 2012.

The following new Standards, Interpretations and Amendments issued by the IASB and the IFRIC are effective for the current period:

1. IFRS 7 Financial Instruments: Disclosures (as amended in October 2010) – Amendments enhancing disclosures about transfers of financial assets.

The adoption of this amendment has not led to major changes in the Group's accounting policies.

**Standards and Interpretations issued but not yet effective in the current period**

The Group elected not to early adopt the following new Standards, Interpretations and Amendments, which have been issued but are not yet effective as per June 30, 2012.

***Standards***

- Annual improvements to IFRSs 2009-2011 (issued in May 2012);
- IFRS 1 First-time Adoption of International Financial Reporting Standards (as amended in December 2010) - Replacement of 'fixed dates' for certain exceptions with 'the date of transition to IFRSs';
- IFRS 1 First-time Adoption of International Financial Reporting Standards (as amended in December 2010) - Additional exemption for entities ceasing to suffer from severe hyperinflation;
- IFRS 1 First-time Adoption of International Financial Standards (as amended in March
- 2012): Government loans;
- IFRS 7 Financial Instruments: Disclosures (as amended in December 2011): Offsetting
- Financial Assets and Financial liabilities;
- IFRS 9 Financial instruments (issued in November 2009) and subsequent amendments (issued in October 2010 and December 2011): classification and measurement of financial assets, as the first part of its project to replace IAS 39;
- IFRS 10 Consolidated Financial Statements (issued in May 2011 and subsequently amended in June 2012): presentation and preparation of consolidated financial statements when an entity controls one or more other entities;
- IFRS 11 Joint Arrangements (issued in May 2011 and subsequently amended in June 2012): arrangement of which two or more parties have joint control;

- IFRS 12 Disclosures of Interest in Other Entities (issued in May 2011 and subsequently amended in June 2012): disclosure of information that enables users of financial statements to evaluate the nature of, and risks associated with, its interests in other entities;

- IFRS 13 Fair Value Measurement (issued in May 2011): defines fair value and sets out in a single IFRS a framework for measuring fair value;

- IAS 1 Presentation Financial Statement (as amended in June 2011) – Amendments to Presentation of Items of Other Comprehensive Income;

- IAS 12 Income taxes (as amended in December 2010) - Limited scope amendment (recovery of underlying assets);

- IAS 19 Employee benefits (as amended in June 2011) – measurement of pension and all other long term benefits + presentation changes in respect of pensions;

- IAS 27 Separate Financial Statements (issued in May 2011): Consolidation requirements previously forming part of IAS 27 have been revised and are now contained in IFRS 10;

- IAS 28 Investments in associated and Joint Ventures (issued in May 2011): accounting methods for investments in associates;

- IAS 32 Financial instruments (as amended in December 2011): Offsetting Financial Assets and Financial liabilities;

***Interpretations***

- IFRIC 20 Stripping Costs in the Production Phase of a Surface Mine

None of the other new standards, interpretations and amendments, which are effective for periods beginning after 1st July 2012 and which have not been adopted early, are expected to have a material effect on the Group's future financial statements.

## VII. STATUTORY AUDITOR'S LIMITED REVIEW REPORT

### Introduction

We have reviewed the accompanying interim consolidated statement of financial position of MDxHealth SA as of 30 June 2012 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.

**Scope of 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.

**Conclusion**

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 30, 2012

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

## VIII. CORPORATE INFORMATION

### Registered office

MDxHealth SA has the legal form of a public limited liability company (société anonyme - SA / naamloze vennootschap - NV) organized and existing under the laws of Belgium. The company's registered office is located at Tour 5 GIGA, Avenue de l'Hôpital 11, B-4000 Liège, Belgium.

The company is registered with the Registry of Legal Persons (registre des personnes morales - RPM / rechtspersonenregister – RPR) under company number RPM/RPR 0479.292.440 (Liège).

**Listings**
Euronext Brussels and Euronext Amsterdam: MDXH

**Financial calendar**
November 15, 2012 – Second business update (Q3 2012)

**Financial year**
The financial year starts on 1 January and ends on 31 December.

**Statutory auditor**
BDO Bedrijfsrevisoren / Réviseurs d'entreprises CVBA/SCRL
Da Vincilaan 9
1935 Zaventem
Belgium

**Availability of the Interim Report**
This document is available to the public free of charge and upon request:
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Tel: +32 4 364 20 70
E-mail: ir@mdxhealth.com

For informational purposes, an electronic version of the Interim Report 2011 is available on the website of MDxHealth at www.mdxhealth.com/investors/documents