

# 2013 INTERIM REPORT

## TABLE OF CONTENTS

<b>I. INTERIM MANAGEMENT REPORT</b> .....	2
<b>II. CONDENSED UNAUDITED CONSOLIDATED STATEMENT OF FINANCIAL POSITION</b> .....	5
<b>III. CONDENSED UNAUDITED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME</b> .....	6
<b>IV. UNAUDITED CONSOLIDATED STATEMENT OF CASH FLOWS</b> .....	7
<b>V. UNAUDITED CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY</b> .....	8
<b>VI. EXPLANATORY NOTES</b> .....	9
<b>VII. STATUTORY AUDITOR'S LIMITED REVIEW REPORT</b> .....	12
<b>VIII. CORPORATE INFORMATION</b> .....	13

*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

#### Key non-audited financials, as of June 30, 2013

Amounts as at and for the six months ended

<i>Euro thousands</i>	June 30, 2013	June 30, 2012
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.

### **Related parties**

Transactions between MDxHealth SA and MDxHealth Inc., which are related parties, have been eliminated in consolidation and are not disclosed in this note. The intercompany services between the two MDxHealth group entities relate to R&D and administrative services carried out by the subsidiary companies on behalf of the parent company and to administrative services carried out by the parent company for the subsidiaries.

Beside remuneration, warrants and bonus there are no other transactions to key personnel than these already mentioned in the 2012 financial statements.

There were no other related party transactions.

### **Principal risks related to the business activities**

The principal risks related to the MDxHealth's business activities have been outlined in the 2012 Registration Document, which is available on the internet at [www.mdxhealth.com/investors/financials.htm](http://www.mdxhealth.com/investors/financials.htm). The risks have not materially changed from those laid out in the 2012 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, 2013 compared to December 31, 2012

*In thousands of EUR*

*According to IFRS*

	as at June 30, 2013	as at Dec 31, 2012
<b>ASSETS</b>		
Intangible assets	20	28
Property, plant and equipment	708	800
Grants receivable (> 1 year)	0	0
<b>Non-current assets</b>	<b>728</b>	<b>828</b>
Inventory	106	0
Grants receivable (< 1 year)	119	348
Trade receivables	871	1,694
Prepaid expenses and other current assets	638	540
Cash and cash equivalents	24,677	11,714
<b>Current assets</b>	<b>26,411</b>	<b>14,296</b>
<b>Total assets</b>	<b>27,139</b>	<b>15,124</b>
<b>EQUITY AND LIABILITIES</b>		
Share capital	25,729	19,153
Issuance premium	30,233	19,203
Accumulated profit/(loss)	-28,748	-19,772
Result of the year	-5,971	-8,976
Share-based compensation	2,684	2,567
Translation reserves	-95	-58
<b>Equity attributable to equity holders</b>	<b>23,832</b>	<b>12,117</b>
<b>Total equity</b>	<b>23,832</b>	<b>12,117</b>
Advance on royalties	9	17
Long-term liabilities	0	0
Long-term lease debt	0	0
<b>Non-current liabilities</b>	<b>9</b>	<b>17</b>
Current portion of lease debt	0	0
Trade payables	2,156	1,661
Grants payable (< 1 year)	0	0
Other current liabilities	1,142	1,329
<b>Current liabilities</b>	<b>3,298</b>	<b>2,990</b>
<b>Total equity and liabilities</b>	<b>27,139</b>	<b>15,124</b>

### III. CONDENSED UNAUDITED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

For six months ended June 30, 2013 and 2012

*In thousands of EUR (except per share amounts)*

*According to IFRS*

	For six months ended	
	June 30, 2013	June 30, 2012
Continuing Operations		
Product and service income	3,033	1,456
Government grant income	0	558
<b>Revenues</b>	<b>3,033</b>	<b>2,014</b>
Cost of goods and services sold	1,357	128
<b>Gross Profit</b>	<b>1,676</b>	<b>1,886</b>
Research and development costs	2,441	2,467
Selling, general and administrative expenses	5,223	3,703
Other operating income	36	28
Other operating expenses	1	4
<b>Total operating charges</b>	<b>7,629</b>	<b>6,146</b>
<b>EBIT</b>	<b>-5,953</b>	<b>-4,260</b>
Financial income	72	153
Financial expenses	90	152
<b>Profit/(loss) before taxes</b>	<b>-5,971</b>	<b>-4,259</b>
Income taxes	0	0
<b>Net Profit/(loss) for the period from continuing operations</b>	<b>-5,971</b>	<b>-4,259</b>
Profit/(loss) for the period from discontinued operations	0	0
<b>Profit/(loss) for the period from continuing operations<sup>1</sup></b>	<b>-5,971</b>	<b>-4,259</b>
<b>Other comprehensive income</b>		
Exchange differences arising on translation of foreign operations	-37	-70
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)	-37	-70
<b>Total comprehensive profit/(loss) for the period (net of tax)<sup>1</sup></b>	<b>-6,008</b>	<b>-4,329</b>
<b>Net profit/(loss) per share – basic &amp; diluted</b>	<b>-0.18</b>	<b>-0.23</b>
Shares used in computing per share amount – basic (number outstanding shares)	34.251.303	18.622.327

<sup>1</sup>: 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, 2013 and 2012

*In thousands of EUR*  
*According to IFRS*

	for six months ended	
	June 30, 2013	June 30, 2012
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Operating Profit/(Loss)	-5,953	-4,260
Depreciation, amortization and impairment results	199	211
Share-based compensation	117	91
Interest paid	-1	-6
Change in inventories	-106	0
(Increase)/decrease in accounts receivable (1)	954	-209
Increase/(decrease) in accounts payable (2)	300	76
Total adjustments	1,463	163
<b>Net cash provided by/(used in) operating activities</b>	<b>-4,490</b>	<b>-4,097</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Interest received	5	48
Gain/(Loss) on disposal of fixed assets	0	3
Other financial profit/(loss)	-22	-41
Investment in intangible assets	0	-6
Purchase of property, plant and equipment	-96	-406
<b>Net cash provided by/(used in) investing activities</b>	<b>-113</b>	<b>-402</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from issuance of shares (net of issue costs)	17,606	0
<b>Net cash provided by/(used in) financing activities</b>	<b>17,606</b>	<b>0</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>13,003</b>	<b>-4,499</b>
<b>Cash and cash equivalents at beginning of year</b>	<b>11,714</b>	<b>11,123</b>
Effect of exchange rates	-40	-73
<b>Cash and cash equivalents at end of period</b>	<b>24,677</b>	<b>6,551</b>

(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
<b>Balance at 1 January 2012</b>	<b>18.622.327</b>	<b>14,008</b>	<b>14,700</b>	<b>-19,772</b>	<b>2,385</b>	<b>-1</b>	<b>11,320</b>
Net Profit/(Loss) for the period				-4,259			-4,259
Income and expenses directly allocated to equity						-70	-70
<b>Total comprehensive income</b>				<b>-4,259</b>		<b>-70</b>	<b>-4,329</b>
Share-based compensation					91		91
<b>Balance at 30 June 2012</b>	<b>18.622.327</b>	<b>14,008</b>	<b>14,700</b>	<b>-24,031</b>	<b>2,476</b>	<b>-71</b>	<b>7,082</b>
<b>Balance at 31 December 2012</b>	<b>25.513.440</b>	<b>19.153</b>	<b>19.203</b>	<b>-28.748</b>	<b>2.567</b>	<b>-58</b>	<b>12.117</b>
<b>Total comprehensive income</b>				<b>-5.971</b>		<b>-37</b>	<b>-6.008</b>
Issuance of shares	8.737.863	6.970	11.030				18.000
SPO costs against capital		-394					-394
Share-based compensation					117		117
<b>Balance at 30 June 2013</b>	<b>34.251.303</b>	<b>25.729</b>	<b>30.233</b>	<b>-34.719</b>	<b>2.684</b>	<b>-95</b>	<b>23.832</b>



## 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 2012.

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 2013. 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.

#### 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 2012, 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 approved by the EU and relevant to its operations and effective for the accounting year starting on January 1, 2013. The Group has not applied any new IFRS requirements that are not yet effective as per June 30, 2013.

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

- Annual Improvements to IFRSs 2009-2011 Cycle (issued by the IASB in May 2012)
- IFRS 1 - First-time Adoption of International Financial Reporting Standards (Amendment March 2012) — Amendments for government loan with a below-market rate of interest when transitioning to IFRSs
- IFRS 7 - Financial Instruments: Disclosures (Amendment December 2011) — Amendments related to the offsetting of assets and liabilities
- IFRS 13 - Fair Value Measurement - Original Issue May 2011
- IAS 1 Presentation of Financial Statements (Amendment June 2011) — Amendments to revise the way other comprehensive income is presented

- IAS 19 - Employee Benefits (Amendment June 2011) — Amended Standard resulting from the Post-Employment Benefits and Termination Benefits projects
- IAS 27 - Consolidated and Separate Financial Statements — Reissued as IAS 27 Separate Financial Statements (May 2011)
- IAS 28 - Investments in Associates — Reissued as IAS 28 Investments in Associates and Joint Ventures (May 2011)
- IFRIC 20 - Stripping Cost in the Production Phase of Surface Mine

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, 2013.

- IFRS 7 - Financial Instruments: Disclosures (Amendment December 2011) — Deferral of mandatory effective date of IFRS 9 and amendments to transition disclosures
- IFRS 9 - Financial Instruments — Classification and Measurement (Original issue November 2009)
- IFRS 9 - Financial Instruments — Reissue to include requirements for the classification and measurement of financial liabilities and incorporate existing derecognition requirements (October 2010)
- IFRS 9 - Financial Instruments (Amendment December 2011) — Deferral of mandatory effective date of IFRS 9 and amendments to transition disclosures
- IFRS 10 - Consolidated Financial Statements – Original Issue May 2011
- IFRS 10 - Consolidated Financial Statements (Amendment June 2012) – Amendments to transitional guidance
- IFRS 10 - Consolidated Financial Statements (Amendment October 2012) – Amendments for investment entities
- IFRS 11 - Joint Arrangements - Original Issue May 2011
- IFRS 11 - Joint Arrangements (Amendment June 2012) – Amendments to transitional guidance
- IFRS 12 - Disclosure of Interests in Other Entities - Original Issue May 2011
- IFRS 12 - Disclosure of Interests in Other Entities (Amendment June 2012) – Amendments to transitional guidance
- IFRS 12 - Disclosure of Interests in Other Entities (Amendment October 2012) – Amendments for investment entities
- IAS 27 - Consolidated and Separate Financial Statements (Amendment October 2012) — Amendments for investment entities
- IAS 32 - Financial Instruments: Presentation (Amendment December 2011) — Amendments relating to the offsetting of assets and liabilities
- IAS 36 – Impairment of Assets (Amendment May 2013) — Recoverable Amounts Disclosures for Non-Financial Assets

- IAS 39 – Financial Instruments: Recognition and Measurement (Amendment June 2013) —  
Novation of Derivatives and Continuation of Hedge Accounting
- IFRIC 21 – Levies (May 2013)

None of the other new standards, interpretations and amendments, which are effective for periods beginning after 1<sup>st</sup> July 2013 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 report to the Board of Directors of *MDxHealth SA* on the review of consolidated interim financial information for the six-month period ended 30 June 2013**

### **Introduction**

We have reviewed the accompanying interim consolidated statement of financial position of MDxHealth 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.

### **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, 22 August 2013

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 6, 2013 – Second business update (Q3 2013)

### 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](mailto:ir@mdxhealth.com)

For informational purposes, an electronic version of the Interim Report 2012 is available on the website of MDxHealth at [www.mdxhealth.com/investors/documents](http://www.mdxhealth.com/investors/documents)