







Developing epigenetic tests

for cancer assessment and the

personalized treatment

of patients.



**REGISTRATION DOCUMENT 2012** 



Personalized Products

Personalized Treatment

Personalized Results



Our "Confirm" products serve as an aid for physicians to assess the presence or absence of cancer.

## Inform MDX...

Our "Inform" products provide prognostic assessment to distinguish between aggressive and non-aggressive tumors as well as the patient's risk of recurrence.

## Pharmaco MDX...

We work with pharma companies to provide epigenetic discovery.

## Predict MD\*

for Glioblastoma

Our "Predict" products provide predictive information to indicate which drug or treatment regimen is likely to be most effective for the individual patient.

### Clinical MDX.

MDxHealth's Clinical Moleclar Diagnostics (Clinical MDx $^{TM}$ ) business is focused on providing physicians with innovative and meaningful assays that aid in the identification and treatment of their cancer patients.







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## RISKS RELATED TO THE BUSINESS

The following risk factors may affect the business, the operating performance and the financial condition and results of MDxHealth as well as the value of an investment in the shares of MDxHealth.

Prospective investors should carefully read the entire registration document and should pay particular attention to the risk factors set forth therein. Additional risks and uncertainties of which MDxHealth is currently not aware or which MDxHealth does currently not consider to be material could also materially and adversely impact its business, its operations and its financial situation or its results.

#### Revised business model

The business model of MDxHealth has considerably changed. In 2010, MDxHealth decided to shift from a discovery license company to a commercial clinical diagnostic company. The previous business model of the Company focused on the out-licensing of cancer screening applications and the discovery of new biomarkers in exchange for eventual royalty fees in the long term. Cancer screening applications often take many years to develop, to get approved and to produce revenues. This out-licensing strategy left the Company excessively dependent on third parties for the development and commercialization of its technology and products. With the new business model, MDxHealth is seeking to retain control of the end-development, launch, promotion, and sales of its core products.

Moreover, MDxHealth intends to sell its products primarily in the U.S. as a testing service via its own U.S. based laboratory facility. At the date of this document, MDxHealth has established a CLIA and CAP accredited U.S.-based laboratory and in 2012 launched its *ConfirmMDx™* for Prostate Cancer test on the U.S. market, but it is still at the early stages of building market awareness, generating sales and obtaining favorable reimbursement determinations from both public (Medicare) and private payors for this new test. MDxHealth may encounter difficulties or delays in its efforts to properly operate and maintain its U.S. based service lab and tests, to increase and maintain sales of its existing test, or to commercialize any candidate tests currently in development.

In addition, MDxHealth continues to maintain its laboratory operations in Belgium and provide commercial tests in Europe and elsewhere. The Company continues to provide pharmaco molecular diagnostic services on a global basis at its laboratory facilities, and these non-ClinicalMDx™ activities still accounted for substantially all of the company's revenue in 2012. MDxHealth is subject to a number of risks and challenges that specifically relate to its international operations. If MDxHealth is unable to manage the challenges associated with its international operations, the growth of its business could be limited.

Furthermore, the Company's existing and candidate tests and its laboratories may not receive or maintain the necessary accreditation and regulatory approvals nor the support of the medical and reimbursement community necessary to obtain or maintain appropriate coverage determinations. In addition, governmental bodies and reimbursement authorities may change the regulation of this industry in a manner that may be detrimental to MDxHealth or increase the costs to commercialize its tests. To increase product sales, MDxHealth will need to expand its sales force and/or partner with companies with existing sales forces in certain fields. Finding, motivating and retaining qualified sales personnel will be important to the commercial success of the products.

If MDxHealth is not successful in accomplishing any of the above objectives, it may not be able to develop and/or commercialize tests and products, raise capital, expand its business, generate revenues or even continue its operations. For additional information, see Section 2.3 "Sales and Marketing Strategy" and Section 2.4 "Billing and Reimbursement."

#### **Availability of Capital**

MDxHealth will likely require additional funding to pursue its business objectives and to continue its operations as planned in the medium to long term. The level of MDxHealth's future financing needs will depend on many factors, including the progress, costs and timing of its research and development activities, the costs of operating its U.S. laboratory facility, the costs and timing of obtaining and maintaining regulatory approvals, licenses and certifications, the costs of obtaining, maintaining and enforcing its patents and other intellectual property rights, the costs and timing of maintaining or obtaining manufacturing for its products, the costs and timing of expanding sales and marketing capabilities and the terms and timing of establishing collaborations, license agreements and other partnerships.

MDxHealth's ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which it may have no or limited control, and MDxHealth cannot guarantee that additional funds will be available to it when necessary on commercially acceptable terms, if at all. In the event where MDxHealth raises funds through the issuance of equity securities, this will dilute its shareholders. In order to raise additional funds through the issuance of equity securities, MDxHealth may be required to obtain shareholder approval to increase Authorized Capital by appropriate amounts, as the current authorized share capital available for issuance expires at the General Shareholders'meeting to be held in 2015 which shall resolve on the annual accounts relating to the accounting year ending on December 31, 2014. There can be no assurance that the shareholders of the Company will authorize additional capital for issuance. MDxHealth may further seek funds through collaborations and licensing arrangements, which may require it to relinquish significant rights to its product-generating platforms or to grant licenses on terms which are not favorable to MDxHealth. If adequate funds are not available on commercially acceptable terms when needed, MDxHealth may be forced to delay, reduce or terminate the development or commercialization of its products, as currently envisaged, or it may be unable to take advantage of future business opportunities.

MDxHealth has received government grants to cover part of the costs of certain R&D projects and expects these grants to be limited in the future. Some of these grants may be lost or need to be repaid if the Company does not abide by the terms and conditions of such grants. The Company is not aware of any reasons to repay part or all of any grants that have been recognized as income to date.

At December 31, 2012, MDxHealth had cash and cash equivalents of EUR 11.7 million compared to a balance of EUR 11.1 million one year earlier. The company has no financial debt. Excluding the net proceeds of EUR 9.7 million raised via a private placement in July 2012, the net cash burn was EUR 9.0 million in 2012. Cash and cash equivalents represented 77% of the total assets at December 31, 2012 compared to 76% one year earlier. The net loss and operating cash burn are expected to increase in 2013 as the Company will be expanding its commercialization efforts with regard to its initial product.

#### **Loss Making Company**

MDxHealth has incurred operating losses since inception (EUR 80 million until end December 2012) and has paid no dividends. MDxHealth may never realize revenues from planned products and services, achieve or sustain profitability, reduce future operating losses, or pay dividends. The extraordinary general shareholders' meeting of June 21, 2010, approved the reduction of the share capital of MDxHealth in the amount of EUR 43.5 million by incorporation of accumulated losses without a reduction in the number of outstanding shares. The company expects to continue to incur losses in the near- to mid-term.

MDxHealth uses the Euro currency for financial reporting purposes. However, MDxHealth already has some of its operating revenues and costs in U.S. Dollars and expects to have a large share of its future revenues and costs in U.S.

Dollars. Unfavorable fluctuations in the exchange rate between the Euro and the U.S. Dollar could have a material negative impact on the financial results of MDxHealth.

In 2011, MDxHealth established CLIA lab and office facilities in the U.S. to assist in its future growth. Additionally, MDxHealth expects to grow and expand the scope of its business in certain product areas, including expansion of its development efforts. Recent and expected future growth will require MDxHealth to implement and improve its operational and financial systems and procedures. If MDxHealth is not able to manage its growth effectively, it may be difficult to execute on its business strategy and earn revenue.

MDxHealth may from time to time have to cease projects or operations in certain areas due to the need to re-allocate resources to the most promising projects or areas. Discontinuance of certain projects or areas of operations may result in one-time extra costs and could damage the relationship with partners involved in the discontinued projects. If MDxHealth is not able to manage the discontinuance of certain projects or areas of operation in an effective and successful manner, this could lead to some extra costs for the Company.

The historical financial losses of MDxHealth, the Company's current cash position and the general economic climate, and the commercialization of *Confirm*MDx™ for Prostate Cancer product on the US market have led MDxHealth to redirect part of it's R&D resources towards sales and marketing. If MDxHealth does not succeed in realizing its core commercial business objectives, then the Company may need to further downsize its activities and objectives and may even need to consider discontinuing all or part of them.

#### **Product Development and Market Acceptance**

In 2012, MDxHealth launched its commercial laboratory test, *Confirm*MDx<sup>™</sup> for Prostate Cancer, on the U.S. market from its CLIA and CAP accredited U.S.-based laboratory, but it is still at the early stages of building market awareness, gaining acceptance by physicians and other healthcare professionals, and obtaining favorable reimbursement determinations from both public (Medicare) and private payors for this new test. The *Confirm*MDx<sup>™</sup> for Prostate Cancer test is reimbursed by a number of private payors and not yet by governmental payors. Revenue of the *Confirm*MDx<sup>™</sup> for Prostate Cancer test have been limited to date, representing less than 10% of total revenues in 2012. Substantially all of the revenues of 2012 was non-clinical revenues. MDxHealth may encounter difficulties or delays in its efforts to properly operate and maintain its U.S.-based service lab, to obtain appropriate reimbursement coverage for the *Confirm*MDx<sup>™</sup> for Prostate Cancer test, or to increase and maintain sales of the *Confirm*MDx<sup>™</sup> for Prostate Cancer test.

In addition to its ConfirmMDx<sup>™</sup> for Prostate Cancer test, MDxHealth intends to develop and commercialize additional products, most of which are in early stages of development. These product candidates may not, or only with a substantial delay, be successfully developed and launched as commercial products and, if launched, may not gain acceptance by physicians and other healthcare professionals. The shift from a discovery license company to a commercial clinical diagnostic company led the Company to reallocate part of it's R&D resources towards commercialization activities. If MDxHealth does not succeed in realizing its core commercial business objectives, then the Company may need to further downsize its R&D activities and objectives and may even need to consider discontinuing all or part of them.

If MDxHealth's tests fail to gain market acceptance, or if its test candidates fail to be commercially launched, this may have a material adverse impact on MDxHealth's ability to generate proper revenues and achieve profitability. Market acceptance and speed of market penetration of MDxHealth's products will depend on, among other things, product performance, competition, safety, cost-effectiveness, convenience and ease of administration, reimbursement, non-invasive aspect of test, ease of handling and shipping of the samples as well as its other advantages over other tests.

MDxHealth is dependent on the results of clinical studies to demonstrate the validation of its products. The results of clinical studies may not show that MDxHealth products add value compared to existing methods, which could necessitate significant financial and other resources for further research and development, whereby commercialization of products could be delayed or may never occur. When running its clinical studies, MDxHealth relies on the availability of clinical samples in the respective bio-banks and the collaboration of medical centers and their researchers to supply human samples for evaluation. Future studies may require prospective sample collection, which would require additional time, expense and effort in the recruitment subjects and sponsorship of a clinical trial. If MDxHealth or any of its collaborators are unable to access sufficient and adequate patient samples, this could have a detrimental effect on the research and development plans of MDxHealth, on the regulatory approval of MDxHealth's products, and on the eventual commercialization of the products. Furthermore, MDxHealth and its collaborators abide by regulations for the collection of human samples. These regulations include obtaining patient consent, maintaining the confidentiality of the patient identification, obtaining approval of clinical trials of institutional (hospital) review boards and/or ethical committees, and obtaining any necessary insurance protection. If MDxHealth and its collaborators were to fail to abide by such regulations or if the regulations were to change in an unfavorable way, this could hinder MDxHealth's research and development plans and activities.

Additionally, MDxHealth's ability to promote, market and distribute its products and its ability to obtain sufficient coverage or reimbursement from third-party payers such as Medicare may impact the commercial success of its products. If medical practitioners do not order its tests, MDxHealth will likely not be able to create demand for its products in sufficient volume for MDxHealth to become profitable. To generate demand, MDxHealth will need to create market awareness of MDxHealth's products and services by visiting the medical community (e.g., oncologists, surgeons and pathologists), through scientific publications, presentations at medical conferences and through commercial partners. Furthermore, the commercial success of MDxHealth will depend in part on the degree to which MDxHealth's products are reimbursed by public health administrations, private health insurers, managed care organizations and other organizations. At the date of this document, the reimbursement environment in the United States is undergoing unprecedented change and uncertainty, resulting from a number of market factors including U.S. federal and state-level budget deficits, federal healthcare reform (Obamacare), and efforts by the medical profession and service providers to create transparency and equity in reimbursements. Given this uncertainty around the reimbursement status and future regulatory environment of some of MDxHealth's products, there can be no assurance that MDxHealth will achieve sufficient or timely reimbursement determinations, which would have a material adverse impact on MDxHealth's ability to generate proper revenues and achieve profitability.

#### Competition

MDxHealth faces significant competition at the level of the technology it uses as well as at the level of the products it intends to sell (see section 2.2). With respect to technology competition, other molecular technologies such as DNA mutation analysis, RNA expression analysis, and sequencing are also targeting the oncology market. Furthermore, other companies are also developing products that detect aberrant gene methylation in cancer. In addition, new services or products using new technologies developed by other companies could adversely affect the demand for MDxHealth's products. With respect to product competition, some of the cancer segments targeted by MDxHealth are served by traditional diagnostics. Such traditional diagnostics tests are often widely used and are relatively inexpensive. MDxHealth's products and tests may take time to or may not be able to change traditional medical practice and tests.

For its ConfirmMDx<sup>™</sup> for Prostate Cancer tissue-based test MDxHealth is aware of the presence of two directly competitive products on the market. In 2011 Mitomics, a privately-held Canadian company, launched an LDT tissue based molecular mRNA test for the diagnosis of prostate cancer. We currently have no information about their sales

volume. The PCA-3 test from Gen-Probe, a urine-based test, is on the U.S. market as an FDA approved test, which may provide a competitive advantage since the *ConfirmMDx™* for Prostate Cancer test is not FDA approved. The PCA-3 test is intended for the same patient population as *ConfirmMDx™* for Prostate Cancer, but its performance has only been established in men who were already recommended by urologists for repeat biopsy and it requires a special clinic office visit and prostate massage procedure to collect an enriched urine specimen. Epigenomics AG has out-licensed a potential prostate cancer marker using a different version of one of the genes in the MDxHealth gene panel (the GSTPi gene). Epigenomics has out-licensed their marker to Quest Diagnostics Inc. and Predictive Biosciences Inc. For both of these potential competitors, the test is still in the development state, the application (urine or tissue), as well as the date of a potential launch of their tests are currently unknown. To the knowledge of MDxHealth, no head-to-head comparison studies with any competing products have been published.

For its *Inform*MDx<sup>™</sup> *for Prostate Cancer* test currently in development, MDxHealth faces potential competition from Genomic Health, who has announced that it is developing a prognostic LDT for prostate cancer, with an expected launch date in 2013. Additionally, Myriad Genetics has a prognostic LDT for prostate cancer, which it markets for the same indication.

For its ConfirmMDx™ Lung Cancer test currently in development, MDxHealth faces potential competition from (i) a test being developed by Epigenomics AG which has published limited data on their test, and (ii) by improved screening techniques being evaluated by different universities. Epigenomics has launched in Europe a methylation based test for Lung Cancer called Epi proLung. This diagnostic test is used for patients suspected of lung cancer, however this kit is not FDA cleared and not offered in the U.S. No head-to-head comparison has been performed between the MDxHealth test and other potential competitive technologies.

For its *Inform*MDx<sup>™</sup> *test for Lung Cancer*, MDxHealth faces potential competition from PinPoint Diagnostics which launched an LDT tests in the US in 2012. The MDxHealth *Lung Inform*MDx<sup>™</sup> test currently under development is designed to identify Stage 1 lung cancer patients that have a high risk of recurrence. The company may face additional competition from established procedures and new entrants to the field in lung cancer.

For MDxHealth's pharmaco molecular diagnostic commercial service activities targeting pharma companies, MDxHealth faces competition from numerous companies with different methylation platforms or different molecular diagnostic technologies such as DNA mutation, sequencing and RNA expression.

#### **Regulatory Risk**

MDxHealth is, or may become, subject to numerous regulations, such as health, safety, environmental and privacy rules and laws, and potential regulatory actions based on the application of such laws. The costs of compliance with applicable regulations, requirements and guidelines could be substantial, and failure to comply could result in sanctions, including fines, injunctions, civil penalties, denial of applications for marketing approval of its products, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly increase MDxHealth's costs, delay the development and commercialization of its product candidates and substantially impair its ability to generate revenues and achieve profitability.

A key element of MDxHealth's strategy is focused on generating sales of its product candidates, which are still in early stage development, in the U.S. MDxHealth plans to introduce its products as Laboratory Developed Tests (LDTs) performed at its laboratory facility established in Irvine, California. In December 2011, MDxHealth's California Irvine facility became a CLIA-accredited laboratory and was also issued a State of California Public Health license. The Centers

for Medicare and Medicaid Services (CMS) who is regulated under the federal government (U.S. Health and Human Services), regulates all U.S. laboratories through the Clinical Laboratory Improvement Amendments (CLIA). CLIA certified laboratories are required to comply with various operational, personnel, facilities administration, quality, assay validation, and proficiency requirements intended to ensure that laboratory testing services are accurate, reliable, and timely. In July, 2012, the Irvine facility was audited by the College of American Pathologists (CAP) and was issued a certificate of accreditation. The College of American Pathologists performs an onsite audit biennially and requires the facility to perform a self-inspection in the interim year. Standards for testing under CLIA are based on the level of complexity of the tests performed by the laboratory. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. All molecular diagnostic tests are considered as high complexity tests. CLIA certification is a prerequisite to be eligible for reimbursement under Medicare and Medicaid. In addition to CLIA requirements, the Company is subject to various state laws. CLIA allows a state to adopt laboratory regulations that are more stringent than those under federal law. For laboratories conducting tests on specimens originating from these states, the testing laboratory must be licensed by that state which are New York, Florida, Maryland, Pennsylvania, California and Rhode Island.

MDxHealth's products are not FDA approved. The ConfirmMDx™ for Prostate Cancer test, launched in 2012 by its CLIA and CAP accredited U.S.-based laboratory, is being commercialized as an LDT service test. Additionally, several non-core products that include MDxHealth's technology are also commercialized as LDT service tests in the U.S. via Laboratory Corporation of America (LabCorp). Although the FDA previously claimed the authority to regulate LDTs that are validated by the developing laboratory and performed only by that laboratory, it has generally exercised enforcement discretion and declined to regulate the majority of tests developed and performed by high complexity CLIA-registered laboratories. In July 2010, however, the FDA indicated that it was reviewing the regulatory requirements applying to LDTs. The FDA continues to examine the LDT market and has not made any final conclusions despite initial indications from the FDA that it would communicate a revised regulatory position in 2011. In view of these developments, there can be no assurance that FDA regulation, including pre-market clearance or approval, will not be required in the future for LDTs applying MDxHealth's technology. If pre-market clearance or approval is required, the business of MDxHealth could be negatively impacted because its CLIA-accredited laboratory may be required to stop offering these LDTs pending pre-market clearance or approval. Furthermore, approval under one CLIA license does not guarantee approval under another, as approvals are linked to validation studies performed by the CLIA-registered laboratory offering the LDT. If new stringent regulation of LDTs were to be implemented in the short term by the U.S. regulatory authorities, and, more in particular if, as part thereof, MDxHealth would be requested to conduct additional clinical trials, for which it would need samples, then that could lead to delays or failure to obtain necessary regulatory approval, which could delay commercialization of the MDxHealth products and increase the costs of developing the products.

In Europe, MDxHealth must obtain a CE Marking and may in some cases need marketing approval from the European Medicine Agency (EMA) before it can commercialize its product candidates as diagnostic kits. Changes in regulatory approval policies or enactment of additional regulatory approval requirements may delay or prevent the Company from obtaining marketing approval for its diagnostic kits or LDTs. Even after regulatory approval, products may be subject to post-marketing or vigilance studies or may be subject to limitations on their indicated uses and may be withdrawn from the market if they are shown to be unsafe or ineffective.

#### **Reliance on Key Personnel and Collaborators**

MDxHealth depends on its ability to recruit and retain key personnel, and failure to do so may impact its ability to execute its business strategy. If MDxHealth is not able to retain its key managers and scientists, this may delay its research and development and future commercial activities and may adversely impact the ability of MDxHealth to

implement its business strategy. As MDxHealth advances its programs and expands its business, it may seek to recruit additional personnel with expertise in areas such as sales and marketing. If recruitment and retention efforts are unsuccessful, MDxHealth may not be able to achieve its objectives in a timely manner, if at all.

MDxHealth also relies on and expects to continue to rely on clinical scientific collaborators to contribute to its biomarker discovery program, biomarker validation and clinical trial studies. If any of MDxHealth's collaborators were to breach or terminate their agreement with MDxHealth or otherwise fail to conduct their collaborative activities successfully and in a timely manner, the research, development or commercialization of the products contemplated by the collaboration could be delayed or terminated.

MDxHealth's relationships with leading physicians, scientists and research institutions are necessary to establish MDxHealth's tests as the future standard of care for cancer diagnosis, prognosis and prediction. If some of MDxHealth's key collaborators determine that MDxHealth tests are not superior to available tests or that alternative technologies would be more effective in the early detection or personalized treatment of cancer, it may be difficult to continue the necessary relationships with leading scientists and research institutions and to establish MDxHealth's products as the future standard of care for cancer diagnosis. This would limit MDxHealth's revenue growth and profitability.

#### **Reliance on Commercial Partners**

MDxHealth's rights to use technologies licensed from third parties are conditional on compliance with certain requirements. When MDxHealth in-licenses or acquires technology from third parties, it is, generally, (i) required to abide by certain terms and conditions in order to maintain its rights to the technology and (ii) dependent on the protection, prosecution, maintenance and enforcement of the intellectual property rights by the licensors. Failure by MDxHealth to respect such terms and conditions may result in loss of the exclusivity on the technology or loss of rights to the technology which could prevent it from developing, manufacturing or selling its products or could allow competition to access the technology and thereby limit or prevent MDxHealth from developing, manufacturing or selling products utilizing that technology. Johns Hopkins University (JHU) is the inventor of a key technology in the field of gene methylation, the core MSP technology, of certain methylation-specific diagnostic markers. In connection with the Company's formation in 2003, MDxHealth received a worldwide exclusive license from JHU to use this methylation technology. This license and other similar licenses can be revoked by JHU in certain cases of material breach by MDxHealth of the terms and conditions of the license agreements, particularly by failing to report on and pay fees related to the underlying patents.

MDxHealth has entered, and intends to continue to enter, into partnership agreements with diagnostic companies for its screening products; with pharmaceutical companies for its companion diagnostic biomarker discovery capabilities, assay development capabilities, and clinical trial testing services; and with research kit companies for its research market products. If certain of these companies were to fail to use or commercialize, or delay the usage or commercialization of, the licensed technology or the products or services of MDxHealth, this could reduce the revenues of MDxHealth significantly. In 2012, MDxHealth entered into an expanded collaboration agreement with Merck KGaA for the commercial development of MDxHealth's MGMT diagnostic test as a companion diagnostic to Merck's drug candidate Cilengitide. However, Merck recently announced that the Phase III trial for Cilengitide did not meet primary endpoints, and therefore it is unlikely that Merck will continue its development of Cilengitide or its support for the development and commercialization of the Company's MGMT test as an FDA-approved companion diagnostic to Cilengitide. Merck's discontinuation of its development support, which accounted for approximately one-third of the Company's total revenues in 2012, will have a material negative impact on the Company's potential revenues from this commercial project.

MDxHealth has entered, and may enter into distribution, agency and marketing partnership agreements with different companies to supplement the efforts of its own sales force in generating market awareness and demand for its products. In 2012, MDxHealth entered into a U.S. co-marketing partnership with Plus Diagnostics to accelerate the launch of its *ConfirmMDx*™ for Prostate Cancer test. Although MDxHealth generally has a direct relationship with the customer ordering the MDxHealth test, if MDxHealth is unable to continue its partnerships or if difficulties are encountered by one or more marketing partners, MDxHealth could lose customer accounts and potential sales, which would materially adversely impact its business, its operations and its financial situation and its results.

In 2003, MDxHealth entered into a license agreement with Ortho-Clinical Diagnostics (OCD) for certain methylation technology. If OCD were to grant sub-licenses of certain technology, dating back to before 2003 and licensed from the Johns Hopkins University, to certain third parties or use the technology itself, then this could hinder the competitive position of MDxHealth.

In order to more efficiently commercialize its tests, MDxHealth has entered into number of partnerships with reference laboratories and diagnostic companies granting rights to offer products based on MDxHealth technologies (see section 2.2.2). While MDxHealth receives royalties and other fees from the sales of its sublicenses on these tests, markers, and use of technology if its partners increase their sales beyond expected levels (in competition with MDxHealth's tests under the same indication), then MDxHealth may possibly realize lower than expected revenues from its own planned products and services, and as such it may not achieve or sustain profitability.

#### **Intellectual Property Risks**

MDxHealth's success is dependent on the continuous and effective protection of its own and in-licensed intellectual property. If MDxHealth or its licensing partners fail to efficiently protect their intellectual property, MDxHealth will be unable to prevent third parties from using proprietary or in-licensed technologies and such third parties will be able to compete more effectively against MDxHealth. The patents of the Company have a life of 20 years and the expiry date may vary by region in the world. The earliest patent on an individual biomarker expires in 2014.

It is not certain that any of MDxHealth's currently pending or future patent applications will result in issued patents, or that any patents issued or licensed to MDxHealth will not be challenged, invalidated or held unenforceable. Issued patents may not be broad enough to provide any meaningful protection. Furthermore, MDxHealth cannot rule out that the U.S. may not acquire, under its so-called march-in rights, a non-exclusive, irrevocable, paid-up license under any of MDxHealth's patent rights. March-in rights allow the U.S. government, under certain conditions, to revoke the exclusivity of patents which are based on research funded by the U.S. federal government.

The current or future intellectual property claims of MDxHealth may be challenged, and new patents of third parties may affect MDxHealth's freedom to operate. MDxHealth may incur substantial costs to protect and enforce its patents and its in-licensed rights. In order to protect or enforce its patent rights, MDxHealth may initiate actions against third parties. Third parties may also initiate actions against MDxHealth. Any actions regarding patents could be financially costly, could divert the management and key personnel from its business, and could put MDxHealth's patents at risk of being invalidated or narrowly interpreted.

MDxHealth also relies on trade secret protection and contractual restrictions to protect its proprietary technology. This only provides limited protection and may not adequately protect MDxHealth's rights. Typically, MDxHealth requires its employees and third parties to sign confidentiality agreements and employees to also sign agreements assigning to MDxHealth all intellectual property arising from their work for MDxHealth. Nevertheless, these measures may not be effective in protecting MDxHealth's intellectual property rights.

The ability of MDxHealth to freely exploit or out-license its technology may be curtailed by the terms and conditions of certain in-licensing agreements and of certain subsidy agreements. These agreements sometimes limit how and where the technology may be exploited.

#### **Liability Risk**

The use or misuse of MDxHealth's products in testing, and the sale, marketing and use of future products based thereon may expose MDxHealth to liability claims. The company's business exposes it to potential product liability risks inherent in the testing, marketing and processing of predictive, or personalized medical products. Additionally, the Company's intention to operate a CLIA-registered lab to provide its tests exposes it to possible litigation based on malpractice, data aggregation errors, or misdiagnoses. The assertion of liability claims against MDxHealth could result in a substantial cost to, and diversion of efforts and management attention by, MDxHealth. If MDxHealth cannot successfully defend itself against product liability and related claims, it may incur substantial liabilities or be required to limit or cancel the commercialization of its products.

Furthermore, MDxHealth's collaborators may face similar liability claims. Any assertion of such claims against MDxHealth's collaborators could adversely affect MDxHealth's collaborations with such parties. While under certain circumstances MDxHealth may be entitled to be indemnified against losses by its corporate collaborators, indemnification may not be available or adequate for MDxHealth should any claim arise. Furthermore, although MDxHealth currently has a product liability insurance policy, there is no guarantee that the coverage is sufficient or that MDxHealth will be able to maintain such insurance in the future or that it will be able to find alternative insurance coverage on reasonable terms.

For clinical and other patient trials, MDxHealth and its collaborators may face liability claims from patients participating in or supplying samples for the trials. Although MDxHealth currently has liability insurance policies for its trials, there is no guarantee that the coverage is sufficient or that MDxHealth will be able to maintain such insurance in the future or that it will be able to find alternative insurance coverage on reasonable terms. For some work that MDxHealth performs for pharmaceutical companies involving potential companion diagnostic tests, MDxHealth may have a liability risk towards the pharmaceutical company in case an error in MDxHealth's work results in directly-related delays or damages to the drug development plans and outcomes.

#### **Strategy Execution Risk**

MDxHealth is dependent on numerous factors to carry-out its strategy, some of which may be beyond its control.

As part of its strategy, MDxHealth intends to develop and commercialize clinical diagnostic tests, perform pharmacodiagnostic research, provide testing services, and develop companion diagnostic tests in collaboration with the pharmaceutical industry. For its Pharmaco Molecular Diagnostics activities, MDxHealth will often be dependent on the pharmaceutical partner for patient samples, drug development, and drug regulatory approval and commercialization and it may take a long time before either the drug or the companion diagnostic are approved for commercialization, if at all. In order to commercialize its Clinical Molecular Diagnostics tests, MDxHealth will need to publicize timely and relevant validation studies to facilitate the acceptance of these tests in the medical community, maintain to operate a U.S. CLIA-registered lab, and maintain a sales force and the necessary commercial support services and infrastructure.

In order to accelerate its current development and commercial strategy, MDxHealth has to invest in personnel and equipment, and its sites. Therefore, MDxHealth will likely require additional funding to pursue its business objectives and to continue its operations as planned in the medium to long term. If adequate funds are not available on

commercially acceptable terms when needed, MDxHealth may be forced to delay, reduce or terminate the development or commercialization of its products, as currently envisaged, or it may be forced to further restructure the Company, its activities, its personnel, and its sites. The prior and any additional restructuring actions could result in unforeseeable costs or damages from areas such as (i) possible litigation from discontinued collaborations, projects, or personnel, (ii) loss of know-how from discontinued personnel and collaborators who may now work with competitors, and (iii) requests for reimbursement of subsidies due to discontinued projects, sites, or employment levels, or insufficient future spending at a regional level.

## 2012 REGISTRATION DOCUMENT

This document is a Registration Document within the meaning of article 28 of the Belgian law of June 16, 2006 on public offering of investment instruments and on the admission of investment instruments to listing on a regulated market ("Loi du 16 juin 2006 relative aux offres publiques d'instruments de placement et aux admissions d'instruments de placement à la négociation sur des marchés réglementés" / "Wet van 16 juni 2006 op de openbare aanbieding van belegginsinstrumenten en de toelating van beleggingsinstrumenten tot de verhandeling op een gereglementeerde markt"). On April 9, 2013, the Belgian Financial Services and Markets Authority (FSMA) approved the English version of this document in accordance with article 23 of the above-mentioned law.

This Registration Document is for MDxHealth SA. The information in this document covers the consolidated situation of MDxHealth SA and its subsidiaries. Throughout this document, MDxHealth SA is frequently referred to as "MDxHealth" or the "Company".

#### **Language of this Registration Document**

MDxHealth prepared this Registration Document in English and it has been translated into French. The English version is legally binding. MDxHealth has verified the consistency between the English and French versions and assumes responsibility for the translation.

#### **Responsibility for this Registration Document**

The Board of Directors of MDxHealth, represented by all its members referred to in Chapter 3, assumes the responsibility for the contents of this Registration Document. The Board of Directors declares that, having taken all reasonable care to ensure that such is the case, the information contained in this document is, to the best of its knowledge, in accordance with the facts and contains no omission likely to affect its import.

#### **Forward-Looking Statements**

This Registration Document contains forward-looking statements and estimates with respect to the anticipated future performance of MDxHealth and the market in which it operates. Certain of these statements and estimates can be recognized by the use of words such as, without limitation, "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will" and "continue" and similar expressions. Actual events are difficult to predict and may depend upon factors that are beyond the Company's control. Therefore, actual results, the financial condition, performance or achievements of MDxHealth, may turn out to be materially different from any future results, performance or achievements expressed or implied by such statements and estimates.

Given these uncertainties, the public is cautioned not to place any undue reliance on such forward-looking statements. Furthermore, these forward-looking statements and estimates are made only as of the date of this document. MDxHealth disclaims any obligation to update any such forward-looking statements or estimates to reflect any change in the Company's expectations with regard thereto, or any change in events, conditions or circumstances on which any such statement or estimate is based, except to the extent required by Belgian law.

#### **Availability of the Registration Document**

The Registration Document is available to the public free of charge upon request to:

MDxHealth SA
Attention: Investor Relations
Tour 5 GIGA Niveau +3
Avenue de l'Hôpital 11
4000 Liège, Belgium
Email: ir@mdxhealth.com

An electronic version of the Registration Document is also available on MDxHealth's website (www.mdxhealth.com).

Posting this Registration Document on the internet does not constitute an offer to sell or a solicitation of an offer to buy any of the shares to any person in any jurisdiction in which it is unlawful to make such offer or solicitation to such person. The electronic version may not be copied, made available or printed for distribution. Other information on the website of the Company or on any other website does not form part of the Registration Document.

#### **Other Available Information**

MDxHealth must file its (restated and amended) articles of association and all other deeds that are to be published in the Annexes to the Belgian Official Gazette with the clerk's office of the commercial court of Liège (Belgium), where they are available to the public. A copy of the articles of association is also available on the Company's website (www. mdxhealth.com).

In accordance with Belgian law, the Company must prepare annual audited statutory and consolidated financial statements. The annual statutory and consolidated financial statements and the reports of the Board of Directors and statutory auditor relating thereto are filed with the Belgian National Bank, where they are available to the public. Furthermore, the Company has to publish summaries of its annual and semi-annual financial statements, as well as interim management statements in accordance with the Belgian Royal Decree of November 14, 2007 relating to the obligations of issuers of financial instruments admitted to trading on a Belgian regulated market ("Arrêté royal relatif aux obligations des émetteurs d'instruments financiers admis à la négociation sur un marché réglementé" / "Koninklijk besluit betreffende de verplichtingen van emittenten van financiële instrumenten die zijn toegelaten tot de verhandeling op een gereglementeerde markt"). These documents are made available on the Company's website.

The company must also disclose price sensitive information and certain other information to the public. In accordance with the afore-mentioned Belgian Royal Decree of 14 November 2007 relating to the obligations of issuers of financial instruments admitted to trading on a Belgian regulated market, such information and documentation will be made available through the Company's website, press releases and the communication channels of Euronext Brussels.



## Key Financial MDxHealth

Condensed consolidated statement of comprehensive income	2012	2011	2010
Revenues	4,602	2,687	2,536
Gross profit	3,699	2,421	2,166
Research and development expenses	5,282	4,805	6,812
Selling, general and administrative expenses	7,462	4,785	3,745
Other operating (income)/expenses	(138)	(72)	(25)
Operating Profit/(Loss) (EBIT)	(8,907)	(7,097)	(8,366)
Financial income	201	214	222
Financial expenses	270	64	85
Income taxes	0	0	24
Net profit / (Loss)	(8,976)	(6,947)	(8,253)
Consolidated statement of financial position	2012	2011	2010
ASSETS			
Total non-current assets	828	771	1,109
Total current assets	14,296	13,921	13,310
Of which cash and cash equivalents	11,714	11,123	10,593
Total assets	15,124	14,692	14,419
LIABILITIES AND SHAREHOLDERS' EQUITY			
Total equity	12,117	11,320	10,723
Non-current liabilities	17	280	626
Current liabilities	2,990	3,092	3,070
Total liabilities and shareholders' equity	15,124	14,692	14,419
	2011	2044	
Consolidated Cash Flow Statement	2011	2011	2010
Operating cash flow	(8,506)	(6,560)	(8,129)
Investing cash flow	(398)	(216)	686
Financing cash flow	9,648	7,304	0
Net change in cash and cash equivalents	744	528	(7,443)
Cash and cash equivalents at end of period	11,714	11,123	10,593



# Activities of MDxHealth

#### 2.1. COMPANY OVERVIEW AND HISTORY

MDxHealth is a molecular diagnostics company that develops and commercializes advanced epigenetic tests and services for cancer assessment and the personalized treatment of patients. Specifically, MDxHealth offers:

**Clinical Molecular Diagnostics (***Clinical***MDx**<sup>™</sup>**) solutions:** Providing physicians with innovative and meaningful tests which aid in the identification and treatment of their cancer patients.

**Pharmaco Molecular Diagnostics (** $PharmacoMDx^{m}$ **) solutions:** Collaborating with pharmaceutical companies on the development of companion diagnostics, biomarker discovery, and clinical trial testing.

MDxHealth's current strategy is to retain full control of the end-development, launch, promotion, and sales of its core products, advanced epigenetic tests for the diagnosis, prognosis and personalized treatment of cancer using its patented molecular technology, Methylation Specific PCR (MSP). This DNA-based MSP technology, originally developed at Johns Hopkins University, is combined with individual patented genes ("biomarkers") that when methylated or non-methylated in patient tumor samples, aid physicians with the diagnosis of cancer, the likely progression of cancer, or the responsiveness of the cancer to certain therapies.

MDxHealth intends to bring its ClinicalMDx $^{\text{m}}$  solutions to the market in the U.S. as laboratory-developed service tests (LDTs) performed by its CLIA-certified and CAP-accredited laboratory facility established in 2011 in Irvine, California. The Company's direct sales and marketing force is being expanded in the U.S. to commercialize MDxHealth's clinical diagnostic tests on the U.S. market, the Company's main geographical focus going forward. In the near-future, these ClinicalMDx $^{\text{m}}$  tests could become a key driver of the revenues and valuation of the Company. MDxHealth launched ConfirmMDx $^{\text{m}}$  for Prostate Cancer in the U.S. market in 2012, and continues to offer its PredictMDx $^{\text{m}}$  for Brain Cancer LDT test from its Belgian laboratory. The other product candidates in the Company's pipeline are at an early stage of development.

MDxHealth was founded in January 2003 and has developed a considerable portfolio of intellectual property (IP). The Company's research and clinical development activities are often carried out in collaboration with world-renowned cancer research institutes. Additionally, the Company has out-licensed patented biomarkers and its MSP technology platform for diagnostic and research purposes for various cancers.

The Company's European headquarters are located in Liège, Belgium and its U.S. headquarters are located in Irvine, California. At the end of 2012, MDxHealth employed a total of 70 employees.

#### 2.2. ACTIVITIES

#### 2.2.1. Molecular Diagnostics in Cancer

MDxHealth is developing and intends to commercialize a robust pipeline of diagnostic, prognostic and predictive molecular diagnostic tests for multiple cancer types by integrating its proprietary epigenetic biomarkers on its patented DNA *Methylation-Specific* PCR platform (MSP). These tests deliver actionable results and can be performed on a variety of tissue types, including formalin-fixed paraffin embedded (FFPE), fresh/frozen tissue, urine, plasma, serum, sputum, broncho-alveolar lavages and stool, using commercially available PCR equipment. The Company's technology is able to detect a few cancer cells in a large background of normal cells found in tissue and in various types of bodily fluids such as urine and sputum. Therefore, the technology is well suited to detect cancer in its earliest stages of development, allowing for earlier more successful and cost-effective treatment.

MDxHealth's *Clinical*MDx<sup>™</sup> solutions include three different product types :

- ConfirmMDx™: tests that will serve as an aid for physicians to assess the presence or absence of cancer.
- InformMDx™: tests that will provide prognostic assessment to distinguish between aggressive and non-aggressive tumors as well as the patient's risk of recurrence.
- *Predict*MDx<sup>™</sup>: tests that will provide predictive information to indicate which drug or treatment regimen is likely to be most effective for the individual patient.

The product portfolio includes diagnostic and prognostic molecular diagnostic tests ( $ConfirmMDx^{m}$  and  $InformMDx^{m}$  tests) for Prostate and Lung cancer, as well as a predictive molecular diagnostic test ( $PredictMDx^{m}$ ) that correlates with certain drug therapies for Brain cancer, each product in various early stages of development. The Company also has numerous additional proprietary biomarkers and earlier-stage diagnostic, prognostic and predictive development projects ongoing in the areas of: bladder, brain, lung, melanoma, colorectal and breast cancer.

All of these tests are intended to augment the existing diagnostic process for patients with cancer while minimizing the need for invasive and costly procedures in cancer-free individuals.

At year end-2012, MDxHealth's main diagnostic products presented the following status of advancement:

	Research		Development		Commercial	
	Discovery	Feasibility	Development	Verification Studies	Validation Studies	Pivotal Trials
<b>Brain Cancer</b>						
PredictMDx <sup>™</sup> LDT						
<b>Prostate Cancer</b>						
<b>ConfirmM</b> Dx <sup>™</sup>						
<i>Inform</i> MDx <sup>™</sup>						
Lung Cancer						
<b>Confirm</b> MDx <sup>™</sup>						
<i>Inform</i> MDx <sup>™</sup>						

In addition, MDxHealth offers  $PharmacoMDx^{TM}$  services and support to pharmaceutical and other drug development companies at all stages of the theranostic development process, including (i) biomarker discovery, selection and optimization, (ii) bioinformatics, (iii) validation of companion diagnostic assays and (iv) clinical trial testing. MDxHealth's  $PharmacoMDx^{TM}$  services, provided to both existing collaborators and on contracted services basis, focus on the identification and development of epigenetic biomarkers and molecular tests into companion diagnostics.

#### 2.2.2. ClinicalMDx™

MDxHealth's Clinical Molecular Diagnostics (ClinicalMDx $^{\text{m}}$ ) solutions are focused on providing physicians with innovative and meaningful tests that aid in the identification and treatment of their cancer patients.

MDxHealth's ClinicalMDx<sup>TM</sup> strategy is to develop and commercialize advanced epigenetic tests through its U.S.-based CLIA certified, CAP-accredited laboratory facility. The ClinicalMDx<sup>TM</sup> business also includes epigenetic products commercialized by our partners and third party sublicensees (see Section 2.5 below).

MDxHealth's *Clinical*MDx™ portfolio is divided into three primary categories including diagnostic, prognostic and predictive molecular diagnostic tests for multiple cancer types. These tests are designed to address current diagnostic dilemmas faced by clinicians and will deliver actionable results to help improve patient management decisions.

MDxHealth's *Clinical*MDx™ Program is focused on three major cancer areas: prostate, lung and brain cancer. Since the Company already has biomarkers and published data in these product areas, the main efforts going forward will be on product development rather than research.

#### **MDxHealth's Prostate Cancer Portfolio**

Prostate cancer is the most frequent cancer in men, with one out of six men being diagnosed with prostate cancer during their lifetime.<sup>1</sup> Annually there are approximately 30 million men screened by the Prostate-Specific Antigen (PSA)<sup>2,3</sup> test resulting in approximately 1.5 million abnormal PSA test results (>4.0)<sup>4</sup> leading to over 900,000 biopsy procedures,<sup>5</sup> of which 240,890 are diagnosed with prostate cancer with 33,720 annual deaths.<sup>6</sup> Although prostate cancer is one of the deadliest cancers in men, its accurate diagnosis and follow-up remain a challenge and come at a considerable cost to the healthcare system. Approximately \$4.4 billion is spent annually on screening, diagnosing and staging and an additional \$9.9 billion is spent annually on treatment of these patients, totaling nearly \$15 billion being spent annually on prostate cancer in the U.S. alone.<sup>3,7</sup> Annually, over \$4 billion is spent on pharmaceuticals for prostate cancer, which is expected to increase to \$8.7 billion by 2019.<sup>8</sup>

Despite documented false-positive rates, and recent criticism of test by the U.S. Preventive Services Task Force during 2011, the American Urological Association continues to recommend the PSA blood test as the gold standard for screening men over the age of 40, combined with a Digital Rectal Exam (DRE). For patients with a rising and/or PSA score ≥4.0, a biopsy is routinely performed to determine if the patient has prostate cancer. The urologist typically uses an 18 gauge needle to obtain between 8 to 12 tissue cores as per the standard of care.<sup>9</sup>

Importantly, an abnormal PSA result can often be caused by other factors including age, infection, inflammation, or other benign conditions such as benign prostatic hypertrophy (BPH). This leads to the inclusion of many non-cancer patients being subjected to prostate biopsies (false-positive PSA). The rate of cancer detection in patients biopsied is approximately 27%, leaving approximately 73% with a negative result for cancer by routine histology and pathology review ( $\sim$ 900,000 annual biopsies, less the 240,890 diagnosed cases =  $\sim$ 27%).<sup>6,10,11</sup>

An elevated PSA and/or abnormal DRE places men at high risk of cancer and as a result they undergo a biopsy procedure, however due to the nature of random sampling and the limitations of histology, many patients may have cancer undetected by pathological review. Studies by urology and pathology opinion leaders, and experienced by most practicing urologists, report that initial prostate biopsy histopathology has a ~25% false-negative rate. Given these reported false-negative histology rates, patients with negative biopsy results, and their urologists, are often left with a sense of anxiety. These results pose a diagnostic dilemma for urologists and their patients, leading many men to receive 2nd, 3rd and sometimes 4th repeat biopsy procedures to rule-out the presence of cancer.

Patients identified as positive for cancer on the initial or subsequent biopsy are assigned a Gleason score (GS) characterizing the primary and secondary grade of tumor present. Scores for each section range from 1 to 5, and combined create the Gleason score ranging from GS 2 to GS 10. Not all cancers detected are clinically significant, some

patients are classified as having low to intermediate risk of progression, with Gleason scores of 2-6, making them likely candidates for non-interventional "active surveillance," whereas others are classified with more aggressive disease, with Gleason scores ranging from 7-10, meriting radical therapy.

However, literature suggests these scores can be subjective resulting in over-grading and over-treatment of some patients, while conversely under-grading and under-treatment of other patients<sup>14</sup>. As a result, urologists and their patients are confronted with the difficult decision of choosing the most appropriate therapy. All of the current patient management and treatment options pose potential risks and side effects. Patients placed on "active surveillance" or "watchful waiting" are at risk of progressive disease if their cancer was under-graded by pathology, whereas patients treated by radical prostatectomy commonly suffer side effects of incontinence and impotence. Patients treated with radiation therapy are at increased risk of developing another form of cancer and morbidity, a high cost to pay if the patient's cancer was over-graded by pathology and the disease may not have progressed.

A recent case study reported in the *New England Journal of Medicine* illustrates the lack of consensus on how to treat prostate cancer patients with low to intermediate risk pathology results. The survey of over 2,000 U.S.-based urologists asked how they would treat an otherwise healthy 63 old male diagnosed with prostate cancer and a Gleason Score of 6 (intermediate risk) in two of twelve core biopsy specimens taken. More than one third, 37% indicated they would perform a radical prostatectomy, 36% answered they would treat with radiation therapy and the remaining 27% responded they would place the patient on "active surveillance." <sup>115</sup>

The American Urological Association, the premier professional association for the advancement of urologic patient care in the U.S., has called for new biomarkers indicating biological aggressiveness "critical to the management of this disease with its highly variable clinical behavior, further stating that "...because of the potential for significant over-detection and overtreatment of prostate cancer, integrating biomarkers of aggressiveness with early detection programs is desirable." <sup>116</sup>

MDxHealth's *Clinical*MDx<sup>™</sup> portfolio includes two products for prostate cancer to augment the accuracy of current diagnostic methods and to help identify potentially aggressive disease to aid in treatment selection:

#### ConfirmMDx<sup>™</sup> for Prostate Cancer

Initially launched in May 2012 by our U.S. CLIA laboratory, *Confirm*MDx<sup>™</sup> for Prostate Cancer addresses false-negative biopsy concerns, helping urologists:

- "Rule-in" men with an initial negative biopsy result who may benefit from an immediate repeat biopsy and testing, thereby helping to identify the presence of cancer in the 20-30% of prostate cancers missed by the initial procedure (false-negative biopsy results).
- "Rule-out" otherwise cancer-free men from undergoing unnecessary repeat biopsies or excessive screening procedures.

#### InformMDx<sup>™</sup> for Prostate Cancer

Currently in development at our U.S. CLIA laboratory, *InformMDx*<sup>™</sup> for Prostate Cancer will help urologists in stratifying:

- prostate cancer patients with indolent disease, who may be safely managed presently without treatment reducing unnecessary radical therapy, side effects, and healthcare costs.
- prostate cancer patients with aggressive prostate cancer who require immediate treatment ensuring timely and appropriate treatment for optimal patient outcome.

ConfirmMDx™ for Prostate Cancer is designed to address the diagnostic dilemma faced by negative biopsy results. Approximately 73% of men who undergo an initial prostate biopsy due to elevated PSA and/or abnormal digital rectal exam (DRE) are found to have a negative biopsy (approx. 650,000 to 680,000 out of the ~900,000 men biopsied annually in the U.S.).¹¹ Of these negative biopsies, potentially 25-30% are false-negatives, thereby delaying cancer detection and possibly critical treatment. Prostate biopsies still miss many cancers and thus cannot conclusively rule-out healthy men from further testing. As doctors are unable to say with confidence that these patients are cancer-free, active follow-up including re-biopsy is often recommended resulting in unnecessary testing on countless cancer-free men annually, many of whom are destined to a painful cycle of repeat biopsies for years to come. The ConfirmMDx™ test will assist physicians, with high sensitivity¹¹ and with a negative predictive value (NPV) of 90%,¹¹8 to rule-out the presence of cancer in the vast majority of men while identifying those men who are more likely have cancer present, supporting re-biopsy and possible treatment.

InformMDx™ for Prostate Cancer will aid in the prognostication of men diagnosed with a Gleason Score ranging from 2 – 6, considered low to intermediate risk for progression (~160,000 men annually).¹¹ The test will help stratify these men with improved precision beyond standard histopathological methods into two risk groups: those with aggressive disease who require immediate treatment and those with more indolent disease who may be safely monitored by "active surveillance," thus potentially avoiding the side effects of impotence and incontinence as a result of radical prostatectomy or risks associated with radiation therapy.

The MDxHealth tissue-based tests are based on the detection of patent-protected epigenetic genes. Methylation of the GST-Pi gene has been shown to be a consistent abnormality found in prostate cancers. APC and RASSF1A methylation are also frequently found in prostate cancer and have demonstrated a "field effect" aiding in the identification of biopsies with false-negative histopathological results.<sup>20</sup>

MDxHealth has extensive validation data for the *Confirm*MDx<sup>™</sup> *for Prostate Cancer* test, which was commercially launched in the U.S. as an LDT via its CLIA-certified, CAP-accredited U.S. lab in H1 2012:

• The Company recently announced the publication of results from a large clinical study on the test in the March 2013 issue of Journal of Urology. The blinded, multicenter study named MATLOC (Methylation Analysis To Locate Occult Cancer), was conducted at University of Edinburgh Urological Cancer Group in the UK, the University Hospital of Liège, Belgium and the Institut de Génétique et Pathologie in Gosselies, Belgium. The investigators compared the performance of the ConfirmMDx™ test to the current standard of care for men with high-risk clinical factors for prostate cancer, but negative biopsy results. Archived tissue samples from previous negative biopsies of 483 men at high risk were tested with the *ConfirmMDx™* assay. The *ConfirmMDx™* test results were then compared to the cancer detection rate in the repeat biopsies conducted on the same patients within 30 months. In a multivariate model, correcting for age, PSA, DRE and histopathological characteristics of the first biopsy, the ConfirmMDx™ test proved to be the most significant, independent predictor of patient outcome with an odds ratio of 3.17 (95% confidence interval: 1.81-5.53) along with atypical cells in the first biopsy (3.17 odds ratio; 95% confidence interval: 1.31-7.70). The study's investigators reported that ConfirmMDx™ accurately identified 64% of the prostate cancer-free men who could safely avoid a repeat biopsy with a negative predictive value (NPV) of 90%. Importantly, testing the previous histopathologically negative biopsy, ConfirmMDx™ for Prostate also correctly identified 68% of men who were harboring undetected prostate cancer, many presenting with clinically significant cancer upon repeat biopsy who would merit aggressive treatment. The clinical investigators from this multi-center study were all independent, academic urologists with no financial links to the company or to the success of the product. All samples were blinded and laboratory testing was conducted without knowledge of the case or control status of the tissues.

- In the Epigenetic Field Effect study in Histologically Benign Prostate Biopsy Cores, presented at the ASCO Genitourinary Cancers Symposium in February 2013, it was shown that GSTP1, APC and/or RASSF1 gene promoter methylation is more prevalent in histologically benign cores from prostate cancer patients diagnosed with Gleason Score (GS) 7 prostate cancer, as compared with low volume GS 6. This study confirms previous findings in a larger cohort of subjects that these "field effect" biomarkers can be useful for detecting cancer adjacent to histologically negative biopsies and may be indicative of occult aggressive prostate cancer. Clinical samples were provided by independent urology and cancer researchers at Harvard Medical School who had no vested interest in the outcome of the results. Again, all samples tested were blinded as to the patient's risk group.
- In a second study presented at the ASCO Genitourinary Cancers Symposium in February 2013, the multi-gene ConfirmMDx™ for Prostate Cancer test demonstrated that epigenetic profiling is a significant predictor for prostate cancer risk, especially to identify those men who should (not) undergo a repeat biopsy following a negative initial biopsy for use in clinical practice. An integrated risk management approach that combines this epigenetic assay with other risk factors, most notably histopathologic features of the cancer-negative initial biopsy, resulted in an improved prediction for the presence of prostate cancer with sensitivity and negative predictive values of respectively 74% and 91%. The mathematical modeling using multifactorial analyses across a number of prostate cancer risk factors was done by the company in conjunction with the bioinformatics group and the University of Ghent Medical Center who functioned as an independent collaborator with no financial interest in the findings.

The MDxHealth *Inform*MDx™ *for Prostate Cancer* test requires validation and is still in early stages of development. Additional studies are underway to further validate the use of MDxHealth's tests and their adoption by urologists for early prostate cancer detection and prognosis prediction. MDxHealth intends to bring its enhanced test to the market together with a focused marketing strategy and direct sales force targeting urologists and pathologists.

In order to more efficiently commercialize its prostate tests, MDxHealth previously granted a sub-license to a limited subset of its prostate cancer markers and MSP technology to LabCorp and to Veridex LLC. LabCorp has been commercializing a prostate tissue test since mid-2008 with limited sales volume to date and Veridex has not yet commercialized its test. The LabCorp prostate test does not interrogate the same panel of genes as used in MDxHealth's *Confirm*MDx™ for Prostate Cancer test, and cannot claim the same validated performance characteristics reported on *Confirm*MDx™. While MDxHealth receives royalties and other fees from the sales of its sublicensees on these tests, markers, and use of technology, if its partners increase their sales beyond expected levels (in competition with MDxHealth's tests under the same indication), then MDxHealth may possibly realize lower than expected revenues from its own planned products and services.

For the ConfirmMDx™ for Prostate Cancer tissue-based test, MDxHealth faces competitive products on the market. The Progensa PCA-3 test from Gen-Probe, an FDA-approved, urine-based test, is on the U.S. market. The PCA-3 test carries the same indication as ConfirmMDx™ for Prostate Cancer, but its performance has only been established in men who were already recommended by urologists for repeat biopsy and it requires an additional patient visit to the urologist to undergo a prostate massage procedure to collect an enriched urine specimen. Additionally, the PCA-3 test offers lower specificity, presenting a significant disadvantage when considering budget impact models, since utilization of the test may actually serve to increase the number of repeat biopsies performed of these assays when applied to the intended patient population. The Budget Impact Model for the ConfirmMDx™ for Prostate Cancer test demonstrates that the ConfirmMDx™ will reduce the number of overall repeat biopsies performed. Epigenomics AG has developed a potential prostate cancer tests using a different version of the GSTPi gene. Epigenomics has out-licensed their marker to Quest Diagnostics Inc. and Predictive Biosciences Inc. For both companies, the product development state, the application (urine or tissue), as well as the date of a potential launch are currently unknown. Mitomics Inc. has a tissue-based

mitochondrial DNA test which was launched in 2011, however the test has limited clinical validation, with only one peer-reviewed, published study on a small cohort of patients from a single institution. Since Mitomics is privately held, it is unknown to what extent their test has gained market share. To the knowledge of MDxHealth, no head-to-head comparison studies with any competing products have been published.

For the InformMDx™ for Prostate Cancer tissue-based test, MDxHealth is aware of two direct competitive product with a similar indication. Myriad Genetics has launched its Prolaris prostate cancer test intended to measure the aggressiveness of a patient's cancer to predict an individual's relative risk of disease progression within ten years. Genomic Health has announced that it is also developing a prognostic LDT. Both companies' tests are targeting the pre-surgery treatment quidance and the post radical prostatectomy recurrence risk indications.

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#### **MDxHealth's Lung Cancer Portfolio**

Globally, lung cancer remains the leading cause of cancer-related death with an estimated 157,300 cancer deaths for 2010 in the United States alone (*American Cancer Society, Cancer Facts and Figures 2010*).

Early diagnosis of lung cancer for patients at high risk of recurrence is a clear unmet medical need. The American Cancer Society projected a total of 221,130 people were diagnosed with lung cancer during 2010 in the U.S. The diagnosis of lung cancer presents many challenges. When sick and symptomatic patients are being screened for cancer, diagnostic findings are often inconclusive and fail to detect the presence of malignancy in patients with suspected cancer.

U.S. incidence of Lung Cancer 221,130/Year Europe incidence of Lung Cancer 388,753/Year

Global incidence of Lung Cancer 1,608,055/Year

Source: ACS 2011, GLOBOCAN 2008

The results of the 53,000 patient national lung screening study (NLST) were recently published (N Engl J Med 2011; 365:395-409). This nine year clinical trial conducted by the U.S. NCI compared spiral ct scanning to standard chest x-rays which had been previously shown to have no benefit as a lung cancer screening modality. The findings indicated a 20% reduction in mortality due to lung cancer in the spiral CT group. While achieving its goal to show efficacy, CT scanning abnormalities lacked specificity to detect only cancer lesions, leading to a very high false positive rate, requiring costly, invasive procedures. The oncology community appears split on the value of spiral CT screening balancing reduced cancer deaths with overall unfavorable health economics and the risks of pulmonary works-ups in patients with false positive results. There is almost universal agreement that a secondary test to better select cancer presence and reduce unnecessary medical procedures would be a true advance. A cancer-specific molecular assay such as *Confirm*MDx<sup>™</sup> *for Lung Cancer* could provide such needed specificity to spiral CT screening.

Lung cancer may be seen on chest radiographs and computed tomography (CT scans). The diagnosis is confirmed with a bronchoscopy or CT-guided biopsy or sputum cytopathology. Treatment and prognosis depend upon the histological type of cancer, the stage (degree of spread), and the patient's performance status. Current lung cancer treatments include surgery, chemotherapy and/or radiation.

MDxHealth is developing two products in the lung cancer field, both still in early stages of development, to improve the accuracy of standard diagnostic procedures for early detection of lung cancer and to address the risk of recurrence in patients with Stage I disease:

ConfirmMDx™ for Lung Cancer – is a molecular test designed for the diagnostic evaluation of tissues, cells or fluid routinely collected bronchoscopy and/or sputum samples. At the time of first bronchoscopy for suspicion of lung cancer, and in approximately 30% of the suspected cancer cases, cytopathology does not provide conclusive results. Inconclusive results lead to unnecessary risky, time consuming and costly additional procedures. The ConfirmMDx™ test is designed to provide physicians with increased accuracy in assessing the presence or absence of cancer warranting additional work-up in assay-positive patients and less invasive follow-up in assay-negative patients. The company recently completed a pilot case/control study testing sputum from nearly 100 patients with and without lung cancer. All testing was performed blinded to patient group and a panel of candidate biomarkers showed very high (>80%) sensitivity and specificity. Further patient cohort studies are currently underway to confirm these findings.

InformMDx<sup>™</sup> for Lung Cancer – is a molecular test which provides physicians with a risk assessment of surgically-resected Stage I lung cancer patients, confirming whether or not the patient is at low risk or high risk of disease recurrence. Adjuvant chemotherapy after surgery is not recommended for the 15% (NCI SEER 2010) of lung cancer patients that are diagnosed with Stage I disease as this therapy is costly and toxic and has not shown a clinical benefit. However approximately 30% (Brock et al. N Engl J Med 2008) of patients with resected Stage I lung cancer suffer disease recurrence which is usually fatal. There is a need for better diagnostic tests to assess the risk of recurrence and to identify which early stage patients could benefit from adjuvant chemotherapy. The InformMDx<sup>™</sup> for Lung Cancer test, when used in conjunction with other clinical risk factors, will help physicians better manage their patients with resectable lung cancer. The completion of retrospective and prospective studies using the marker panel in the same population of patients is considered to be sufficient validation of the use of this test in clinical practice.

Using the Company's patented MSP methylation technology, Johns Hopkins Medical Center identified prospective biomarkers associated with the characterization and evaluation of early stage lung cancer aggressiveness in an exploratory

clinical trial in 2007. The Company has licensed the exclusive rights to these markers from JHU for this indication. Results from this initial retrospective clinical trial led to a publication in the *New England Journal of Medicine*. An additional prospective study is underway to validate the use of this assay for lung cancer recurrence risk, collecting and testing tumor and lymph node samples from patients who are followed for clinical outcome after lung cancer surgery.

For its *Confirm*MDx™ for Lung Cancer test, MDxHealth faces potential competition from (i) a test being developed by Epigenomics AG which has published limited data on their test only in bronchial lavage fluid, and (ii) by improved screening techniques being evaluated by different universities. No head-to-head comparison has been performed between the MDxHealth test and other potential competitive technologies. Epigenomics has launched in Europe a methylation based test for lung cancer called Epi proLung. This diagnostic test is used for patients suspected of lung cancer, however this kit is not FDA cleared and not offered in the U.S. For its *Inform*MDx™ test for Lung Cancer, MDxHealth faces potential competition from PinPoint Diagnostics which launched its LDT test in the US in January 2012. The MDxHealth *Inform*MDx™ for Lung Cancer test currently under development is designed to identify Stage 1 lung cancer patients that have a high risk of recurrence. The Company may face additional competition from established procedures and new entrants to the field in lung cancer.

#### MDxHealth's Brain Cancer Portfolio

Grade 4 glioma (glioblastoma; GBM) is a highly aggressive form of brain with a dismal rate of survival. The median overall survival for adult GBM patients is between 12 to 16 months. There are few therapy options for newly diagnosed GBM patients; the last advancement occurring in 2005 with the FDA approval of the alkylating agent temozolomide. In the US there are approximately 9,000 individuals diagnosed with GBM each year. The majority of these patients will receive temozolomide/radiotherapy treatment, as the current standard-of-care, despite the evidence that over half of all GBM patients on this therapy will not do better than with radiation therapy alone.

Post-hoc analysis of the clinical study on which the temozolomide FDA approval was based showed that the greatest treatment benefit occurred with patients who exhibited methylation of the MGMT gene (Hegi et al. NEJM March 2005). The study showed that the median overall survival of MGMT methylated patients was 21.7 months vs. 12.7 for patients with no MGMT methylation. With this knowledge, clinical studies are being designed to address this insufficient treatment of MGMT non-methylated patients. Studies are planned to either select patients for a new experimental therapy or to stratify the patients into the control or experimental arms of the studies. Knowing which patient may or may not respond to the current standard-of-care is key to the future analysis of clinical studies in GBM.

*PredictMDx*<sup>™</sup> *for Brain Cancer* (Glioblastoma) is an epigenetic molecular diagnostic test for Brain Cancer (Glioblastoma) that assesses the methylation status of the MGMT gene which is correlated with response to drug therapy.

A landmark study published in *The New England Journal of Medicine* in March 2005 reported on the methylation status of MGMT in tumor tissues from patients with advanced brain tumors. In this study, and numerous others, patients with tumors that were methylated for MGMT were far more likely to have a favorable response to standard alkylating agent therapy than those with unmethylated MGMT. A new study published in 2011 in the Journal of Clinical Oncology further confirmed the potential of the Company's MGMT test for brain cancer treatment as a companion diagnostic.

The MGMT gene is a crucial DNA repair gene. MDxHealth's *Predict*MDx<sup>™</sup> for Brain Cancer test determines the methylation status of the MGMT gene in tumor tissue, and can be used as a predictive assay to provide actionable information in the treatment of brain cancer. The MDxHealth MGMT gene test has shown the ability, through testing

on thousands of patients, to distinguish which cancer patients are likely to respond to the most commonly used class of brain cancer drugs called alkylating agents. This patented methylated gene test is attractive to pharmaceutical companies developing new brain cancer drugs since they can more easily target their new drugs to the patients who usually do not respond to the traditional alkylating agent drug regime.

MDxHealth currently provides *Predict*MDx<sup>™</sup> *for Brain Cancer* testing services in Europe. The test is currently being used in several multi-center brain cancer clinical trials to confirm the utility of this biomarker in routine clinical practice. Until recently, the most of advanced of these development efforts was being undertaken in collaboration with Merck KGaA of Darmstadt, in connection with the development of Merck's drug Cilengitide for patients with newly diagnosed brain tumors (glioblastoma), including a Phase III clinical trial (CENTRIC) and Phase II clinical trial (CORE). However, Merck has recently announced that the Phase III trial for its drug Cilengitide did not meet primary endpoints, and therefore it is unlikely that Merck will continue its development of Cilengitide or its support for the development and commercialization of the Company's MGMT test as an FDA-approved companion diagnostic to Cilengitide. Merck's discontinuation of its development support will have a material negative impact on the Company's potential revenues from this commercial project.

Under a service-testing license for North America received from MDxHealth, LabCorp currently commercializes the LDT (laboratory developed test) version of the MGMT test in North America. MDxHealth's strategy has been designed taking in account this pre-existing out-licensing agreement to LabCorp. We believe that it will not limit the Company's business strategy, as the Company has retained exclusive rights to (i) sell the MGMT tests to pharmaceutical companies performing clinical trials (ii) develop and commercialize MGMT kits and (iii) develop an FDA approved assay that can be sold globally. Additionally, the Company has rights to offer and sell the MGMT test worldwide as a *Clinical*MDx<sup>™</sup> product, including as an LDT in the U.S.

#### 2.2.3. PharmacoMDx™

The cost of cancer care continues to rise and challenge healthcare budgets throughout the world. Better targeting of expensive chemotherapies is needed to optimize existing resources and patient outcomes.

MDxHealth believes that it is well positioned to become a key source of epigenetic DNA methylation-based solutions for oncology. MDxHealth's *Pharmaco*MDx™ business program is designed to help:

Physicians and Healthcare Providers:

- Distinguish between drug responders and non-responders
- · Personalize the treatment of each individual patient
- Optimize treatment options and patient outcomes

#### Pharmaceutical Companies:

- Identify and develop targeted drug therapies
- Demonstrate higher drug efficacy rates
- · Expedite the regulatory approval of drugs
- Reduce the overall costs of drug development

The opportunity to apply diagnostics to improve therapeutic treatments (companion diagnostics) is significant especially in oncology. On average, oncology therapeutics exhibit efficacy rates of approximately 25% (Spear et al., Trends Mol Med 2001). The consequences of low response rates are enormous in terms of quality of life and cost of care, forcing patients to seek additional treatment options and contend with medical bills from ineffective treatments. The successful application of methylation-based biomarkers can have a significant impact on improving treatments outcomes in the field of oncology.

MDxHealth's *PharmacoMDx*™ programs, which are all in early stages of research and development, aim at providing personalized treatment solutions designed to assist physicians in more effectively treating cancer. The term *Companion Diagnostics* is used to describe a diagnostic test that is specifically linked to a known drug, vaccine or other therapeutic. This linkage could be important in the therapeutic application and clinical outcome of a drug (personalized medicine) or an important component of the drug development process because Companion Diagnostic assays predict which drug or treatment regimen is likely to be most effective for a specific patient. By analyzing the molecular make-up of the individual patient's tumor, the goal of predictive tests is to provide information to the physician for a rational optimization of each patient's drug therapy.

In December 2012, MDxHealth entered into a collaboration agreement with the Ghent University (UGent) to establish NXTGNT, a new Center in Pharmaco (Epi)genomics. The mission of the NXTGNT joint-venture is to accelerate innovation in personalized medicine by using advanced technology, knowledge and expertise in (epi)genetics. MDxHealth's goal is to leverage the collaborative expertise of NXTGNT to offer solutions to its pharamaceutical company collaborators focused on the discovery and application of effective individualized epigenetic-based diagnostic and personalized therapeutic products.

The formation of the NXTGNT joint venture is the result of many years of productive collaboration between MDxHealth and multiple epigenetics and bioinformatics groups within Ghent University. NXTGNT, which is located at Ghent University within the laboratory of Pharmaceutical Biotechnology, houses MDxHealth's research team and lab equipment for development of epigenetic tests together with the Ghent University team for (epi)genetic sequencing. NXTGNT works in close collaboration with the Laboratory of Bioinformatics and Computational Genomics, located at the UGent Faculty of BioEngeneering, providing extensive expertise in epigenetic characterization and computing and visualization of (epi)genomic datasets.

#### **Pharmaco**MDx™ Business

MDxHealth's *PharmacoMDx*<sup>™</sup> program is designed to deliver more effective diagnostic opportunities for pharmaceutical companies in support of their drug development programs. Regulatory authorities, such as the U.S. FDA, have started to require pharmaceutical companies to integrate companion diagnostics into the drug development process, particularly in connection with targeted therapies, to ensure safety and efficacy, and control costs. As a result, pharmaceutical companies increasingly rely on companion diagnostic tests to stratify patients for clinical trials (i.e. select those patients for whom the drug under investigation would be most effective). This allows pharmaceutical companies to conduct clinical trials faster and with smaller patient cohorts.

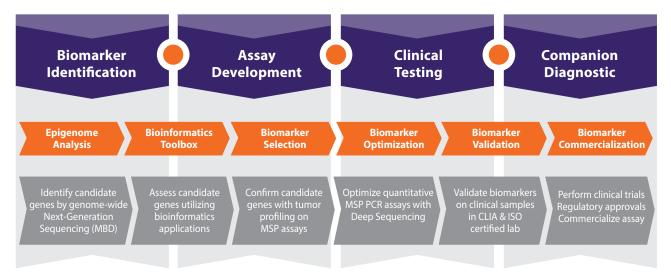
An increasing number of examples of pairing a diagnostic (Dx) test to a therapeutic (Rx) drug are arising. Patient advantages include: improvements in median survival rates and in overall response rates to chemotherapy. For pharmaceutical companies, advantages include: potential increases in likelihood of successful clinical trial outcomes/endpoints, fast-track approval with the FDA based on the test/drug combination data, abbreviated drug development and approval timelines. Regulatory agencies (FDA and EMA) are encouraging the use of biomarkers (theranostics) in

prescribing decisions. The FDA and EMA are pushing for biomarker testing to be performed prior to prescribing certain drugs and the FDA has even recently started reporting a table of genomic biomarkers that it considers valid in guiding the clinical use of approved drugs.

The *PharmacoMDx*™ testing services that MDxHealth offers support all stages of the drug/diagnostic (i.e. theranostic) development process, including (i) biomarker identification, selection and optimization, (ii) bioinformatics, (iii) validation of companion diagnostic assays and (iv) clinical trial testing.

### The Pharmaco MDx Integrated Platform

Supporting all stages of the drug diagnostic development process.



Some examples of MDxHealth's *PharmacoM*Dx<sup>™</sup> business offerings include:

Biomarker identification, genome-wide epigenetic profiling, selection and optimization – Epigenetic treatment followed by expression arrays (pharmacological unmasking) identifies transcripts under control of methylation. This approach, which results in genes that are functionally responding to the treatment by being re-expressed, has provided numerous novel cancer-specific methylation events over the past decade. Genome-wide epigenetic profiling is being complemented by MBD2\_Seq, which is more open-ended, as no prior probes need to be spotted on an array, resulting in a true genome-wide epigenetic profile. The workflow has been further refined to handle small fresh clinical samples. By applying its high-throughput biomarker identification platform, MDxHealth is helping various pharmaceutical companies, such as GlaxoSmithKline Biologicals and Abbott, to discover and evaluate methylation biomarkers that will identify those patients most likely to respond to cancer treatments in development.

<u>Candidate Genes Approach</u> – MSP (methylation specific PCR) allows the examination of hundreds genes on hundreds of samples. Precompiled arrays, called prediction arrays, containing all DNA damage and response genes, have been tested on many different sample types ranging from cell lines and xenografts to primary samples of different origin and matched normals. In addition to MSP, MDxHealth typically performs epigenetically-optimized deep sequencing profiles on primary material to lock the position of the primers by 454 bisulphite sequencing.

<u>Clinical trial service testing</u> – MDxHealth has assisted a number of pharmaceutical companies, including Merck Serono and Roche, to incorporate epigenetic testing into clinical trials for new cancer therapies, and MDxHealth provides clinical trial testing services through its own lab facilities as well as in collaboration with contract reference labs. With the results of these *Pharmaco*MDx<sup>™</sup> trials and many others underway, it is anticipated that patients with advanced brain and other cancers will ultimately be treated with targeted therapies with the goal of improved survival benefit and overall patient outcomes.

#### 2.3. SALES AND MARKETING STRATEGY

MDxHealth offers its *Confirm*MDx<sup>™</sup> for Prostate Cancer test, and intends to bring additional *Clinical*MDx<sup>™</sup> service products to the U.S. market, as centralized laboratory-developed service tests (LDTs) performed in its CLIA-certified and CAP-accredited laboratory in Irvine, California. The Company does not anticipate needing FDA-approval for its diagnostic service tests. In contrast to IVDs (In-Vitro Diagnostic kits), which require FDA approval prior to commercialization, LDTs generally require less time to develop and bring to market. In July 2010, the FDA indicated that it was reviewing the regulatory requirements applying to LDTs, thus there can be no assurance that FDA regulation, including pre-market review or approval, will not be required in the future for LDTs. MDxHealth intends to conduct the appropriate clinical validation trials to demonstrate the clinical efficacy and utility of its tests, as well as support adoption of these tests by the clinical community. The Company will perform the required internal correlation and validations studies to certify the performance of its tests in its CLIA service lab. In this fashion, MDxHealth launched the *Confirm*MDx<sup>™</sup> for Prostate Cancer test in mid-2012, following clinical validation studies.

In 2013, the ConfirmMDx<sup>™</sup> for Prostate Cancer test is expected to be a key driver of the revenues and valuation for the Company. In 2012 and prior years, substantially all of the Company's revenues were derived from non-ClinicalMDx<sup>™</sup> activities, including: (i) royalties on out-licensing agreements, (ii) PharmacoMDx<sup>™</sup> services rendered, and (iii) government grants in Europe. However, with the transition of the Company's business model starting in 2010 from a discovery license company to a commercial clinical diagnostic company, and based on the opening of a U.S.-based lab in California, the receipt of CLIA and CAP accredition by the U.S. lab, and the launch in 2012 of the ConfirmMDx<sup>™</sup> for Prostate Cancer test on the U.S. market, MDxHealth expects its ClinicalMDx<sup>™</sup> revenues to outpace its other revenue sources in 2013.

In the U.S., which is the Company's primary geographical focus, MDxHealth's *Clinical*MDx<sup>™</sup> service tests will, when commercially launched, be sold to physicians via a direct sales and marketing force. The products that fall into this category include (i) the *Confirm*MDx<sup>™</sup> for Prostate Cancer and *Inform*MDx<sup>™</sup> for Prostate Cancer tests (ii) the *Confirm*MDx<sup>™</sup> for Lung Cancer tests, and (iii) the *Predict*MDx<sup>™</sup> for Brain Cancer test. In anticipation of the launch of the *Confirm*MDx<sup>™</sup> for Prostate Cancer test in mid-2012, the Company established its own sales force in early 2012. Additionally, to help to build market awareness of the test, the Company engaged PLUS Diagnostics, a leading U.S. anatomic pathology company, to co-promote the *Confirm*MDx<sup>™</sup> test through its existing national network of urologists. In early 2013, the Company further expanded its direct U.S. sales and marketing force with the goal to accelerate commercialization of *Confirm*MDx<sup>™</sup> for Prostate Cancer test in the urology market, and to support products in the Company's pipeline.

Although the focus is the U.S. market, MDxHealth currently provides  $PredictMDx^{m}$  for Brain Cancer testing services in Europe, and may consider selling its other  $ClinicalMDx^{m}$  tests in Europe as CE-marked services offerings or reagent kits via a distributor(s) and out-licensing the applications in other regions of the world. MDxHealth is currently performing  $PredictMDx^{m}$  for Brain Cancer testing service under contract to several pharmaceutical companies that are performing clinicial trials, and the test is currently being used in several multi-center brain cancer clinical trials to confirm the

utility of this biomarker in routine clinical practice. In the case of kit partners, the partners will typically perform final assay development, regulatory clinical trials, manufacturing, and distribution of the product. Under a service-testing license for North America received from MDxHealth, LabCorp currently commercializes an LDT (laboratory developed test) version of the MGMT (*PredictMDx™* for Brain) test in the U.S. MDxHealth's *PharmacoMDx™* solutions support pharmaceutical and biotech companies at all stages of the drug/diagnostic development process, and cover a range of services including (i) biomarker identification, selection and optimization, (ii) bioinformatics, (iii) validation of companion diagnostic assays and (iv) clinical trial testing (v) regulatory submission and (vi) commercialization. MDxHealth has partnered with a number of drug developers to provide *PharmacoMDx™* services. The company has partnered with GSK Biologicals to provide services to assist in the development of a potential companion diagnostic tests with GSK Biologicals' immunotherapeutic cancer (vaccine) program and it has performed an early-stage biomarker identification project with Clovis Oncology, after it assumed the rights to Pfizer's PARP inhibitor compound. MDxHealth's *PharmacoMDx™* services, provided to both existing collaborators and on contracted services basis, generated the majority of the revenue of MDxHealth in 2012 and are expected to remain a significant portion of revenues in 2013.

In the field of prostate cancer, MDxHealth's product program faces competition from established procedures and potential new entrants to the field. Today, one molecular methylation-based prostate tissue test licensed by MDxHealth is on the U.S. market through LabCorp. Epigenomics AG is developing urine- and tissue-based prostate tests based on DNA methylation technology and has out-licensed a prostate biomarker to certain U.S. CLIA labs. Mitomics Inc. offers a tissue-based mitochondrial DNA test that was first launched in 2011. Gen-Probe Inc. has developed the PCA3 urine based test that is currently offered through a CLIA lab in the U.S. Since none of these companies issue test-level utilization data, it is unknown to what extent their tests have gained market share. In 2007, LabCorp obtained a nonexclusive license to perform laboratory-based diagnostic testing services in North America on prostate tissue samples using selected MDxHealth DNA methylation biomarkers. Sales of this prostate test remain limited as LabCorp does not appear to be actively promoting the services or investing resources to sponsor clinical trials to further validate the utility of its test, which does not include the same panel of markers as used in MDxHealth's ConfirmMDx™ for Prostate Cancer test. For the *Inform*MDx™ for Prostate Cancer tissue-based test, MDxHealth is aware of two direct competitive product with a similar indication. Myriad Genetics has launched its Prolaris prostate cancer test intended to measure the aggressiveness of a patient's cancer to predict an individual's relative risk of disease progression within ten years. Genomic Health has announced that it is also developing a prognostic LDT., Both companies' tests are targeting the pre-surgery treatment guidance and the post radical prostatectomy recurrence risk indications. In the area of lung cancer, MDxHealth faces competition from established procedures and new entrants to the field. In the field of pharmaco-molecular diagnostics (companion diagnostics), MDxHealth faces competition from companies with various molecular diagnostic technologies such as DNA mutation, sequencing and RNA expression. The MDxHealth MGMT test, PredictMDx™ for Brain Cancer, is in clinical trials with several pharmaceuticals drugs in development for brain cancer treatment, it faces limited competition, and revenues from sales of the test are not material. Under a servicetesting sublicense for North America received from MDxHealth in 2008, LabCorp currently commercializes a version of the MGMT test in North America as an LDT. We believe that it will not limit the Company's business strategy, as MDxHealth has retained exclusive rights to (i) sell the MGMT tests to pharmaceutical companies performing clinical trials (ii) develop and commercialize MGMT kits and (iii) develop an FDA approved assay that can be sold globally. Additionally, the Company has rights to offer and sell the MGMT test worldwide as a ClinicalMDx™ product, including as an LDT in the U.S.

MDxHealth has out-licensed its screening products, methylation specific PCR technology and some biomarkers to strategic partners. The Company has out-licensing agreements with partners focused in the following areas: stool-based

colorectal cancer screening, blood-based colorectal cancer screening, prostate cancer tests, urine-based bladder cancer detection and monitoring tests, cervical cancer screening or triage test, and brain cancer testing. MDxHealth has also out-licensed its MSP technology and certain biomarkers to third party kit companies who may incorporate the technology and markers into the products they sell to the research market, such as academic investigators. The main out-licensing deals include technology licenses for MSP research kits. In exchange for these licenses, MDxHealth typically negotiates up-front licensing fees, as well as royalty and milestone payments for future product sales. Out-licensing is not a core strategy of the Company, and most of these existing out-licensing deals are not currently generating material revenues for MDxHealth. Predictive Biosciences has launched its CertNDx for Bladder Cancer assay and it is expected to continue to generate modest income in the coming years. Once the technology applications are licensed-out, MDxHealth has no or insignificant on-going costs associated with these applications. Further discussions around its strategic partners are outlined in the section on strategic partners.

#### 2.4. BILLING & REIMBURSEMENT

In 2012, MDxHealth established in-house billing operations to support *Clinical*MDx<sup>™</sup> testing in the U.S., and actively billed insurance companies and other payors. To further expand its billing department, MDxHeath hired a Director of Billing and Reimbursement in October 2012 to manage onsite day-to-day billing and collections. In the first half of 2013, MDxHealth plans to continue to expand its billing and collections department to maximize reimbursement and company growth, aligning with projections.

In 2012, the Company began recognizing revenue for its *Clinical*MDx<sup>™</sup> products and services, based on the *Confirm*MDx<sup>™</sup> for Prostate Cancer test launched in May 2012. The Company initiated billing to U.S. third party private insurance payors in Q4 2012 for tests performed in 2012. MDxHealth has held claims to Medicare and will pursue payment once Medicare has reviewed and approved the company's medical dossier and finalizes its reimbursement determination for the test, expected in 2013. The Company's revenue recognition policy at this time is primarily based on cash collections. Uncollected outstanding billable cases have therefore generally been excluded from the Company's 2012 revenues. However, as billing and reimbursement trends are established with each payor, the Company is transitioning to an accrual-based revenue recognition policy.

In the U.S., medical service providers promote their products and services to medical professionals who prescribe these services and products to their patients. The payment for the rendered services and products to patients are mostly paid by third party payors who are government payors such as Medicare, Medicaid, or Veterans Administration, and private health insurance payors who provide health insurance to individuals usually through employer sponsored health benefit programs. The private payors represent approximately 60% of medical reimbursements while 40% is handled through government programs such as Medicare. A small percentage of payments for medical services are paid directly by patients. Even though Medicare represents the smaller percentage of reimbursements in the United States, it is represents a key reimbursement benchmark that is used by private payors. Private payors usually pay a muliple above Medicare rates. The U.S. budget deficit, healthcare reform (Obamacare), and efforts by the medical profession and service providers to create transparency and equity in reimbursements has created unprecedented change and uncertainty. This uncertainty creates risks in the amount of reimbursement MDxHealth will recieve for its *Confirm*MDx<sup>™</sup> for Prostate Cancer and the timing of reimbursements.

• Significant industry changes have affected the diagnostics laboratory industry, impacting coding, coverage and reimbursement, with material industry announcements and changes occurring on a frequent basis. The following is a summary of the reimbursement landscape in the U.S. at the date of this document.

#### Private Payors:

- In 2012, MDxHealth filed claims for reimbursement with private payors using pre-existing molecular stacking CPT codes applicable for *ConfirmMDx™* for Prostate Cancer testing. The benefit levels vary per insurance product, with higher patient cost share across commercial, third party payers. To ensure uninterrupted access, MDxHealth has developed financial assistance programs based on individual patient circumstances.
- Effective January 1, 2013, the American Medical Association (AMA) CPT® Editorial panel responsible for establishing CPT codes retired the pre-existing molecular stacking CPT codes that MDxHealth had used during 2012, and established new miscellaneous CPT codes for molecular diagnostics. Therefore, for testing performed in 2013, MDxHealth intends to bill a patient's insurance company for the *ConfirmMDx™* for Prostate Cancer test using the new miscellaneous code for molecular diagnostics, and to seek unique codes for its tests through the American Medical Association and Centers for Medicare and Medicaid Services under the new evolving guidelines. MDxHealth will pursue case-by-case reimbursement where policies are not in place, or payment history has not been established or for patients needing financial assistance in compliance with state and federal laws.

#### Governmental Payors (Medicare, etc.):

- MDxHealth has delayed submitting claims for reimbursement to government programs such as Medicare, and in accordance with industy practices for new tests, is holding such claims until Medicare has reviewed and approved the company's medical dossier and finalizes its reimbursement determination for the test, expected in 2013, at which time it may submit such claims for payment.
- On September 20, 2012, the Centers for Medicare and Medicaid Services (CMS) announced that Noridian Administrative Services (NAS) has been awarded the contract for the administration of Medicare Part A and Part B fee-for-service claims in A/B MAC Jurisdiction E, which was previously called Jurisdiction 1. The Jurisdiction E A/B MAC serves beneficiaries in California, Nevada, and Hawaii, as well as U.S territories of American Samoa, Guam, and the Northern Mariana Islands. Palmetto GBA appealed this award. On January 16, 2013, CMS denied the protest. CMS has not yet announced new effective dates, however is working with Palmetto GBA and Noridian on this transition.
- The Molecular Diagnostic Program (MolDx), a formal program to evaluate code and price molecular diagnostic services, developed and managed by Palmetto GBA, is under separate contract with CMS. CMS has not release information regarding changes to this contract. MDxHealth is well prepared should this contract be implemented nationally. In accordance with the MolDx program, MDxHealth applied for and received a Test Identifier Code for ConfirmMDx™ for Prostate Cancer. As part of the MolDx program technology assessment requirement, MDxHealth prepared and submitted its scientific dossier, which is currently under review. MDxHealth expects to receive Medicare coverage from Palmetto during the second quarter of 2013, in which case MDxHealth will bill Palmetto Medicare using a molecular miscellaneous code also referred to as a not otherwise classified (NOC) code in conjunction with our assigned PTI number.

In February 2013, a pivotal health economics study for the *Confirm*MDx<sup>™</sup> for Prostate Cancer test was published in the American Health & Drug Benefits journal. Authored by a prestigious team of experts, Wade Aubry MD, Robert Lieberthal PhD, Arnold Willis MD, Grant Bagley MD JD, Simon M. Willis MS III5, Andrew Layton BA, this budget impact analysis demonstrates achievable cost savings of MDxHealth's *Confirm*MDx<sup>™</sup> for Prostate Cancer test, which is used by urologists to identify men who may avoid unnecessary repeat prostate biopsies, thereby reducing overall healthcare

spending. This analysis is an essential tool for payers to examine affordability for budgeting and instituting coverage decisions for reimbursement of prostate cancer diagnostics.

In Q1, 2013, MDxHealth will begin developing, a cost effectiveness analysis to evaluate cost- efficiencies associated with outcomes not investigated by design in a budget impact model. Many payers and policy makers require both analyses when evaluating coverage for new diagnostics.

With the goal to accelerate adoption and widespread payer coverage of the *Confirm*MDx<sup>™</sup> test, the Company is preparing a clinical utility study designed to provide real-world insight as to how urologist's incorporate test results into treatment decisions. The Company believes that a positive outcome for this study would further validate achievable savings described in the budget impact manuscript. This clinical utility study is planned to begin during the first half of 2013.

# 2.5. STRATEGIC PARTNERS

#### 2.5.1. PharmacoMDx™ Partners

MDxHealth collaborates with a range of pharmaceutical companies in the identification and development of biomarkers for potential use as companion diagnostics for their therapeutic drugs or vaccines. MDxHealth usually derives revenues from providing R&D and clinical testing services to these partners. The identity of these partners is not always disclosed. In addition to the pharmaceutical collaborations described in detail below, MDxHealth has entered into collaborations in this manner with other pharmaceutical companies such as Abbott Laboratories and F. Hoffmann-La Roche Ltd.

#### **Merck Serono**

In 2008, MDxHealth entered into a licensing and testing agreement with Merck KGaA of Darmstadt, Germany (now Merck Serono). Under the terms of the agreement, MDxHealth provided MGMT gene promoter methylation testing services for Merck's clinical trial program of Cilengitide. The MDxHealth MGMT test has been used in two Merck clinical trials together with its drug Cilengitide for patients with newly diagnosed brain tumors (glioblastomas), including a Phase III clinical trial (CENTRIC) and Phase II clinical trial (CORE). Patient selection for these Merck trials was based on the MGMT gene promoter methylation status of their tumor tissue.

In 2012, MDxHealth entered into an expanded collaboration agreement with Merck KGaA for the commercial development of MDxHealth's MGMT diagnostic test as a companion diagnostic to Merck's drug candidate Cilengitide. However, Merck has recently announced that the Phase III trial for Cilengitide did not meet primary endpoints, and therefore it is unlikely that Merck will continue its development of Cilengitide or its support for the development and commercialization of the Company's MGMT test as an FDA-approved companion diagnostic to Cilengitide.

# GlaxoSmithKline Biologicals (GSK)

In 2010, MDxHealth expanded its existing relationship with GlaxoSmithKline Biologicals (GSK) to pursue the development and testing of new companion diagnostic tests that can potentially be used with GSK's immunotherapeutic oncology program. MDxHealth's collaboration with GSK was initiated in 2007 under a Wallonia-BioWin grant concerning mutual research in the immunotherapeutic oncology field. Under the expanded agreement signed in 2010, GSK is collaborating with MDxHealth to assess the potential use of one of MDxHealth's DNA methylation specific PCR biomarkers in GSK's immunotherapy development program.

# Pfizer (transferred to Clovis Oncology)

In 2010, MDxHealth entered into a collaboration agreement with Pfizer to pursue the identification and development of an MDxHealth biomarker predicting response to Pfizer's cancer drug candidate for PARP inhibition, PF-01367338. However in 2011, Pfizer out-licensed their compound to Clovis Oncology, effectively handing over the entire program and future development rights. After the transfer, MDxHealth continued to work with Clovis in the identification and feasibility stage of this project. Newcastle University (UK) also participated in the collaboration. The collaboration is assessing the potential to develop an MDxHealth test as a companion diagnostic test to guide treatment decisions in treatment of ovarian and breast cancers with the PARP drug candidate.

## 2.5.2. ClinicalMDx™ Partners

#### **Predictive Biosciences**

In 2010, MDxHealth entered into an exclusive license agreement with Predictive Biosciences for diagnostic applications in bladder cancer. Under the terms of the agreement, Predictive Biosciences obtained exclusive rights in the United States for the use of a number of MDxHealth's DNA methylation biomarkers in bladder cancer testing of urine, blood and other bodily fluids. MDxHealth retained exclusive worldwide rights to these markers in tissue-based bladder cancer tests. In return, MDxHealth received an upfront license payment and is entitled to receive, subject to certain conditions, milestone payments and royalties on net sales. In Q4 2011, Predictive Biosciences launched its CertNDx for Bladder Cancer assay with its first indication of hematuria screening. It is expected that the second indication, bladder cancer recurrence monitoring, will be launched in 2013.

#### **Exact Sciences**

In 2010, MDxHealth entered into an exclusive license agreement with Exact Sciences Corporation for stool-based screening of colorectal cancer. Under the terms of the agreement, Exact Sciences obtained exclusive, worldwide rights to use up to two of MDxHealth's DNA methylation biomarkers in stool-based detection of colorectal cancer, as well as non-exclusive access to MDxHealth's MSP platform technology for use with those biomarkers. In return, MDxHealth received an upfront license payment and is entitled to receive, subject to certain conditions, milestone payments and royalties on net sales.

In January 2011, following Exact Sciences' completion of preliminary studies, MDxHealth announced the election by Exact Sciences to include an MDxHealth methylation biomarker, together with MDxHealth's MSP platform technology, in Exact Sciences' ColoGuard<sup>TM</sup> stool-based DNA colon cancer screening test. This confirmation triggered a milestone payment to MDxHealth from Exact Sciences.

Exact Sciences is developing Cologuard with the goal to provide a more accurate non-invasive diagnostic test to screen for the early stages of colorectal cancer, as compared to the current standard of care, Faecal Immunochemical Testing (FOBT), which aims to detect small amounts of blood in stool samples. The most recent data on over 1,000 patients indicates that the Cologuard test has 98% sensitivity in detecting cancer and 57% sensitivity in pre-cancerous lesions, and a 90% specificity. Exact Sciences is sponsoring a 12,500 patient, pivotal trial (DeeP-C) in 87 centres, the initial results of which are expected to be announced in Q1 2013. In December 2012 and January 2013, Exact Sciences submitted the first and second modules, respectively, of its modular premarket approval application (PMA) to the U.S. Food and Drug Administration (FDA) for Cologuard. Exact Sciences reports that it intends to submit the final clinical module with the FDA in Q2 2013 and the product could be on the market in 2014.

#### Self-screen

In 2010, MDxHealth entered into an exclusive joint-venture agreement with Self-screen B.V. for confirmation testing of cervical cancer. Under the terms of the agreement, Self-screen and MDxHealth each contributed certain intellectual property rights and research and development efforts in the field of cervical cancer testing in vaginal swab and scraps, fluids washes and other body fuilds, MDxHealth received the worldwide commercialization rights to any cervical epigenetic cancer test developed in the joint venture, and Self-Screen obtained a limited non-exclusive license to use MDxHealth's MSP platform technology and certain cervical cancer biomarkers to provide cervical cancer testing services in certain identified northern-European countries.

In 2013, Self-screen plans to submit its application to obtain CE aproval for its cervical cancer test.

#### **PLUS Diagnostics**

In April 2012, MDxHealth entered into an agreement with PLUS Diagnostics to co-promote MDxHealth's *Confirm*MDx<sup>™</sup> for Prostate Cancer assay in the United States. PLUS Diagnostics, a leading U.S. anatomic pathology company that offers a full range of multi-specialty services, is helping to supplement the efforts of MDxHealth's direct sales force to build awareness of *Confirm*MDx<sup>™</sup> for Prostate Cancer through its national network of urologists.

#### Veridex

In December 2010, MDxHealth entered into two non-exclusive licenses with Veridex LLC (a Johnson & Johnson Company) for the use of certain of MDxHealth's proprietary DNA methylation products in colorectal and prostate cancer screening. Under the agreements, Veridex licensed non-exclusive rights for the performance of service testing at its own laboratories worldwide using MDxHealth's DNA methylation biomarkers for use in blood-based detection of colorectal cancer, as well as tissue- and urine-based detection of prostate cancer. In return, MDxHealth is entitled to receive, subject to certain conditions, milestone payments and royalties on net sales. The new license agreements replace prior agreements first entered into with Veridex LLC in 2004 granting exclusive worldwide rights to prostate cancer testing services and kits. These license grants to Veridex were the result of an agreement between MDxHealth and Ortho-Clinical Diagnostics, Inc. (OCD, a Johnson & Johnson Company) that was entered into in 2003, when MDxHealth acquired certain methylation markers and technology from Tibotec-Virco (a Johnson & Johnson Company). Under the terms of this 2003 agreement, MDxHealth agreed to first offer to OCD the exclusive right to license, at commercially reasonable terms, any product in the human in vitro diagnostics field that contains those technology components that were once owned by Tibotec-Virco. Since 2003, MDxHealth has offered products under this first right to license option in the fields of prostate, lung, colon, cervical, brain and bladder cancer, of which Veridex has exercised its license rights only for Prostate and blood-based colon, each on a non-exclusive basis for service testing.

# LabCorp

In 2008, MDxHealth granted to LabCorp a royalty bearing sublicense to the MGMT test (for the North American market only, of indefinite duration, and limited to service testing only). To date, the MGMT tests sales by LabCorp remain very limited since the U.S. market use of the test is still essentially for pharmaceutical clinical trials for which the rights have been retained by MDxHealth. MDxHealth retained certain rights to develop and commercialize the MGMT test as a companion diagnostic on a worldwide basis. In 2007, LabCorp obtained a non-exclusive license to perform laboratory-based diagnostic testing services in North America on prostate tissue samples using selected MDxHealth DNA methylation biomarkers. Sales of this prostate test remain limited as LabCorp does not appear to be actively

promoting the services or investing resources to sponsor clinical trials further validating the utility of the test. In 2008, LabCorp began to commercialize the two afore-mentioned tests in North America.

#### 2.5.3. ResearchMDx Partners

# **MSP Platform Technology**

To support the increasing worldwide adoption of our MSP (methylation-specific PCR) platform technology, MDxHealth has granted non-exclusive licenses to a number of multinational corporations to supply research-use kits designed for use on the MSP platform. Licensees include EMD Serono (formerly Millipore a division of Merck Serono), Qiagen and Takara, each of which have obtained royalty bearing, non-exclusive, worldwide, and of indefinite duration sublicenses to the MSP methylation platform technology for use in the scientific research market only. MDxHealth receives a royalty fee on all current and future sales for this market segment.

#### **Academic and Clinical Collaborators**

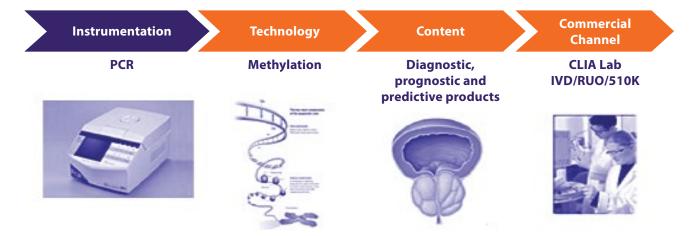
MDxHealth collaborates on research and clinical development with many of the world's leading cancer research institutes. These important relationships provide the Company with additional resources and expertise for clinical marker validation as well as access to patient samples for testing. The large number of academic institutions and government medical centers and organizations in the U.S. and Europe, with which MDxHealth collaborates on a regular basis, include the Johns Hopkins University Medical Institutions (U.S.), Duke University Medical Center (U.S.), the GROW Institute at the University Hospital of Maastricht (The Netherlands), University of Edinburgh (UK), and the University of Liège (Belgium).

In December 2012, MDxHealth entered into a collaboration agreement with the Ghent University to establish NXTGNT, a new Center in Pharmaco (Epi)genomics. The mission of the NXTGNT joint-venture is to accelerate innovation in personalized medicine by using advanced technology, knowledge and expertise in (epi)genetics. MDxHealth's goal is to leverage the collaborative expertise of NXTGNT to offer solutions to its pharamaceutical company collaborators focused on the discovery and application of effective individualized epigenetic-based diagnostic and personalized therapeutic products.

The formation of the NXTGNT joint venture is the result of several years of productive collaboration between MDxHealth and multiple epigenetics and bioinformatics groups within Ghent University. NXTGNT, which is located at Ghent University within the laboratory of Pharmaceutical Biotechnology, houses MDxHealth's research team and lab equipment for development of epigenetic tests together with the Ghent University team for (epi)genetic sequencing. NXTGNT works in close collaboration with the Laboratory of Bioinformatics and Computational Genomics, located at the UGent Faculty of BioEngeneering, providing extensive expertise in epigenetic characterization and computing and visualization of (epi)genomic datasets.

# 2.6. TECHNOLOGY AND PLATFORM

MDxHealth's technology platform is called MSP (Methylation-Specific-PCR), which is a patented DNA-based technology that functions on standard commercial PCR equipment. MSP is a powerful and accurate platform with the ability to detect a single cancer cell among thousands of healthy cells in any type of bodily fluid or tissue. MDxHealth has patents and other intellectual property rights on the MSP platform and on a broad portfolio of biomarkers targeted at individual genes that are used in its different products.



#### **MDxHealth Technology**

MDxHealth uses a molecular epigenetic technology to improve cancer diagnosis and treatment. Individual genes (DNA biomarkers) in the human body can become modified in the presence of cancer. MDxHealth has the ability to identify these modifications at the genomic level providing the physicians with a tool to aid in the diagnosis of cancer, assess the risk of recurrence (metastasis) of the cancer, and predict an individual patient's likely response to cancer treatment.

DNA methylation is a valuable tool for assessing cancer because methylated DNA biomarkers occur in almost all malignancies. Gene methylation is a control mechanism that regulates gene expression in DNA and occurs when a methyl group is added to one of the four building blocks of DNA, a cytosine. In several diseases, however, the promoter regions that carry the instructions to produce an essential protein can be over- or hypermethylated, effectively inhibiting protein production. Hypermethylation of genes, such as tumor suppressor genes, is associated with the presence and development of most cancers. And while changes in DNA methylation were initially thought to be the result of cancerous transformations, it is increasingly believed that it plays an active, causative role.

The pattern of gene hypermethylation in tumor cells is often specific to the tissue of origin and can be used to improve cancer detection, assess risk of recurrence, and predict a tumor's response to therapy.

#### **Methylation Specific PCR (MSP)**

The components of MDxHealth's molecular tests consist of a epigenetic technology for sensitive detection of methylation in DNA (known as "MSP" or "Methylation-Specific-PCR"), as well as a number of cancer specific methylation markers.

Precise mapping of DNA methylation patterns in CpG islands has become essential for understanding diverse biological processes such as the regulation of imprinted genes, X chromosome inactivation, and tumor suppressor gene silencing in human cancer. MSP can rapidly assess the methylation status of virtually any group of CpG sites within a CpG island, independent of the use of methylation-sensitive restriction enzymes. An MSP assay entails initial modification of DNA by sodium bisulfite, converting all unmethylated, but not methylated, cytosines to uracil, and subsequent amplification with primers specific for methylated versus unmethylated DNA. MSP requires only small quantities of DNA, is sensitive to 0.1% methylated alleles of a given CpG island locus, and can be performed on DNA extracted from formalin-fixed paraffinembedded samples (FFPE). MSP eliminates the false-positive results inherent to previous PCR-based approaches, which relied on differential restriction enzyme cleavage to distinguish methylated from unmethylated DNA.

# **Patents and Licensing**

MDxHealth believes that its patent portfolio places the Company in a highly competitive position in the realm of molecular cancer diagnostics. MDxHealth holds exclusive rights to a broad array of issued and pending patents in multiple countries worldwide covering the methylation technology platform and multiple methylation genetic markers. MDxHealth continues to be at the forefront of researching and understanding the link between cancer and methylation and how this link can be translated into meaningful *Clinical*MDx™ and *Pharmaco*MDx™ products and services.

Core to MDxHealth's intellectual property portfolio is the patent family covering the Methylation-Specific Polymerase chain reaction (MSP) process, which represents a groundbreaking advance in applied genomics. Methlylated DNA-based measurement, combining the MSP platform with target biomarkers, enables meaningful comparisons of gene expression responses in a variety of pre-clinical and clinical settings.

Below is a selected summary of MDxHealth's patent portfolio, broken into two groups of patents. The first group of patents includes foundational molecular technology patents that have issued in the U.S., Japan, Canada, Israel and the major European countries. The second group of patents includes cancer specific biomarker panels for tumor detection and profiling and includes over 10 granted patents and over 20 international pending patents.

#### **Epigenetic Detection Technology-Methylation-Specific PCR (MSP)**

	Title	Patent Reference No
MSP Technology	Method of detection of methylated nucleic acid using agents which modify unmethylated cytosine and distinguish modified methylated and non-methylated nucleic acids (WO, EP: Methylation-Specific Detection)	WO97/46705
	Nested Methylation-Specific Polymerase Chain Reaction Cancer Detection Method	WO 02/18649
Amplifluor Technology	Nucleic acid amplification oligonucleotides with molecular energy transfer labels and methods based thereon	WO98/02449
MethyLight* technology	Process for high throughput DNA methylation analysis	WO 00/70090
Heavy Methyl* technology	Highly sensitive method for the detection of cytosine methylation patterns	WO 02/072880
Microarray* technology	Method for determining the degree of methylation of defined cytosines in genomic DNA in the sequence context 5'-CpG-3'	WO 02/18632
	Method for producing complex DNA methylation fingerprints	WO99/28498
Scorpion* patent rights	Method for the detection of cytosine methylations in DNA	EP 1654388

MDxHealth's process for detecting methylation in DNA, called Methylation-Specific PCR, was invented at Johns Hopkins University. The detection technology is extremely sensitive, which is necessary when looking for early-stage cancer, as only one to ten tumor cells may be present in a sample containing thousands of healthy cells. Patents on the MSP technology have been granted in key markets such as Europe, United States, Canada, and Japan. In addition, the MDxHealth methylation technology portfolio comprises patent families on various improvements on MSP technology (\*non-exclusive license from third party). There are various patents covering the methylation detection technology

and their duration varies per region and per patent. The patents of the Company have a life of 20 years and the expiry date may vary by region in the world. The earliest patent on an individual biomarker expires in 2014.

The methylation detection patents are in-licensed from the Johns Hopkins University and from the Lovelace Respiratory Research Institute.

# **Epigenetic Markers for Tumor Profiling**

Marker	Title
	Genetic Diagnosis of Prostate Cancer
Prostate Cancer	Method of Detection of Prostate Cancer
markers	Tumor Suppressor Gene
	Characterizing Prostate Cancer
Lung	Detection and Prognosis of Lung Cancer
Cancer Markers	Methylation Markers and Methods of Use
Brain Cancer	Method of Predicting the Clinical Response to Chemotherapeutic Treatment with Alkylating Agents
Markers	Improved Methylation Detection
	Methylation Markers for Early Detection and Prognosis of Colon Cancers
Colon	Improved Methods of Detecting Colorectal Cancer
markers	Epigenetic Change in Selected Genes and Cancer
	Early Detection and Prognosis of Colon Cancers
Bladder Cancer	Novel Markers for Bladder Cancer Detection (I)
markers	Novel Markers for Bladder Cancer Detection (II)
	Novel Methylation Marker
Other Cancer	HIN-1, a Tumor Suppressor Gene
markers	Improved Detection of MAGE-A Expression
	Improved Detection of Gene Expression

Methylation markers are genes that are known to be abnormally methylated in cancer. MDxHealth has a portfolio of owned or in-licensed methylation markers. Many of these markers have been shown to be highly sensitive and specific in oncology applications and have been, in many instances, described in peer-reviewed journals. There are various patents covering the methylation markers and their duration varies per region and per patent. The earliest patents expire in some regions in 2014 and the patent life on others in filing may be up to 20 years. Some marker patents are in-licensed, some are jointly-owned, and some are filed solely by MDxHealth.

MDxHealth considers patent protection of the technologies, on which its products are based, to be a key factor to its success. The intellectual property portfolio of MDxHealth is managed by an in-house intellectual property team, which works in close collaboration with qualified external patent attorneys both in Europe and the United States.

# 2.7. GROUP STRUCTURE/SUBSIDIARIES

In 2012, MDxHealth SA owned three subsidiaries:

- i. MDxHealth Inc., a fully owned company, incorporated under the laws of Delaware, U.S., with its principal office at 15279 Alton Parkway, Suite 100, Irvine CA 92618. This subsidiary operates a CLIA-accredited laboratory (1.249 m²), from which it commercially launched the Company's *ConfirmMDx™* for Prostate Cancer test in mid-2012.
- ii. MDxHealth PharmacoDx BVBA, a fully owned company, incorporated under the laws of Belgium, with registered office at Franklin Rooseveltlaan 348/J, 9000 Ghent, Belgium. This subsidiary primarily performs R&D work for pharmaceutical companion diagnostic projects, marker discovery and for assay-design improvements.
- iii. OncoMethylome Sciences BV, a fully owned company, incorporated under the laws of The Netherlands, with registered office at Tour 5 GIGA, Avenue de l'Hôpital 11, 4000 Liège. This subsidiary was inactive in 2012.

In December 2012, both MDxHealth PharmacoDx BVBA and OncoMethylome Sciences BV were liquidated. OncoMethylome Sciences BV was a subsidiary without employees and the remaining employees of MDxHealth PharmacoDx BVBA were all transferred to MDxHealth SA. In 2013, MDxHealth Inc. is the only fully owned subsidiary of MDxHealth.

On December 31, 2012, MDxHealth SA delisted from Euronext Amsterdam, and is now only listed on the Euronext Brussels exchange.

# 2.8. HUMAN RESOURCES

On December 31, 2012, MDxHealth had 70 employees, 54% of whom contributed to research and development activities. The ratio of the number of women to men in the Company is 1 to 1. MDxHealth selects talented people to participate and drive its development programs. The Company's scientific staff has expertise in molecular biology, PCR and oncology amongst other disciplines.

The overall employment level of the Group remained relatively unchanged in 2012, however there were the following changes that occurred:

- The employment level increased in the United States in 2012 as the Company has a CLIA commercial laboratory in Irvine, California and is expanding its U.S. lab operations as well as its Sales and Marketing Teams.
- The employment level in Europe remained stable.

Total Headcount Evolution	Dec 31, 2012	Dec 31,2011	Dec 31,2010
Total	70	39	37
<b>Headcount Evolution by Department</b>			
Research & Development	36	26	25
Sales, General, and Administrative	34	13	12
Total	70	39	37
Headcount Evolution by Group Entity			
MDxHealth SA (Belgium)	20	22	23
MDxHealth Pharmaco-Diagnostics BVBA (Belgium)	0	4	7
OncoMethylome Sciences BV (The Netherlands)	0	0	1
MDxHealth Inc. (U.S.A)	50	13	6
Total	70	39	37

# 2.9. LEGAL PROCEEDINGS

MDxHealth is not involved in any legal proceedings. To date, the only legal proceedings that MDxHealth has been involved in was a case filed against MDxHealth, Inc. in 2011. This case involved a U.S. employee whose employment contract was terminated in 2011. The case was resolved prior to commencement of formal court proceedings and without any material financial impact on the Company.

#### 2.10. GOVERNMENT REGULATION

# 2.10.1 Health, Safety and Environment

Each MDxHealth office and laboratory is governed by the local laws on health, safety, and the environment. MDxHealth makes it a priority to ensure the health and safety of its employees, and to minimize its impact on the environment. As such, the Company is in compliance in all material respects of health, safety and environmental legislation and has obtained all necessary permits to conduct its current business.

# 2.10.2 Product Regulation

MDxHealth intends to bring its products to the market initially via testing services performed by its commercial CLIA-accredited laboratory in the United States. Currently, MDxHealth plans that it will be offering the tests in Europe with a partner(s) as CE-marked kits or in the U.S. as FDA-approved test; however the priority in the near-future will be the development and commercialization of U.S.CLIA service tests.

Commercialization of testing services in service laboratories in the United States is governed by quality system provisions outlined in the congressional Clinical Laboratory Improvement Amendments of 1988 (CLIA). When tests are commercialized as diagnostic kits in the United States, they require regulatory approval by the Food and Drug Administration (FDA) either through a 510(k) (Class II) or Premarket Approval (PMA) (Class III). In Europe, diagnostic test kits must bear the regulatory CE-mark, which is an assertion that the product is in conformance with the European Union In-Vitro Diagnostics Directive.

The Company's Irvine, California laboratory facility has procured the required Federal and state licensures necessary to conduct testing within the U.S. In addition to the CLIA certificate of accreditation, the Irvine facility has been accredited

by the College of American Pathologists. The College of American Pathologists (CAP) is an accrediting agency for the Centers for Medicare and Medicaid Services (CMS). The CAP certificate regulates work performed and defines standards covering personnel, facilities administration, quality systems and proficiency testing for the Company's U.S. lab facility. To maintain its CAP certificate, MDxHealth will be subject to survey and inspection every two years to assess its compliance to the CLIA standards. Additionally, although not required to perform clinical laboratory testing in the U.S., certification to ISO 9001:2008 has been obtained through DEKRA notified body and registrar. This certification is important since it is recognized by the pharmaceutical industryln addition to CLIA requirements, the Irvine facility is subject to various state laws. CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have instituted their own out-of-state licensure requirements. Currently the states of New York, Maryland, Pennsylvania, Rhode Island, Florida and California have implemented such licensing requirements. State laws in addition to the federal laws require that laboratory personnel meet certain qualifications, specify performance of quality control, and prescribed record maintenance requirements as well as proficiency testing.

Laboratory-developed tests (LDTs) are tests which are used solely within one laboratory and are not distributed or sold to any other labs or health care facilities. LDTs still must go through rigorous analytical and/or clinical validation procedures and meet performance criteria before results are used for decisions regarding patient care. The federal government, through the CMS, highly regulate the development, evaluation, and use of LDTs.

Initially, laboratories manufactured LDTs that were simple, well-understood laboratory tests or tests which diagnosed rare diseases and conditions that were intended to be used by physicians and pathologists within a single institution in which both were actively part of patient care. These tests were ordinarily either well-characterized, low-risk diagnostics or for rare diseases for which adequate validation would not be feasible and the tests were being used to serve the needs of the local patient population. In addition, the components of traditional LDTs were regulated individually by FDA as ASRs (analyte specific reagents) or other specific or general purpose reagents, and the tests were (and are currently) developed and offered in CLIA high-complexity laboratories with extensive experience in using the tests.

Today, many LDTs use complex elements that may not be FDA-regulated. Further, these tests are often used to assess high-risk but relatively common diseases and conditions and to guide critical treatment decisions. Some LDTs are performed in geographically distant commercial laboratories instead of within the patient's health care setting under the supervision of a patient's pathologist and treating physician. In addition, even when FDA-approved tests are available for a disease or condition, laboratories often continue to use LDTs that have not been reviewed by the agency. Finally, an increasing number of LDT manufacturers are corporations with publicly traded assets rather than hospitals or public health laboratories, which represents a significant shift in the types of tests developed and the business model for developing them.

While the FDA has for some time regulated in vitro diagnostic products ("IVDs") as medical devices, and has taken the position that it has the authority to regulate LDTs, the agency has exercised what it describes as "enforcement discretion" and has not actively regulated LDTs. At this time, the FDA believes that a risk-based application of oversight to LDTs is the appropriate approach to achieve the desired public health benefits. FDA is evaluating feedback from stakeholders, including laboratory professionals, clinicians, patients, and industry, to define the issues that pose the greatest risk to the public health. This is currently still being reviewed by FDA and comments from industry.

#### 2.11. FACILITIES

# Belgium, Liège and Ghent

The Group's headquarters and MDxHealth's registered and main administrative office and assay development facility is

based in Liège, Belgium. MDxHealth currently leases 342 m² of research and office space in the Giga tower of the Liège University Hospital site (Centre Hospitalier Universitaire, "CHU"). The facilities are ISO-certified. MDxHealth SA pharma research laboratories (168 m²) are located at the campus of the University of Ghent, building FFW at the Harelbekestraat 72, 3rd floor, 9000 Ghent.

#### **United States, Irvine, CA**

MDxHealth, Inc., the Company's U.S. subsidiary, leases facilities located at 15279 Alton Parkway, Suite 100, Irvine, CA 92168. The space leased in Irvine is 1.249 m<sup>2</sup> of laboratory and office space. The lab facilities are CLIA-certified and CAP-accredited.

# 2.12. INVESTMENT POLICY

MDxHealth has not made firm commitments on material investments. However the Company intends to increase its capital expenditures in 2013, primarily for the continued growth of its US-based commercial laboratory. Further equipment will likely be needed for the handling of the prostate test volume (test launched in May 2012) and for handling service activities performed for pharmaceutical partners.

# 2.13. RECENT TRENDS AND EVENTS

There are no significant recent trends between end of the fiscal year 2012 and the printing of this registration document.

In 2013, the Company made the following normal course of business announcements:

- Publication of the multicenter clinical trial of ConfirmMDx™ for Prostate Cancer in the Journal of Urology (February 2013)
- Publication of the health economics study of ConfirmMDx™ for Prostate Cancer in the Journal of American Health
   & Drug Benefits (February 2013)
- The Company's commercial partner, Merck KGaA, announced that its Phase III clinical study for its drug candidate cilengitide did not meet its primary endpoints (February 2013).

With regard to trends that are reasonably likely to have a material effect on MDxHealth in 2013, MDxHealth believes the following can be noted:

- The Company is accelerating the sales efforts of ConfirmMDx™ for Prostate Cancer. In its Irvine, CA facility, the Company will continue to focus on the development and validation of its own tests to support its ClinicalMDx™ service offerings through its CLIA laboratory. In 2013 the Company continues with the development of epigenetic assays for it's CLIA Lab. In Belgium, the Company will focus on assay development and service activities for its pharmaceutical partners.
- For the fiscal year 2013, the Company expects strong revenue growth, and is expecting the majority of revenues to come from its *Clinical*MDx<sup>™</sup> products and services. In the course of 2013 the Company expects to receive Medicare coverage for its *Confirm*MDx<sup>™</sup> test. Operating expenses are expected to increase primarily from the expansion of sales and marketing efforts in the U.S. Accordingly, 2013 net loss and cash burn are expected to increase versus 2012, while R&D expenses are expected to be remain at current levels.



Corporate Governance Statement

# 3.1. GENERAL PROVISIONS

This chapter 3 summarizes the main rules and principles of MDxHealth's Corporate Governance Charter. The complete charter is available on the MDxHealth website, at www.mdxhealth.com.

The Company's corporate governance charter was adopted in accordance with the recommendations set out in the Belgian Corporate Governance Code 2009 (the "2009 Code"), issued on March 12, 2009 by the Belgian Corporate Governance Committee (replacing the 2004 edition). The company has adopted the 2009 Code as its reference code. The 2009 Code is based on a "comply or explain" system. Belgian listed companies should follow the 2009 Code, but can deviate from its provisions and guidelines (though not from the principles) provided they disclose the justifications for such deviation. MDxHealth complies with the principles of Belgian Code for Corporate Governance, but believes that certain deviations from its provisions are justified in view of the Company's particular situation. The deviations of MDxHealth are explained in this Chapter 3 and are valid under the law of 6 April, 2010.

# 3.1.1 Board of Directors

The Board of Directors' role is to pursue the long-term success of the Company by providing entrepreneurial leadership and enabling risks to be assessed and managed. The Board of Directors acts as a collegiate body. Pursuant to the Belgian Company Code and the articles of association of the Company, the Board of Directors should be composed of at least three directors. In accordance with the principles of corporate governance, the Board of Directors will, to the extent possible, be composed of at least five directors of which at least three directors are independent directors. To the extent possible, at least half of the board shall consist of Non-Executive Directors. Currently, the Board of Directors comprises 7 directors, of which 3 are independent directors and 6 are Non-Executive Directors. The directors of the Company are appointed by the general shareholders' meeting.

The Company's Board of Directors strives to maintain a well-balanced general diversity at the Board of Directors. Currently, there are 2 female directors among a total of 7 board members (representing a ratio of 29% female directors against 71% male directors). The Company is using its best efforts to ensure that the Board of Directors will meet the 2/3 gender diversity requirement by January 1, 2018.

The Board of Directors is a collegial body, and deliberates and makes decisions as such. Excluding the board committee meetings, throughout 2012 the Board of Directors met 9 times. All directors were present or represented for these 9 meetings.

#### 3.1.2. Chairman

The chairman of the Board of Directors is responsible for the leadership of the Board of Directors. The chairman takes the necessary measures to develop a climate of trust within the Board of Directors, contributing to open discussion, constructive dissent and support for the decisions of the Board of Directors. The chairman promotes effective interaction between the board and the executive management. The chairman establishes a close relationship with the CEO, providing support and advice, while fully respecting the executive responsibilities of the CEO.

The Board of Directors appoints a chairman amongst the Non-Executive Directors. Currently, Mr. Edward L. Erickson is the chairman of the Board of Directors.

# 3.1.3. Independent Directors

Effective as of January 8, 2009, new rules entered into force for Belgian publicly-listed companies with respect to the

criteria for the independence of directors (article 526ter of the Belgian Company Code).

The three independent MDxHealth directors listed in table 3.1.4 meet these definitions for independence which include the following criteria:

- 1. have not held a position as an executive member of an administrative body, as a member of the executive committee or as a person charged with the daily management of the company or one of its affiliates during the five-year period preceding their election;
- 2. have not exercised more than three successive mandates as Non-Executive Director of the Company, with a maximum of twelve years;
- 3. have not been members of the executive management of the Company or one of its affiliates, during the three-year period preceding their election;
- 4. have not received a compensation or other significant advantage of a financial nature from the Company or one of its affiliates, with the exception of the tantièmes and the compensation they may receive or have received as Non-Executive member of the administrative body or member of the supervisory body;
- 5. do not own any rights relating to shares representing 10% or more of the total share capital or of a class of shares of the Company. If they own less than 10%: (i) such rights, together with other rights held by companies controlled by the director concerned may not equal or exceed 10%, or (ii) the disposal of such shares or the exercise of the rights attached thereto may not be subject to any contractual arrangement or unilateral undertaking from the independent directors;
- 6. do not represent a shareholder that satisfies the criteria set forth under point 5;
- 7. have not or have not had during the past fiscal year a significant business relationship with the Company or one of its affiliates, directly or as shareholder, member of the administrative body or the executive management of a company or person who has such a relationship;
- 8. have not been a shareholder or employee of the current or previous statutory auditor of the Company or one of its affiliates during the three-year period preceding their election;
- 9. are not an executive member of the administrative body of another company in which an Executive Director of the Company is a Non-Executive member of the administrative body or member of the supervisory body, and have no other important ties with Executive Directors of the Company through positions with other companies or bodies; and
- 10. do not have a close family member (meaning a spouse or legal partner or relative up to the second degree) who is a member of the administrative body or the executive committee, who is charged with the daily management or who is a member of the executive management of the Company or one of its affiliates, or who does not comply with any of the other criteria mentioned in points 1 to 9 above.

# 3.1.4. Composition of the Board of Directors

There were no changes to the composition of the Board in the course of 2012. In the course of 2011, two directors resigned from MDxHealth: (i) Hilde Windels BVBA, represented by Mrs. Hilde Windels, and (ii) ING Belgium NV, represented

by Mr. Denis Biju-Duval. Mrs. Hilde Windels (an independent director and chair of the Audit Committee) was replaced by Mrs. Ruth Devenyns (an independent director who was also named chair of the audit committee). Mrs. Devenyns filled the seat vacated by Mrs. Windels based on a decision of the Board of Directors. Mrs. Devenyns membership on the Board was subsequently approved by a decision of the annual general shareholders meeting in May 2012. Gengest BVBA, represented by its permanent representative Rudi Mariën, became a non-independent director of MDxHealth following the resignation of ING Belgium NV based on a decision of the Board of Directors. Mr. Mariën's membership on the Board was subsequently approved by a decision of the annual general shareholders meeting in May 2012.

The table below describes the composition of the Board of Directors as of the date of this Registration Document.

Name	Age on Dec 31, 2012	Position	Term Start <sup>(1)</sup>	Term End <sup>(2)</sup>	Professional Address
		Chairman, Non-Executive Independent Director	2010	2013	Tour 5 GIGA, Av. de l'Hôpital 11, 4000 Liège, Belgium
Dr. Jan Groen 53		Executive, Director	2010	2013	Tour 5 GIGA, Av. de l'Hôpital 11, 4000 Liège, Belgium
Dr. Karin L. Dorrepaal	51	Non-Executive Director (Independent prior to Q4 2009)	2007	2013	Tour 5 GIGA, Av. de l'Hôpital 11, 4000 Liège, Belgium
Mr. Mark Myslinski	57	Non-Executive Independent Director	2010	2013	Tour 5 GIGA, Av. de l'Hôpital 11, 4000 Liège, Belgium
Edmond de Rothschild Invest- ment Partners, represented by Mr. Raphaël Wisniewski	42	Non-Executive Director	2005	2013	47, Rue du Faubourg St-Honoré, 75401 Paris Cedex 8, France
Gengest BVBA, represented by Mr. Rudi Mariën	67	Non-Executive Director	2011	2013	Karel van de Woestijnestraat 1-3, 9000 Gent, Belgium
Mrs. Ruth Devenyns	48	Non-Executive Independent Director	2011	2015	Kardinaal Sterckxlaan 47 1860 Meise, Belgium

#### Notes:

- 1) With the exception of Mrs. Ruth Devenyns, whose mandate was confirmed at the annual general shareholders' meeting held in May 2012, all directors were appointed or re-appointed by the ordinary general shareholders' meeting held on May 28, 2010 for a term of three years.
- 2) The term of the mandates of all directors will expire immediately after the annual general shareholders' meeting held on May 31, 2013.

The following paragraphs contain brief biographies of each of the directors or in case of corporate identities being director, their permanent representatives, with an indication of other mandates as member of administrative, management or supervisory bodies in other companies during the previous five years (with the exception of the subsidiaries of the Company):

Mr. Edward L. Erickson has 30 years of executive and board level experience in diagnostics, therapeutics, and life science research products having served as president, CEO or a director of over a dozen companies in these industries. He currently serves as a director of Saladax Biomedical, Inc., where he was previously President and CEO. Saladax is a privately-held diagnostics company developing and commercializing companion diagnostic and therapeutic dose management assays. He also serves as a director of CertiRx Corporation, a privately-held company in the field of document and product authentication and anti-counterfeiting. Prior to joining Saladax, he served as President and CEO of BioNanomatrix, Inc., a privately-held genomics company developing and commercializing proprietary DNA analysis systems. Previously, he was the Chairman, President and CEO of Cellatope Corporation, a private company developing diagnostic products in the field of autoimmune diseases. Prior to that, he served in top leadership roles, including president, CEO and/or chairman, of three venture-capital backed medical products companies, Cholestech, Immunicon, and DepoTech, which successfully completed initial public offerings under his leadership. Earlier in his career, he held senior executive positions at The Ares-Serono Group and Amersham International. Mr. Erickson holds an MBA with High Distinction from the Harvard Graduate School of Business Administration and B.S. and M.S. degrees from the Illinois Institute of Technology. He did military service as an officer in the U.S. Navy's nuclear submarine force.

**Dr. Jan Groen** joined MDxHealth in 2010 and has more than 25 years of experience in the clinical diagnostic industry, with a particular focus on emerging technologies, product development and commercialization. Dr. Groen was previously the president of Agendia, Inc. and COO of Agendia B.V., responsible for their United States and European diagnostic operations, respectively. Prior to this, he served as vice-president of research & development at Focus Diagnostics, Inc., a subsidiary of Quest Diagnostics, in California. Dr. Groen has held numerous management and scientific positions at ViroClinics B.V., the Erasmus Medical Center, and Akzo-Nobel. Dr. Jan Groen is a supervisory board member of IBL International B.V. Dr. Groen holds a Ph.D. degree from the Erasmus University Rotterdam and published more than 125 papers in international scientific journals in the field of clinical diagnostics.

**Dr. Karin Dorrepaal** was in 2011 on the Supervisory Board of Ergo Versicherungsgruppe and on the advisory committees of Triton Private Equity. Dr. Dorrepaal received her Ph.D. in medicine from the Free University of Amsterdam and her MBA from the Erasmus University Rotterdam School of Management. Until 2004, Dr. Dorrepaal was a vice president of Booz and Company, Management Consultants, where she specialized in the pharmaceutical industry and advised on issues regarding strategy, sales, marketing and supply chain. From 2004 until 2006, Dr. Dorrepaal served on the executive board of Schering AG, where she was responsible for Schering's Global Business Unit Diagnostic Imaging as well as its Supply Chain and Procurement.

**Mr. Mark D. Myslinski** currently serves as Chief Commercial Officer for Saladax Biomedical, Inc. Previously, Mr. Myslinski was President and CEO of Rapid Pathogen Screening, Inc, SVP and General Manager of Diagnostics at Hologic Inc., CEO of RedPath Integrated Pathology, Inc, and was a Johnson & Johnson executive where his responsibilities included building a new, worldwide evidence-based medicine function for the Ortho Clinical Diagnostics, Inc. For five years, Mr. Myslinski was also General Manager of Veridex, LLC a division of Ortho Clinical Diagnostics, Inc. focused on molecular and cellular diagnostics that achieved rapid sales growth under Mr. Myslinski's tenure. Mr. Myslinski also held executive roles in the venture-backed start-ups InterScope Technologies and Precision Therapeutics, both focused on the field of pathology with an emphasis on cancer.

**Mr. Raphaël Wisniewski** is a partner at Edmond de Rothschild Investment Partners. Previously, Mr. Wisniewski worked in the investment banking divisions at Goldman Sachs International and Salomon Smith Barney and in the finance department at Générale de Santé International. He is a director at Genticel, Regado Biosciences, Poxel, Implanet, EOS Imaging, Vessix Vascular, and Cellnovo. Mr. Wisniewski holds a degree from HEC and a D.E.A. in Economics and Finance from IEP Paris.

**Mr. Rudi Mariën** is the Vice President of Cerba European Lab and President and Managing Director of Gengest BVBA and Biovest CVA. Through his management company, Gengest BVBA, Mr. Mariën has board mandates in different stocklisted and private biotech companies (BioCartis NV, Devgen NV, Quest For Growth NV, Actogenix NV, Pharmaneuroboost NV, and Oystershell NV). Mr. Mariën was co-founder, reference shareholder and Chairman of Innogenetics, and has been the founder, shareholder and Managing Director of several clinical reference laboratories. He was also the founder, shareholder and Managing Director of the Barc Group, a leading international centralized clinical laboratory, exclusively dedicated to pharmaceutical studies. Mr. Mariën holds a degree in pharmaceutical sciences from the University of Gent, and is specialized in clinical biology.

Mrs. Ruth Devenyns has a long standing experience in the biotechnology sector. A former analyst and investment banker, Ruth Devenyns was in charge of the venture capital activities in the sector at KBC Private Equity until end of March 2012. She was involved in several IPO's, private placements and M&A-transactions and held various directorships including Ablynx, Applied Maths and Pronota. At KBC Private Equity she also managed various investments in agrobiotech and seed companies such as CropDesign and Ceres. In June 2012 she joined Korys, the investment structure of the Colruyt family, and became an independent director of Euronext-listed Devgen until its acquisition by Syngenta in December 2012. Currently, Ruth Devenyns is a director at Biocartis, representing Korys, and director of FlandersBio, the biotech sector organisation in Flanders.

#### Litigation statement concerning the directors or their permanent representatives

At the date of this registration document, none of the directors, or in case of corporate entities being director, none of their permanent representatives, of the Company, other than those indicated in the paragraph below, has for at least the previous five years:

- any conviction in relation to fraudulent offenses;
- held an executive function in the form of a senior manager or a member of the administrative, management or supervisory bodies of any company at the time of or preceding any bankruptcy, receivership or liquidation, or has been subject to any official public incrimination and/or sanction by any statutory or regulatory authority (including any designated professional body), except for:
- (i) Mr. Edward Erickson who was CEO, chairman, and also held other executive and Non-Executive positions through June 2007 at the company Immunicon Corporation prior to its filing for bankruptcy in June 2008, for which the bankruptcy trustee has initiated legal proceedings against Mr. Erickson and other directors and managers of the bankrupt company.
- (ii) Mrs. Ruth Devenyns was a director of 2 US companies that filed for bankruptcy, PR Pharmaceuticals in 2008 and Altea Therapeutics in 2011.
- (iii)Mr. Raphaël Wisniewski who was a director at 2 companies which were liquidated in 2008, Nautilus Biotech and Androclus Therapeutics.
- has ever been disqualified by a court from acting as a member of the administrative, management or supervisory bodies of any company or from acting in the management or conduct of affairs of any company.

# 3.1.5. Committees of the Board of Directors

The Board of Directors of MDxHealth has set up two permanent committees, the audit committee and the nomination

and remuneration committee. The committees are advisory bodies only and the decision-making remains within the collegial responsibility of the Board of Directors.

#### 3.1.5.1. Audit Committee

Effective as of January 8, 2009, new rules entered into force for Belgian publicly-listed companies with respect to (i) the establishment and tasks of the audit committee, (ii) the criteria for the independence of directors (see section 3.1.3), and (iii) the appointment of and dismissal of statutory auditors (see section 3.6).

With respect to the new rules covering the establishment of the audit committee, the following is applicable to MDxHealth:

- MDxHealth has had an Audit Committee in place since the Company's inception.
- According to the new rules, MDxHealth would meet the size criteria in order to operate without a separate audit committee, but the Company has chosen to continue operating with a separate audit committee.
- The new rules require that the audit committee be composed of Non-Executive Directors, which is and has always been the case for MDxHealth's audit committee.
- The new rules require that the audit committee be composed of at least one independent director with the
  necessary competence in auditing and accounting, which is and has always been the case for MDxHealth's audit
  committee.
  - Mrs. Ruth Devenyns, who assumed the position of Audit Committee Chairperson after August 2011, meets the criteria of independence:
    - She is in her first mandate on the Board of MDxHealth and has never held any Executive management position with the Company.
    - She owns no shares in the Company. She has been granted 6,000 warrants in 2012 entitling her to subscribe to the Company's shares. However, this does not prejudice her independence in the sense of article 526ter of the company code because (i) the number of warrants granted to non-executive directors is limited, (ii) the shareholders' general meeting approved such grant by approving the May 2012 Stock Option Plan on June 15,2012 and (iii) the granting of a limited number of warrants to non-executive directors was recommended by the nomination and remuneration committee in order to attract and retain talents in the Company.
    - She fulfills the other criteria of independence as listed in section 3.1.3.
  - Mrs. Ruth Devenyns meets the criteria of necessary competence in auditing and accounting:
    - She has worked in the venture capital sector

MDxHealth's audit committee must be composed of at least three members and is limited to Non-Executive Directors. The committee appoints a chairman amongst its members. The chairman of the Board of Directors should not chair the committee.

The role of the audit committee is to assist the Board of Directors in fulfilling its financial, legal and regulatory monitoring responsibilities. The committee reports regularly to the Board of Directors on the exercise of its duties, identifying any

matters in respect of which it considers that action or improvement is needed, and making recommendations as to the steps to be taken. The audit review and the reporting on that review cover the Company and its subsidiaries as a whole. The specific tasks of the audit committee are outlined in the Company's governance charter and include the following:

- · to monitor the financial reporting process;
- to monitor the effectiveness of the Company's internal control and risk management systems;
- to monitor the Company's internal control and risk management;
- to monitor the internal audit (where applicable) and related activities;
- to monitor the statutory audit of the annual statutory and consolidated financial statements, including the followup of questions and recommendations by the statutory auditor and, as the case may be, the auditor responsible for the audit of the consolidated financial statements;
- to review and monitor the independence of the statutory auditor, and, as the case may be, the auditor responsible for the audit of the consolidated financial statements, and in particular the provision of additional services to the Company.

The following directors are currently members of the audit committee: Mrs. Ruth Devenyns (chairperson), Mr. Edward Erickson and Dr. Karin Louise Dorrepaal, Non-Executive Directors.

The audit committee is a collegial body, and deliberates and makes decisions as such. The audit committee met 3 times in 2012. All members of the audit committee were present or represented at all meetings.

#### 3.1.5.2. Nomination and Remuneration Committee

The Belgian Act of April 6, 2010 relating to the improvement of the corporate governance for publicly listed companies and autonomous governmental companies, and amending the regulation relating to professional prohibitions in the banking and financial sector ("Loi visant à renforcer le gouvernement d'entreprise dans les société cotées et les entreprises publiques autonomes et visant à modifier le régime des interdictions professionelles dans le secteur bancaire et financier" / "Wet tot versterking van het deugdelijk bestuur bij de genoteerde vennootschappen en de autonome overheidsbedrijven en tot wijziging van de regeling inzake het beroepsverbod in de bank- en financiële sector") introduced a new article 526quater in the Belgian Company Code requiring qualifying publicly listed companies to establish a remuneration committee as from the first accounting year started after the date of publication of said Act (i.e. April 23, 2010).

With respect to these new rules covering the establishment of the remuneration committee, the following is applicable to MDxHealth:

- Although this legal obligation to establish a remuneration committee would only apply for MDxHealth as from the accounting year started on January 1, 2011, MDxHealth has had a nomination and remuneration committee in place since the Company's IPO in June 2006.
- According to the new rules, MDxHealth would meet the size criteria in order to operate without a separate nomination and remuneration committee, but the Company has chosen to continue operating with a separate nomination and remuneration committee.
- The new rules require that the nomination and remuneration committee be composed of Non-Executive Directors, which is and has always been the case for MDxHealth's nomination and remuneration committee.

MDxHealth's nomination and remuneration committee must be composed of at least three members and must be composed exclusively of Non-Executive Directors. The committee appoints a chairman amongst its members. The chairman of the Board of Directors can chair the committee, but should not chair the committee when dealing with the designation of his successor. The CEO should participate to the meetings of the committee when it deals with the remuneration of other executive managers.

The role of the nomination and remuneration committee is to make recommendations to the Board of Directors with regard to the election of directors, the remuneration policy for Non-Executive Directors and the resulting proposals to be submitted to the shareholders' meeting, the remuneration policy for executive management, and to review and periodically update an overall remuneration policy for all personnel and directors of the Company. The committee's tasks are further described in the Company's corporate governance charter.

The following directors are members of the nomination and remuneration committee: Mr. Edward Erickson, independent director, Mr. Mark Myslinski (chairman of the committee) independent director, and Mr. Rudi Mariën, non-independent director.

The nomination and remuneration committee is a collegial body, and deliberates and makes decisions as such.

The nomination and remuneration committee met 6 times in 2012. All of the committee members attended all of the committee meetings.

# 3.1.6 Process for Evaluating the Board, its Committees, and its Individual Directors

Every year the Board of Directors will, under the lead of its Chairman, assess its size, composition, performance and those of its committees, as well as the contribution of each director.

This evaluation process has five objectives:

- assessing how the Board of Directors and its committees operate,
- · checking that the important issues are suitably prepared and discussed,
- checking the Board's and committees' current composition against the desired composition,
- evaluating the actual contribution of each director's work, the director's presence at Board and committee meetings and his involvement in discussions and decision-making, and
- evaluating whether the fees and costs of the full board and individual directors is in line with the performance of the Company and the performance of the individual director.

The Chairman can organize an individual meeting with each director to discuss these items, including the director's own performance and the performance of his colleague directors. The conclusions resulting from these individual meetings will be submitted to the Board by the Chairman.

An individual evaluation of each director will be conducted every year as part of the global evaluation of the Board and each time the Board considers his or her nomination for reappointment by the General Shareholders' Meeting. The Non-Executive Directors should assess their interaction with the executive management at least once a year. To this end they will meet at least once a year in the absence of the Executive Directors.

#### 3.2 EXECUTIVE MANAGEMENT

The Board of Directors has appointed the executive management of the Company. The terms of reference of the executive management have been determined by the Board of Directors in close consultation with the CEO.

Effective April 26, 2010 Dr. Jan Groen was appointed as CEO of MDxHealth.

The key management positions in 2012 are illustrated below:



# 3.2.1. Chief Executive Officer

The CEO is appointed, and can be removed, by the Board of Directors of the Company.

The CEO is charged by the Board of Directors with the day-to-day management of the Company and is therefore also managing director of the Company. In this function, the CEO has the following general responsibilities:

- the implementation of the decisions of the Board of Directors, within the strategy, planning, values and budgets approved by the Board of Directors,
- overseeing the different central departments and business units of the Company, and reporting to the Board of Directors on their activities.
- the development of proposals for the Board of Directors relating to strategy, planning, finances, operations, human resources and budgets, and other matters that are to be dealt with at the level of the Board of Directors.

The specific tasks of the CEO are further described in the Company's corporate governance charter.

# 3.2.2. Other Members of Executive Management Team

The other members of the executive management team, being the heads of the main activities and central departments (and their divisions) of MDxHealth, are appointed and removed by the CEO in close consultation with the Board of Directors of the Company.

The main tasks of the executive management are to organize their department in accordance with the guidelines determined by the CEO and to report to the CEO on the operation and activities of their department.

# 3.2.3.Composition of the Management Team

The composition of the Management Team is set out below and reflects the situation at the date of this report.

Name	Position	Age on Dec 31, 2012
Dr. Jan Groen	Chief Executive Officer (CEO)	53
Mr. Francis Ota	Executive VP of Finance	60
Mr. Joseph Sollee	Executive VP of Corporate Development and Legal Affairs	48
Mr. Christopher Thibodeau	Executive VP of Commercial Operations	42

The executive management does not constitute an executive committee (comité de direction / directiecomité) within the meaning of article 524bis of the Belgian Company Code.

Following are biographies of the executive management team members (also referred to as executives).

# **Dr. Jan Groen, Chief Executive Officer**

Dr. Jan Groen joined MDxHealth in April 2010 and has more than 25 years of experience in the clinical diagnostics industry, with a particular focus on emerging technologies, product development and commercialization. Dr. Groen was previously the president of Agendia, Inc. and COO of Agendia B.V., responsible for their United States and European diagnostic operations, respectively. Prior to this, he served as VP of Research & Development at Focus Diagnostics, Inc., a subsidiary of Quest Diagnostics, in California. Dr. Groen has held numerous management and scientific positions at ViroClinics B.V., the Erasmus Medical Center, and Akzo-Nobel. Dr. Jan Groen is a supervisory board member of IBL International B.V.

Dr. Groen holds a Ph.D. degree in Medical Microbiology from the Erasmus University Rotterdam, a BSc in Clinical Laboratory Studies and has published more than 125 papers in international scientific journals in the field of clinical diagnostics.

#### Mr. Francis Ota, Executive Vice President of Finance

Mr. Ota joined MDxHealth in March 2012 and served as a Senior Finance Executive with a number of leading healthcare companies. Prior to joining MDxHealth, Mr. Ota served as CFO of Captek Holdings, a specialty nutraceutical company.

Prior to that, he was Senior Director of Finance at Focus Diagnostics, Inc. a CLIA service laboratory acquired by Quest Diagnostics in 2006. Mr. Ota also held senior finance roles with Medtronic and Hewlett Packard.

Francis Ota earned a Master in Business Administration (MBA) from the Haas School of Business, University of California Berkeley and a Bachelor of Science in Finance and International Business from Leeds School of Business, University of Colorado, Boulder.

#### Mr. Joseph Sollee, Executive Vice President of Corporate Development and Legal Affairs

Mr. Sollee has provided legal counsel to MDxHealth since its inception in 2003, and in April 2008 joined our management team. Prior to joining the Company, Mr. Sollee served as Special Counsel with the law firm of Kennedy Covington (now K&L Gates), where he led the Life Sciences Practice Group. Mr. Sollee has more than 15 years of experience in the biotech industry, and has held senior legal and management positions at Triangle Pharmaceuticals and TherapyEdge. In addition, he has practiced as a corporate attorney in the Washington D.C. legal firm Swidler & Berlin and as an investment banker at Smith Barney in New York.

Mr. Sollee received a Juris Doctorate in Law and a Master's degree in International & Comparative Law from Duke University, a BA degree from Harvard University, and has been awarded New York, Washington D.C. and North Carolina legal bar certifications.

# Mr. Christopher Thibodeau, Executive Vice President of Commercial Operations

Mr. Thibodeau joined MDxHealth in September 2010 and brings over 15 years of sales, marketing and commercial leadership experience in the diagnostics area. As Vice President Commercial Operations, he is responsible for developing and executing MDxHealth's key strategic sales & marketing and business development initiatives. Prior to joining MDxHealth, Mr. Thibodeau served as Senior Director of Marketing at Agendia Inc., Vice President of Sales and Marketing for Numira Biosciences, National Director of Sales U.S. LABS (an industry leader in cancer diagnostic and genomic testing services); and sales and marketing management roles at Ventana Medical.

Mr. Thibodeau holds a BA degree from the East Stroudsburg University in Pennsylvania and studied French at the Faculté des Lettres in Nancy, France.

#### Litigation statement concerning the management

The Company is not aware of any conviction of any member of the executive management in the previous five years for fraud or indictable offences, or of any involvement in bankruptcy, late payment, or forced liquidation. Each executive management team member has represented that he or she has not been convicted in the previous five years for fraud or indictable offences, or of any involvement in bankruptcy, late payment, or forced liquidation.

# 3.2.4. 2012 Remuneration Report

The following report has been prepared by the nomination and remuneration committee and approved by the board of directors of MDxHealth. This section 3.2.4. contains the remuneration report as referred to in Article 96,§3 of the Belgian Company Code (Code des Sociétés/ Wetboek van Vennootschappen) ), as amended by the Law of April 6, 2010 (the "Remuneration Report").

The Remuneration Report has been prepared by the nomination and remuneration committee and has been approved by the board of directors of the Company on February 27, 2013.

The Company has reviewed the remuneration policy of its management, executive and Non-Executive Directors in light of article 96 of the Belgian Company Code (*Code des Sociétés/Wetboek van Vennootschappen*), as amended by the Law of April 6, 2010 and as supplemented by the relevant provisions of the Belgian Corporate Governance Code and the Law of November 7, 2011 modifying the Belgian Company Code in relation with the share-based remuneration of Non-Executive Directors of listed companies, and has prepared this Remuneration Report in accordance with the requirements contained therein.

#### 3.2.4.1. Procedure adopted in 2012

#### (i) Procedure adopted to develop a remuneration policy

During 2012, MDxHealth has continued to apply widely the remuneration policy applied in 2011. In conformity with the applicable legislation, the nomination and remuneration committee of the Board of Directors, composed of non-executive members of the board, has the tasks (i) to formulate proposals on the remuneration policy applicable to directors, managers and other executives, as well as on the determination of their remuneration on an individual basis, and (ii) to prepare the remuneration report to be inserted in the corporate governance statement of the annual report.

The remuneration report is submitted to a vote by the annual general shareholders' meeting.

The nomination and remuneration committee met on December 6, 2011 and made recommendations to the Board of

Directors, which were approved by the same on December 7, 2011 and by the annual general shareholders' meeting on May 25, 2012.

The main recommendations implemented in 2012, which aim at better aligning the interests of the board members with the goal of the Company, can be summarized as follows:

- the setting in place of an equity incentive program, including a general pool of stock options in the form of warrants, for management and other personnel;
- the non granting of fees to non-independent directors for serving on the Board;
- the demand (but not the request) to independent directors serving as representatives of investors that own an amount of Company shares greater than the five percent (5%) transparency filing threshold to waive their board fees;
- the change from the variable component of Board remuneration to a fixed annual compensation scheme;
- the annual grant of six thousand (6,000) stock warrant to each non-executive board member, under the terms of a Company warrant program.

These recommendations, as reflected in the remuneration policy, were implemented in 2012 and are still applicable for the accounting year 2013.

#### (ii) Procedure adopted to determine the level of remuneration

#### a) Directors

Annually, the nomination and remuneration committee reviews the fee levels paid to directors and compares them to fee levels paid at other comparable companies.

Grants of warrants to directors are recommended by the non-conflicted members of the nomination and remuneration committee, reviewed by the Board of Directors and submitted to the general shareholders' meeting for approval. Non-executive directors may be entitled to warrants. Such warrants must be approved by a general shareholders' meeting. The warrants are used to attract, motivate, and retain key talents at the director level. The number of warrants granted to non-executive directors has remained low compared to the number of total outstanding security instruments. Non-executive directors are not entitled to bonuses, fringe benefits or pension benefits.

Non-executive board members who provide services to the Company outside of the formal board meetings or board committee meetings, must have their work and fees pre-approved by the non-conflicted members of the nomination and remuneration committee. These fees are then submitted for approval at the ensuing annual general shareholders' meeting.

For the executive director position, the nomination and remuneration committee proposes remuneration changes and bonuses, if any to the Board of Directors for approval.

# b) CEO and managers

The remuneration of the executive management is designed to attract, retain and motivate executive managers. The level and structure of the remuneration are subject to an annual review by the nomination and remuneration committee to take into account market practice. The annual review does not provide mechanisms for automatic adjustments, except for changes that are legally required.

The fixed remuneration level, the variable bonus, and the objectives of the CEO are reviewed by the nomination and remuneration committee, compared to industry and market levels, and confirmed by the Board of Directors. The Board of Directors sets the Company objectives and the personal objectives of the CEO.

The CEO sets the personal objectives of the other executive managers. He recommends grants of warrants, bonuses and changes, if any, in the fixed remuneration of executive managers to the nomination and remuneration committee. The nomination and remuneration committee reviews these recommendations and compares them to industry and market practices. It then proposes the warrant grants, bonuses and remuneration changes, if any, to the Board of Directors, and to the extent required by applicable law, to the general shareholders' meeting, for approval.

#### 3.2.4.2. Declaration on the remuneration policy

#### (i) Remuneration policy in 2012

The Board of Directors determines, upon recommendation of the nomination and remuneration committee, the remuneration policy for directors and managers.

#### a) Directors

The remuneration policy for non-executive and executive directors was modified at the annual shareholders' meeting of May 25, 2012.

#### Non-executive directors

The non-executive directors are remunerated on the basis of a pre-defined fixed annual retainer fee. The fee level is the applicable fixed annual retainer fee approved at the last annual general shareholders' meeting concerning this matter, i.e.:

- EUR 35,000 for the Chair of the Board of Directors;
- EUR 30,000 for the Chair of the Audit Committee;
- EUR 28,000 for the Chair of the Nomination and Remuneration Committee; and
- EUR 25,000 for any other director.

A record of board attendance is maintained by the secretary to the Board of Directors. This record is then reviewed by the Board of Directors and confirmed by the approval of the board minutes. Regular attendance at scheduled meeting of the board of directors, including committee meetings, is expected. In the event that that a director fails to attend at least 75% of the scheduled meeting of the board of directors during a calendar year, the board may reduce such director's applicable annual retainer fee by a pro rata amount to reflect actual attendance.

Apart from the above remuneration, directors will be entitled to a reimbursement of out of pocket expenses actually incurred to participate to board meetings.

Although all non-executive directors have the right to receive the foregoing applicable annual retainer fee, the board suggests that each non-independent director elect, in his or her discretion, to waive its right to receive such fees. In calendar year 2012, the two non-independent directors, who have not held an executive position within the Company, agreed to waive their director' fees.

The mandate of non-executive directors can be terminated at any time without any compensation. Non-executive directors do not receive any form of pension plan benefits from the Company.

The Company has not made any loans to the members of the board of directors.

#### Executive directors

Executive directors do not receive any remuneration for their position as a director. Executive directors are only remunerated for their role as executive managers. These individuals receive a fixed remuneration plus a variable bonus that is linked to their personal achievements and the achievements of the Company. They do not receive any additional remuneration for the exercise of their board mandate. The mandate of executive directors may be terminated at any time without any form of compensation. Their remuneration package is approved by the general shareholders' meeting. The CEO is the only executive director of the Board of Directors of the Company and he does not earn any remuneration in respect of his executive director position.

• Relative importance of the components of remuneration

The relative importance of the various components of remuneration as referred to in article 96, §3, al. 2, c) of the Belgian Company Code, is provided under section C. (i) of this Remuneration Report.

#### b) CEO and managers

Each member of the executive management is entitled to a basic fixed remuneration designed to fit responsibilities, relevant experience and competences, in line with market rates for equivalent positions. The majority of the annual remuneration is a fixed compensation amount. There is no minimum nor maximum variable bonus.

The CEO has a fixed remuneration, a fixed bonus and a variable bonus linked to the performance of the Company and to his capacity to manage remuneration costs.

The management team members receive a fixed remuneration plus a variable bonus that is linked to their personal achievements (i.e. experience, know-how, education, skills, responsibilities, and performance) and the achievements of the Company. The remuneration is closely linked to performance. Bonuses, if any, are linked to identifiable objectives and to special projects and are set and measured on a calendar-year basis. Non performers are not retained in the Company.

The performance objectives of the management team members are primarily evaluated with regard to the following criteria: (i) respect of the board-approved annual budget, (ii) share value, and (iii) meeting measurable operational targets. The various objectives and their weighting may differ for the individual managers. The nomination and remuneration committee of the board of directors meets annually to review the performance of the managers, to compare the actual measurable results to the objectives that were pre-defined by the committee, and to establish the measurable objectives for the ensuing calendar year.

Each member of the executive management who is a salaried employee may be entitled to a number of fringe benefits, which may include participating in a defined contribution pension or retirement scheme, disability insurance, a company car, a mobile telephone, internet access and/or a laptop computer according to general Company policy, and other collective benefits (such as hospitalization insurance and meal vouchers).

In 2012, all the members of the executive management (excluding the former CFO) were engaged on the basis of an employment contract. The employment contracts are generally for an indefinite term, with a trial period. The employment contracts may be terminated at any time by the company, subject to a severance payment in line with market standards. The employment contracts include, where appropriate, non-competition undertakings, as well as confidentiality and IP transfer undertakings (that will try to seek maximum protection of the Company's interests, under applicable laws and subject to the employee's agreement).

Executive members who are engaged on the basis of a services contract do not receive fringe benefits, except that they may be provided with a mobile phone and laptop computer according to General Company policy, and they qualify for reimbursement of expenses incurred while carrying out their professional responsibilities.

Executive managers of the Company that are employed under employee contracts are entitled to enroll in defined-contribution type pension plans (such as 401K plans in the United States). The assets of these pension plans are held and managed by third-party organizations and the Company only makes contributions to these plans during the term of service of the employee. Executive managers of the Company that are engaged on the basis of a service agreement are not entitled to any pension plans or pension plan contributions from the Company.

#### c) Warrants

Stock Options granted by the Company generally take the form of warrants in the sense of article 496 et seq. of the Belgian Company Code.

Warrants can periodically be awarded to managers, directors, employees, or even certain consultants, primarily as a retention and motivation tool. Warrants typically vest over time (subject to the beneficiary remaining with the Company) and can only be exercised after a specific period of time, except where the Company decides otherwise. There was no significant change in the remuneration policy in 2012.

# (ii) Expected changes with respect to accounting year 2013 and the following accounting year.

No significant change to the remuneration policy of Directors and Executive managers is envisaged for 2013 and 2014.

The bonuses of the management team members for 2013-2014 will be primarily linked to the following objectives:

- respect of the board-approved annual budget, with a focus on revenue growth and cash-flow management
- share value measured against a relevant industry index
- · meeting measurable operational targets, including specific product development and commercialization goals

# 3.2.4.3. Remuneration amounts for the reported year

# (i) Remuneration earned by the Non-Executive Directors for the reported year

The following table provides the 2012 compensation of the Non-Executive Directors in function at the date of this document.

Name	Position <sup>1</sup>	Pro-rata of annual retainer fee <sup>2</sup> (EUR K)	Other services (EUR K)	Total <sup>3</sup> (EUR K)
Edward Erickson	NED - Board Chair, member AC & NRC	35	0	35
Karin Dorrepaal	NED – member AC	25	0	25
Raphaël Wisniewski	NED	0	0	0
Rudi Mariën	NED – member NRC	0	0	0
Mark Myslinski	NED –NRC Chair	28	0	28
Ruth Devenyns	NED – AC Chair	30	0	30
Total for current non-ex	ecutive Board members	118	0	118

#### Notes

During the course of 2012, the composition of the Board of Directors did not change.

During the course of 2012, the Company has not deviated from its remuneration policy for the non-executive directors. The total remuneration and benefits paid to the all directors (both executive and non-executive directors, and including the CEO remuneration) in 2012, 2011 and 2010 was EUR 640,000, 645,000 and EUR 436,000 respectively (gross amount, excluding VAT and stock based compensation).

On May 23, 2006, the Board of Directors decided, with application of Article 523 of the Belgian Company Code, that the Company will indemnify the directors against any claim by a third party based on directors' liability, except in the event of gross negligence and willful misconduct. Therefore the Company has taken out directors' liability insurance. The insurance policy was renewed in 2012. Additionally, on August 1, 2012, the Company's U.S. subsidiary, MDxHealth, Inc., entered into indemnification agreements directly with each of its directors, as well as each director of the Company, to indemnify each such person for liabilities to the extent that they may arise from, or claims therefor which are based on, U.S.-associated activities of the U.S. subsidiary or of the Company, including any claims based on a theory of derivative liability in the right of the U.S. subsidiary.

#### (ii) Remuneration earned by the Executive Director for the reported year

Dr. Jan Groen is not remunerated for his position as an Executive Director of the Company. Neither is he entitled to any severance pay in case of termination his mandate as an Executive Director of the Company.

<sup>1: &</sup>quot;NED" = Non-Executive Director, "ED" = Executive Director, "AC" = Audit Committee, "NRC" = Nomination & Remuneration Committee

<sup>2:</sup> Fixed annual retainer fees were paid for calendar year 2012 based on shareholder approval of the new remuneration policy for directors

<sup>&</sup>lt;sup>3</sup>: Excludes expense reimbursement and warrants. No other form of remuneration exists for directors.

# (iii) Remuneration earned by the CEO for the reported year

Dr. Jan Groen was hired as CEO starting April 26, 2010. He is remunerated on the basis of his executive management position. The CEO has a variable bonus linked to the performance of the Company, which can amount to a maximum of 30% of his annual compensation, and a fixed annual bonus of maximum EUR 22,000, linked to its capacity to manage human resources costs. Excluding the value of warrants, the remuneration and benefits provided to the CEO in 2012 were comprised as follows:

	Euro (EUR)
Fixed gross remuneration <sup>1</sup> :	377,000
Bonuses paid and awarded <sup>2</sup> (gross)	85,000
Pension benefits:	13,000
Other benefits <sup>3</sup> :	30,000
Total	505,000

#### Notes:

- 1: Total cost to the Company, including employer social security contributions and vacation pay accrual.
- 2: Excludes value of 45,000 warrants the Board of Directors has agreed to issue to the CEO as a bonus for 2012 performance (see below). Excludes value of 130,000 warrants already created, issued, and accepted in 2010, 30,000 warrants already created, issued, and accepted in 2011, and the IFRS cost of the 45,000 warrants already created, issued, and accepted in 2012.
- 3: Includes Company-paid housing, Company car, meal vouchers, and other similar benefits. Excludes reimbursement of normal professional expenses such as telephone and Company travel expenses.

The total service fees paid to the CEO in 2012, 2011 and 2010 were EUR 505,000, EUR 524,000 and EUR 317,000, respectively (gross amount, excluding VAT and stock based compensation). It is to be noted that the present CEO was hired in and as from April 2010. Previously, the CEO was Herman Spolders BVBA, represented by its permanent representative Mr. Herman Spolders.

Dr. Jan Groen holds no shares in the Company. However, upon being hired in April 2010 he was granted 130,000 new warrants in the Company. The warrants were granted at the extraordinary general shareholders' meeting of June 21, 2010 and have the following characteristics:

- Exercise price of EUR 2.07 (one stock option (warrant) gives right to buy one share)
- Vesting: straight-line on a quarterly basis over 4 years (no vesting if less than one year of service or employment is provided)
- Duration of options: 5 years

The IFRS share-based compensation of the above 130,000 warrants granted in 2010 amounts to EUR 162,000.

Dr. Groen was granted an additional 30,000 new warrants in the Company at the Board of Directors' meeting of May 27, 2011 and have the following characteristics:

- Exercise price of EUR 1.71 (one stock option (warrant) gives right to buy one share)
- Immediate and full vesting of all stock options on the date of grant (December 7, 2010)
- Duration of options: 10 years

The IFRS share-based compensation of the above 30,000 warrants granted in 2011 amounts to EUR 26,000.

At the board meeting of December 7, 2011, the non-conflicted members of the Board of Directors agreed to the following bonus for the performance of Dr. Jan Groen in 2011:

- EUR 82,000 cash bonus
- 45,000 new warrants (employee stock options) formally issued on March 15, 2012 to vest straight-line over 4 years. The exercise price is based on the 30-day average market price prior to their issuance. The warrants are not exercisable until after the third anniversary the date of their grant.

The IFRS share-based compensation of the above 45,000 warrants granted in 2012 amounts to EUR 51,000.

At the board meeting of December 5, 2012, the non-conflicted members of the Board of Directors agreed to the following bonus for the performance of Dr. Jan Groen in 2012:

- EUR 85,000 cash bonus
- 45,000 new warrants (employee stock options) formally granted on January 1, 2013 to vest straight-line over 4 years. The exercise price is based on the 30-day average market price prior to their grant. The warrants are not exercisable until after the third anniversary the date of their grant.

The IFRS share-based compensation of the above 45,000 warrants granted in 2012 amounts to EUR 52,000.

During the course of 2012, the Company has not deviated from its remuneration policy for the executive director.

#### (iv) Remuneration earned by other Executive Managers

The 2012 combined remuneration package of the 3 other executive management team members (excluding the CEO) - i.e. Christopher Thibodeau, Joseph Sollee and Francis Ota - including employer taxes, together with the remuneration of Decofi sprI (represented by Philip Devine), the former CFO of the Company, was EUR 928,000.

	Euro (EUR)
Fixed gross remuneration <sup>1</sup> :	762,000
Bonuses paid and awarded <sup>2</sup> (gross)	117,000
Pension benefits:	19,000
Other benefits <sup>3</sup> :	30,000
Total	928,000

#### Notes:

- 1: Includes employer taxes and vacation pay accrual. Excludes VAT.
- 2: Excludes value of warrants the Board of Directors has agreed to issue to certain other executive managers.
- 3: Includes for some individuals a Company car, meal vouchers, and other similar benefits. Excludes reimbursement of normal professional expenses such as telephone and Company travel expenses.

The total remuneration and benefits paid to the executive management team members (including the CEO) in 2012, 2011 and 2010 was EUR 1.4 million, EUR 1.3 million and EUR 0.9 million, respectively (gross amount, excluding VAT and stock

based compensation). In the aforementioned figures, the service fees and board fees of the managers hired on the basis of a service agreement are included with the salaries of the other management team members. The number of managers included in the definition of the Executive Management Team has been reduced over the recent years to fit the new company strategy.

Cash bonuses were awarded to certain management team members in 2012 (in addition to stock option bonuses mentioned in this report) as follows (amounts exclude employer taxes):

CEO	EUR 85,000
EVP Corp. Dev. & Legal Affairs	EUR 39,000
EVP Commercial Operations	EUR 66,000
EVP Finance	EUR 12,000

The primary performance objectives for the bonuses of the above management team members in 2012 were the following:

- respect of the board-approved annual budget, with a focus on cash-flow management
- share value measured against a relevant industry index
- meeting measurable operational targets, such as the commercialization of its *Confirm*MDx<sup>™</sup> for Prostate test and attainment of revenue targets

In the course of 2012, no warrants or other rights were exercised by or lapsed for the executive managers.

During the course of 2012, the Company has not deviated from its remuneration policy for the executive managers.

#### (v) Warrants to be granted in 2013

In addition, based on a decision of the Board of Directors on December 5, 2012, the Company has contractually agreed to grant new warrants to certain executive managers in 2013, as part of the 2012 bonuses.

Grantee	Warrants
CEO	45,000
EVP Corp. Dev. & Legal Affairs	35,000
EVP Commercial Operations	30,000
EVP Finance	10,000

These warrants have the following characteristics:

- Exercise price based on the 30-day market average price in the period preceding the date of grant (one warrants shall entitle its owner to acquire one share);
- Vesting: straight-line on a quarterly basis over 4 years (no vesting if less than one year of service or employment is provided) although the vesting period may start on a date earlier than the date of the grant of the warrants;

- Exercise Period: the warrants are not exercisable until after the third anniversary the date of their grant;
- Duration of warrants: 10 years.

#### (vi) Special provisions of the contractual relationship of the Executive Managers

The executive managers have contractual agreements which date from before the entry into force of the law of April 6 2010 on corporate governance in public and listed companies and are in conformity with common employment law.

# More specifically:

- the employment contract with Dr Jan Groen provides that if the employment contract is terminated for a reason other than serious misconduct, he will be entitled to a severance pay of three (3) months gross remuneration per initiated period of five (5) years of service with the company, however, such severance pay will be at a minimum equivalent to nine (9 months) of gross remuneration. This agreement was entered into on April 3, 2010, i.e. before the entry into force of the law of April 6, 2010 on corporate governance in public and listed companies;
- the employment contract with Mr Joseph Sollee provides that if the employment contract is terminated for a reason other than serious misconduct, he will be entitled to a severance pay of four (4) months gross remuneration and benefits; this period is extended to six (6) months in case of a change of control; and
- the employment contract with Mr Christopher Thibodeau provides that if the employment contract is terminated for a reason other than serious misconduct, he will be entitled to a severance pay of three (3) months gross remuneration and benefits.
- the employment contract with Mr Francis Ota provides that if the employment contract is terminated for a reason other than serious misconduct, he will be entitled to a severance pay of three (3) months gross remuneration and benefits.

The service contract with Decofi sprl (represented by Philip Devine (former CFO)) was terminated in 2012. In accordance with the termination provisions of the contract, Decofi sprl received an indemnity payment equal to ten (10) months of the service fees at the then applicable monthly rate.

The contracts with the Executive managers and the executive director do not include a provision as referred to in Article 96, §3, al 2, 11° of the Belgian Company Code. There is no contractual clause in the employment contracts or service agreements with the executive directors/management stating that the variable part of the remuneration based upon faulty financial information will be recovered by the Company.

#### (vii) 2012 Share-based compensation of Directors and Executive Managers

During the course of 2012, the following share-based compensation was given to Directors and Executive managers of MDxHealth:

- Each non-executive director received 6,000 new warrants
- Dr. Jan Groen, CEO and executive director, received 45,000 new warrants
- The 3 other current members of the Executive management team received a total of 75,000 new warrants
- No warrants were granted in 2012 to the former member of Executive management, Decofi sprl (represented by Philip Devine (former CFO))

The warrants granted to non-executive directors on August 15, 2012 have the following characteristics:

- Exercise price of EUR 1.52 (one stock option (warrant) gives right to buy one share)
- Cliff vesting over 1 year for all beneficiaries
- Duration of options: 10 years

The warrants granted to executive management were awarded at the Board of Directors' meeting of March 15, 2012 and have the following characteristics:

- Exercise price of EUR 1.72 (one stock option (warrant) gives right to buy one share)
- Straight-line vesting over 4 years for all beneficiaries
- Exercise Period: the warrants are not exercisable until after the third anniversary the date of their grant;
- Duration of warrants: 10 years

The company has not materially deviated from its remuneration policy during the financial reported year.

# 3.3 SHARES AND WARRANTS HELD BY DIRECTORS AND EXECUTIVE MANAGEMENT

The tables below provide an overview of the shares and warrants held by the Non-Executive Directors and by executive management.

While some of the institutional shareholders also serve as a board members (see sections 3.1.4 and 4.8), none of their respective permanent representatives own any shares or warrants in the Company. As far as is known by the Company, the Non-Executive Directors hold the following financial instruments in MDxHealth:

As at Dec. 31, 2012	Shares		Shares Warrants		Total shares and warrants	
	Number	% of total shares outstanding	Number	% of fully diluted shares	Number	% of total shares outstanding
Mr. Edward Erickson	0	0%	11,000	0.04%	11,000	0.04%
Mr. Mark Myslinski	0	0%	11,000	0.04%	11,000	0.04%
Dr. Karin Dorrepaal	0	0%	21,000	0.08%	21,000	0.08%
Mrs. Ruth Devenyns	0	0%	6,000	0.02%	6,000	0.02%
M. Rudi Mariën	0	0%	6,000	0.02%	6,000	0.02%
M. Raphaël Wisniewski	0	0%	6,000	0.02%	6,000	0.02%
Total	0	0%	61,000	0.23%	61,000	0.23%

The table below provides an overview of the shares and warrants held by the executive management, including the Executive Directors. The numbers mentioned in the table below do not include the warrants referred to in section 3.2.4.6 that have not yet been created and/or issued but which the Company has agreed to create and issue to the executive managers as set forth therein.

As at Dec. 31, 2012	Shares		Warrants		Total shares and warrants	
	Number	% of total shares outstanding	Number	% of fully diluted shares	Number	% of fully diluted shares
Dr. Jan Groen (1)	0	0%	205,000	0.78%	205,000	0.78%
Other Executive Managers (1)	0	0%	190,000	0.72%	190,000	0.72%
Total	0	0%	395,000	1.50%	395,000	1.50%

#### Note:

#### 3.4 INTERNAL CONTROL AND RISK MANAGEMENT SYSTEMS

The company has implemented a number of standard control and management systems for a company of its size and industry sector.

At the Board of Directors level, there is a periodic review and approval of the following main topics:

- Overall strategy and strategic options
- 5-year business plan and company goals
- Ensuing year budget and targets
- · Comparison of actual results and budgeted figures
- Material in-licensing and out-licensing opportunities and deals
- Material supplier, contractor, and partnership opportunities and deals
- Hiring, motivation, and retention of key talent
- Remuneration and benefits
- Review and approval of press releases
- Financial statements
- Internal controls

Management of the Company is organized on the basis of plans, departments, projects, and corresponding budgets and targets. Progress on the core projects, budgets, and plans are reviewed on a periodic basis. The management has clearly aligned responsibilities as described in the job descriptions which are prepared for all employees of the Company.

A set of measures has been taken to assure the quality of the financial and management information, amongst others:

- · The appointment of qualified personnel in key positions with all entities of the Company
- The definition of a set of standard procedures for key activities such as steps for the approval, purchasing and payment of services and goods

<sup>1)</sup> The other executive management team members are identified in section 3.2.3 above.

- The request for the external auditors to pay special attention to areas with specific company and industry risk
- The request for specialized consultants to assist in designing and/or reviewing key procedures, systems, or reports
- The audit committee or individual directors periodically review and are consulted on key matters and procedures and when needed external specialist assistance is sought

A significant part of the Company's funds are spent on research and development projects. To ensure control and management of such projects, the Company has a number of measures, amongst others:

- Use of design-control procedures in the development of all products
- · Each project has its specific development plan which is periodically updated and reviewed
- R&D and commercial services are performed in an ISO-certified laboratory
- External experts are used for advising on the projects (market research studies, scientific advisory board, clinical advisors, etc.)
- Both in-house and external intellectual property specialists manage the IP portfolio
- Audits of its laboratory facilities are performed by external specialists and by big pharmaceutical companies using the Company's services
- Environmental, safety, and security permits are obtained where necessary and staff is trained on relevant procedures

The legal department of MDxHealth under supervision of the CEO, together with the management team has set up internal procedures in order to ensure that acts performed within or by the Company are in compliance with the existing laws and external regulations. The management is also responsible to comply with internal regulations and the Board of Directors is ensuring that the management is respecting the general policies and the corporate plans.

The risks, which the Company is subject to, have been discussed at the start of this document. Risks with respect to infrastructure – such as fire, unwanted access and power failures - have been minimized by taking appropriate measures. For assets which are crucial for the continuity of the Company, being it equipment for R&D or stored human samples, measures have been taken to minimize the risk of loss or destruction of such assets. Next to avoiding risks in this respect, where possible, insurance has been taken to cover loss of these assets, always based however on an economical justification whereby the risk is evaluated against the price to insure the risk. With respect to complying with regulations concerning safety at work, working with biotechnological material and environmental matters in general, appropriate measures were taken within the Company to guarantee compliance with these regulations and to operate with and within the required permits in this respect.

The IT department is responsible for the continuity of the platforms used by the Company to support its operations as well as for the implementation of system access controls and safely storing data. Appropriate measures were taken to assure the continuity of the operations of the Company taking into account the requirements of the different departments.

All employees of the Company are instructed on the rules and policies of the Company via a booklet of work rules, the terms of their employment contracts, standard operating procedures defined by task/area, and by numerous documents (such as the Dealing Code) that are distributed and explained to the personnel. The directors and key

consultants are subjected to the same standard procedures and rules when and where appropriate.

The IP-portfolio, for the protection of knowledge and proprietary technology, is actively managed by evaluating on a regular basis the costs to maintain such protection versus the benefits of doing this. Furthermore it is clearly communicated to employees on how to deal with confidential information (and rules are in place on how to share such information with third parties.

The Board periodically reviews and provides instructions to the management team on how to manage credit risks, interest risks, exchange risks, and liquidity risks. As an example, the Board has given instructions on what type of financial instruments the Company can place its cash and on which it is not allowed to do so. The management also seeks external specialized advice on managing such risks.

# 3.5 COMPLIANCE WITH AND DEVIATIONS FROM THE 2009 BELGIAN CORPORATE GOVERNANCE CODE

MDxHealth has adopted the 2009 Belgian Corporate Governance Code as its reference code. It complies to a large extent with the provisions of this Code, but believes that certain deviations are justified in view of the Company's specific situation. In line with the "comply-or-explain" principle of said Code, it should be noted that MDxHealth does not fully comply with the following provisions:

- Given the size of the Company, no internal audit function exists at this time.
- Although, according to the 2009 Code, Non-Executive Directors should not be entitled to performance-related remuneration such as bonuses, stock related long-term incentive schemes, fringe benefits or pension benefits, the Board of Directors is however of opinion that, for a company of the size of MDxHealth, it may be necessary to issue warrants to Non-Executive Directors, with a view to attracting directors with the relevant expertise and experience.
   All Non-Executive independent directors nominated before the May 2012 annual general shareholders' meeting have been awarded warrants.

#### 3.6 CONFLICTS OF INTEREST AND RELATED PARTIES

Article 523 of the Belgian Company Code provides for a special procedure within the Board of Directors in the event of a possible conflict of interest of one or more directors with one or more decisions or transactions by the Board of Directors. In the event of a conflict of interest, the director concerned has to inform his fellow directors of his conflict of interest in advance of the conflict and must act in accordance with relevant rules of the Company Code. For an overview of the various conflicts of interest, please refer to the statutory report of the Board of Directors (section 6.4).

Article 524 of the Belgian Company Code provides for a special procedure that applies to intra-group or related party transactions with affiliates. The procedure applies to decisions or transactions between the Company and affiliates of the Company that are not a subsidiary of the Company. It also applies to decisions or transactions between any of the Company's subsidiaries and such subsidiaries' affiliates that are not a subsidiary of the Company. The procedure does not apply to decisions or transactions in the ordinary course of business at customary market conditions, and transactions or decisions with a value of less than 1% of the consolidated net assets of the Company. Such transactions have not occurred.

In 2012, MDxHealth is aware of 1 instance of a potential conflict of interest between the duties the members of its Board of Directors and their private interests or other duties, on the other hand. In this case, Rudi Mariën, the board director

representing Gengest BVBA on the Board of MDxHealth SA excused himself from all decisions in connection with the issuance of the new shares in the framework of the private placement of July 2012. Rudi Mariën indirectly owns shares in MDxHealth, through Biovest Com. VA, a shareholder of MDxHealth.

#### 3.7. DEALING CODE

The rules and procedures that apply when board members and executive managers deal in MDxHealth securities are defined in the Company's Dealing Code. The code prohibits board members and executive managers from dealing with MDxHealth securities during periods prohibited by applicable laws and regulation or during specific closed periods announced by the Company. The dealing code is available in its entirety on the Company's website (www.mdxhealth. com).

#### 3.8. STATUTORY AUDITOR

BDO Réviseurs d'Entreprises Soc. Civ. SCRL, a civil company, having the form of a cooperative company with limited liability (société coopérative à responsabilité limitée/ coöperatieve vennootschap met beperkte aansprakelijkheid) organized and existing under the laws of Belgium, with registered office at Da Vincilaan 9, 1935 Zaventem, Belgium, represented by Mr. Bert Kegels was re-appointed on May 25, 2012 as the statutory auditor of the Company for a term of 3 years ending immediately after the closing of the annual shareholder's meeting to be held in 2015. BDO has been the statutory auditor since January 10, 2003. Mr. Bert Kegels has represented BDO since May 29, 2009.

The proposal of the Board of Directors to elect the auditor is submitted to the general shareholders' meeting upon proposal by the audit committee.

The statutory auditor and, as the case may be, the auditor responsible for the audit of the consolidated financial statements, confirms annually in writing to the audit committee his or her independence from the Company, discloses annually to the audit committee any additional services provided to the Company, and discusses with the audit committee the threats to his or her independence and the safeguards applied to mitigate those threats as documented by him or her.

The Company expensed EUR 98 thousand in fees to the auditor in 2012. The fees are broken down as follows:

- Statutory of EUR 35 thousand
- · Audit fee for consolidated and stand-alone financials of EUR 12 thousand
- Other audit missions for EUR 19 thousand
- · Other consulting missions for EUR 32 thousand



The Company, Its Shares and Shareholders

## 4.1. NAME, REGISTERED OFFICE AND INCORPORATION

The company was incorporated on January 10, 2003 under the name OncoGenome Sciences (and later OncoMethlylome Sciences) for an unlimited duration. At the occasion of the extraordinary general shareholders' meeting held on October 5, 2010 the Company's name was changed into MDxHealth. The company has the legal form of a public limited liability company (société anonyme - SA / naamloze vennootschap - NV) organized and existing under the laws of Belgium. Pursuant to the Belgian Company Code, the liability of the shareholders is limited to the amount of their respective committed contribution to the capital of the Company.

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).

#### **4.2. COMPANY PURPOSE**

The corporate purpose of MDxHealth is set forth in article 3 of its articles of association and reads as follows:

The Company's corporate purpose is to engage in Belgium and abroad, in its own name and on behalf of third parties, alone or in collaboration with third parties, in the following activities:

- All forms of research and development on or involving biological cells and organisms (including gene methylation) and chemical compounds, as well as the industrialization and commercialization of the results thereof;
- The research and development of biotechnological or derivative products that could have a market value
  in applications related to human and animal healthcare, diagnostics, pharmacogenomics and therapeutics,
  based amongst other things on the technology of genetics, genetic engineering and detection, chemistry and
  cell biology;
- The commercialization of the aforementioned products and application domains;
- The acquisition, disposal, exploitation, commercialization and management of intellectual property, property and usage rights, trade marks, patents, drawings, licenses and any other form of know how.

The Company is also authorized to engage in all commercial, industrial, financial and real estate transactions, which are directly or indirectly related to, or that may be beneficial to the achievement of, its corporate purpose.

It can, by means of subscription, contribution, merger, collaboration, financial participation or otherwise, take interests or participate in any company, existing or to be incorporated, undertakings, businesses and associations in Belgium or abroad.

The Company can manage, re-organize or sell these interests and can also, directly or indirectly, participate in the board, management, control and dissolution of companies, undertakings, business and associations in which it has an interest or a participation.

The Company can provide guarantees and security interests for the benefit of these companies, undertakings, businesses and associations, act as their agent or representative, and grant advances, credit, mortgages or other securities.

### 4.3. HISTORY OF SHARE CAPITAL

At the end of 2012, the issued capital of MDxHealth amounted to EUR 20,351,568.70 represented by 25,513,440 common shares without nominal value.

6,891,113 new shares were issued in 2012 as part of a private placement with institutional investors on July 4, 2012.

The table and notes below provide an overview of the history of MDxHealth's share capital since its incorporation.

Date	Transaction	Number of shares issued	Issue price per share (EUR)	Issue price per share post stock-split (EUR)	Capital increase (EUR)	Share capital after transaction (EUR)	Share Issuance Premium after transaction (EUR)	Aggregate # of shares after capital increase
Incorporation								
Jan. 10, 2003	Incorporation <sup>(1)</sup>	202,975	0.30	0.06	61,500.00	61,500.00	0	202,975
Phase I Financi	ing Round December 20, 20	02 (Preferred	l A Shares)					
Feb. 7, 2003	Capital increase in cash <sup>(2)</sup>	197,025	20.00	4.00	3,940,500.00	4,002,000.00	0	400,000
Jun. 30, 2003	Capital increase in cash <sup>(3)</sup>	33,333	20.00	4.00	666,660.00	4,668,660.00	0	433,333
Sep. 30, 2003	Capital increase in cash(4)	218,139	22.31	4.46	4,866,681.09	9,535,341.09	0	651,472
Jun. 20, 2004	Capital increase in cash <sup>(5)</sup>	195,504	23.87	4.77	4,666,680.48	14,202,021.57	0	846,976
Phase II Financ	ing Round October 19, 200	5 (Preferred	B Shares)					
Oct. 28, 2005	Capital increase in cash <sup>(6)</sup>	375,000	24.00(7)	4.80(7)	9,000,000.00	23,202,021.57	0	1,221,976
Mar. 31, 2006	Capital increase in cash <sup>(8)</sup>	193,548	31.00	6.20	5,999,988.00	29,202,009.57	0	1,415,524
Stock Split								
May 23, 2006	Stock split 5/1	/	/	/	/	/	0	7,077,620
Initial Public O	ffering and Exercise of Over	-Allotment V	Varrants					
Jun. 30, 2006	Capital increase in cash <sup>(9)</sup>	2,933,334	7.50	7.50	22,000,005.00	51,202,014.57	0	10,010,954
Jun. 30, 2006	Capital decrease(10)	/	/	/	-10,217,809.00	40,984,205.57	0	10,010,954
Jun. 30, 2006	Capital increase through exercise of warrants <sup>(11)</sup>	440,000	7.50	7.50	1,817,200.00	42,801,405.57	1,482,800.00	10,450,954
Exercise of Wa	rrants							
Apr. 18, 2007	Capital increase through exercise of warrants <sup>(12)</sup>	182,560	4.70	4.70	747,666.16	43,549,071.73	1,593,731.31	10,633,514
Private Placem	nent							
Oct. 19, 2007	Capital increase in cash <sup>(13)</sup>	1,063,351	10.00	10.00	4,354,954.02	47,904,025.75	7,872,287.29	11,696,865
Exercise of War	rrants							
Oct. 25, 2007	Capital increase through exercise of warrants <sup>(14)</sup>	50,837	4.73	4.73	208,202.93	48,112,228.68	7,904,487.77	11,747,702
Exercise of War	rrants							
Apr. 24, 2008	Capital increase through exercise of warrants <sup>(15)</sup>	61,120	4.59	4.59	250,316.96	48,362,545.64	7,934,871.81	11,808,822
Nov.5 , 2008	Capital increase through exercise of warrants <sup>(16)</sup>	19,375	4.73	4.73	79,350.31	48,441,895.95	7,947,140.25	11,828,197
Private Placem	nent							
Dec. 18, 2008	Capital increase in cash(17)	1,332,877	6.29	6.29	5,458,797.75	53,900,693.70	10,872,138.83	13,161,074
Exercise of Wa	rrants							
Apr. 17, 2009	Capital increase through exercise of warrants <sup>(18)</sup>	24,540	4.49	4.49	100,503.57	54,001,197.27	10,881,808.74	13,185,614

Reduction of S	Reduction of Share Capital									
Jun. 21, 2010	Share Capital reduction(19)	/	/	/	/	10,517,661.90	10,881,808.74	13,185,614		
<b>Private Placem</b>	Private Placement									
Apr. 8, 2011	Capital increase in cash <sup>(20)</sup>	5,436,713	1.50	1.50	4,336,865.96	14,854,527.86	14,700,012.24	18,622,327		
<b>Private Placem</b>	Private Placement									
Jul. 4, 2012	Capital increase in cash(21)	6,819,113	1.45	1.45	5,497,070.84	20,351,568.70	19.202.971,61	25,513,440		
<b>Current Situati</b>	Current Situation									
Per statutory accounts						20,351,568.70	19.202.971,61	25,513,440		
Per IFRS consolidated accounts (22)						19,151,437.31	19.202.971,61	25,513,440		

#### Notes

- 1) The shares were subscribed to by BBL NV/SA (ING Belgium NV/SA) (202,974 shares) and PolyTechnos Venture Fund II GmbH & Co KG (1 share). On January 30, 2003, 200,000 shares were transferred to the management and consultants of the Company. Of these 200,000 shares, 199,999 shares were transferred by BBL NV/SA (ING Belgium NV/SA) and 1 share was transferred by PolyTechnos Venture Fund II GmbH & Co KG.
- 2) The shares were subscribed to by BBL NV/SA (ING Belgium NV/SA) (97,025 shares), PolyTechnos Venture Fund II GmbH & Co KG (11,833 shares), PolyTechnos Venture Fund II LP (47,500 shares), PolyTechnos Venture Fund Beteiligungs GmbH (6,667 shares), PolyTechnos Partners & Team GmbH (667 shares), Technowal SA (16,667 shares), Société d'Investissement du Bassin Liégois (SIBL) SA (8,333 shares and Société de Développement et de Participation du Bassin de Liège (Meusinvest) SA (8,333 shares). At the same occasion, two different classes of shares were created, i.e., the common shares and the preferred A shares. All shares issued at this occasion and 2,975 shares issued at incorporation were reclassified as preferred A shares. The remaining 200,000 shares are common shares.
- 3) The shares were all subscribed to by Life Sciences Partners II B.V.
- 4) The shares were subscribed to by ING Belgium NV/SA (89,646 shares), PolyTechnos Venture Fund II GmbH & Co KG (4,997 shares), PolyTechnos Venture Fund II LP (20,062 shares), PolyTechnos Venture Fund Beteiligungs GmbH (2,816 shares), PolyTechnos Partners & Team GmbH (281 shares), Technowal SA (14,940 shares), SIBL SA (7,471 shares), Meusinvest SA (7,471 shares), Life Sciences Partners II B.V. (61,490 shares) and Mr. Pierre Hochuli (8,965 shares).
- 5) The shares were subscribed to by ING Belgium NV/SA (83,787 shares), PolyTechnos Venture Fund II GmbH & Co KG (7,435 shares), PolyTechnos Venture Fund II LP (29,850 shares), PolyTechnos Venture Fund Beteiligungs GmbH (4,190 shares), PolyTechnos Partners & Team GmbH (419 shares), Technowal SA (13,965 shares), SIBL SA (6,982 shares), Meusinvest SA (6,982 shares) and Life Sciences Partners II B.V. (41,894 shares).
- 6) The shares were subscribed to by ING Belgium NV/SA (105,658 shares), PolyTechnos Venture Fund II GmbH & Co KG (9,376 shares), PolyTechnos Venture Fund II LP (37,641 shares), PolyTechnos Venture Fund Beteiligungs GmbH (5,284 shares), PolyTechnos Partners & Team GmbH (528 shares), Technowal SA (19,484 shares), Meusinvest SA (9,742 shares), Life Sciences Partners II B.V. (58,453 shares), Mr. Pierre Hochuli (3,834 shares), BioDiscovery II FCPR (100,000 shares), Innovation Discovery 3 FCPI (10,500 shares), Sogé Innovation Evolution 2 FCPI (9,750 shares) and Sogé Innovation Evolution 4 FCPI (4,750 shares).
- 7) The issue price was EUR 24 (or EUR 4.80 after stock split), being EUR 16.77 (or EUR 3.35 after stock split), being the fractional value of the shares, increased with EUR 7.23 (or EUR 1.45 after stock split), being the issue premium, per share. The total amount of the issue premium was immediately incorporated in the share capital of the Company.
- 8) This capital increase was executed pursuant to and in accordance with the terms and conditions of an agreement entered into on October 19, 2005 with respect to the Phase II financing round. The shares were subscribed to by ING Belgium NV/SA (54,533 shares), PolyTechnos Venture Fund II GmbH & Co KG (2,420 shares), PolyTechnos Venture Fund II LP (9,714 shares), PolyTechnos Venture Fund Beteiligungs GmbH (14,996 shares), PolyTechnos Partners & Team GmbH (137 shares), Technowal SA (10,056 shares), Meusinvest SA (5,028 shares), Life Sciences Partners II B.V. (30,169 shares), Mr. Pierre Hochuli (1,979 shares), BioDiscovery II FCPR (51,613 shares), Innovation Discovery 3 FCPI (5,419 shares), Sogé Innovation Evolution 2 FCPI (5,032 shares) and Sogé Innovation Evolution 4 FCPI (2,452 shares).

- 9) On May 23, 2006, the general shareholders' meeting of the Company decided to increase the Company's share capital with the issuance of new shares in connection with an initial public offering. The capital increase was completed on June 30, 2006. At the same time, all existing shares of the Company were converted into ordinary shares.
- 10) On May 23, 2006, the general shareholders' meeting of the Company decided to decrease the Company's share capital with an amount of EUR 10,217,809 through incorporation of losses. The capital decrease was completed on June 30, 2006.
- 11) On May 23, 2006, the general shareholders' meeting of the Company decided to create an over-allotment warrant. The over-allotment warrant was granted to ING Belgium NV/SA and Fortis Bank NV/SA to cover over-allotments in connection with the initial public offering by the Company. On June 30, 2006, the share capital was increased through exercise of 440,000 over-allotment warrants and the issuance of 440,000 new ordinary shares.
- 12) On April 18, 2007, 182,560 new shares were issued for an aggregate issue price of EUR 858,597.47 with respect to the exercise of warrants in March 2007. The exercised warrants were vested warrants related to the Warrant Plans of 2004, 2005, and March 2006 which had been granted to employees, directors, and consultants.
- 13) On October 19, 2007, 1,063,351 new shares were issued for an aggregate issue price of EUR 10,633,510.00 with respect to a private placement of new shares with institutional and qualified investors.
- 14) On October 25, 2007, 50,837 new shares were issued for an aggregate issue price of EUR 240,403.19 with respect to the exercise of warrants in September 2007. The exercised warrants were vested warrants related to the Warrant Plans of 2004, 2005, March 2006, November 2007, and April 2007 which had been granted to employees, directors, and consultants.
- 15) On April 24, 2008, 61,120 new shares were issued for an aggregate issue price of EUR 280,701.00 with respect to the exercise of warrants in March 2008. The exercised warrants were vested warrants related to the Warrant Plans of 2004 and March 2006 which had been granted to employees and consultants.
- 16) On November 5, 2008, 19,375 new shares were issued for an aggregate issue price of EUR 91,618.75 with respect to the exercise of warrants in September 2008. The exercised warrants were vested warrants related to the Warrant Plans of 2004, 2005, and March 2006 which had been granted to employees, directors and consultants.
- 17) On December 18, 2008, 1332,877 new shares were issued for an aggregate issue price of EUR 8,383,796.33 with respect to a private placement of new shares with institutional and qualified investors.
- 18) On April 17, 2009, 24,540 new shares were issued for an aggregate issue price of EUR 110,173.48 with respect to the exercise of warrants in March 2009. The exercised warrants were vested warrants related to the Warrant Plans of 2004 and March 2006 which had been granted to employees and consultants.
- 19) On June 21, 2010, the Extraordinary General Shareholders' meeting approved the formal reduction of the share capital in accordance with article 614 of the Belgian Company Code through the incorporation (and neutralization) of (accumulated) sustained losses as demonstrated from the approved annual accounts as per December 31, 2009, without reducing the total number of issued and outstanding shares, in order to improve the ratio of the Company's net assets vis-à-vis its share capital. Therefore, the share capital was reduced by EUR 43,483,535.37, bringing the share capital from EUR 54,001,197.27 to EUR 10,517,661.90.
- 20) On April 8, 2011, 5,436,713 new shares were issued for an aggregate issue price of EUR 8,155,070 with respect to a private placement of new shares with institutional and qualified investors.
- 21) On July 4, 2012, 6,819,113 new shares were issued for an aggregate issue price of EUR 10,000,000.17 with respect to a private placement of new shares with institutional and qualified investors.
- 22) For the consolidated IFRS accounts, the IPO expenses of June 30, 2006 and the expenses of the private placement of October 2007, December 2008, April 2011 and July 2012 were recorded as a reduction in the share capital, whereas they were recorded as an expense for the statutory accounts.

#### **4.4 AUTHORIZED CAPITAL**

By virtue of the resolution of the extraordinary general shareholders' meeting held on June 15, 2012, the Board of

Directors has been expressly authorized to increase the share capital in one or more transactions with an amount of up to EUR 14,854,527.86 (the "Authorized Capital"), subject to certain limitations and conditions described below. The Board of Directors can exercise this power for a period starting on the date of the publication of the relevant resolution of the extraordinary general shareholders' meeting in the Annexes to the Belgian Official Gazette and ending on the date of the annual general shareholders' meeting to be held in 2015 which shall resolve on the annual accounts relating to the accounting year ending on December 31, 2014. This authorization may be renewed in accordance with the relevant legal provisions.

The capital increases to which can be decided according to this authorization, can take place in accordance with the modalities as are to be decided by the board of directors, such as:

- by means of contribution in cash or in kind, within the limits as permitted by the Belgian Company Code,
- through conversion of reserves and issuance premiums,
- with or without issuance of new shares, with or without voting rights,
- through issuance of convertible bonds, subordinated or not,
- through issuance of warrants or bonds to which warrants or other tangible values are attached, and/or
- through issuance of other securities, such as shares in the framework of a stock option plan.

In the framework of the use of its powers within the framework of the authorized capital, the board of directors can limit or cancel the preferential subscription right of the shareholders in the interest of the company, subject to the limitations and in accordance with the conditions provided for by the Belgian Company Code.

This limitation or cancellation can also occur to the benefit of the employees of the company and its subsidiaries, and, to the extent permitted by law, to the benefit of one or more specific persons that are not employees of the company or its subsidiaries.

If, following a capital increase that has been decided within the framework of the authorized capital, an issuance premium is paid, the board of directors is authorized and obliged to book the amount of such issuance premium onto the account "Issuance Premiums", that shall serve as guarantee for third parties in the same manner as the company's share capital and which, apart from the possibility to convert this reserve into share capital, can only be disposed of in accordance with the rules provided by the Belgian Company Code for amendments to the articles of association.

By virtue of the resolution of the extraordinary general shareholders' meeting held on June 15, 2012, the board of directors has also been expressly authorized to increase the share capital in one or more transactions following a notification by the Belgian Financial Services and Markets Authority that it has been informed of a public takeover bid on the company's financial instruments, through contributions in cash with cancellation or limitation of the preferential subscription rights of the shareholders (including for the benefit of one or more well defined persons who are not employees of the company) or through contributions in kind, with issuance of shares, warrants or convertible bonds, subject to the terms and conditions provided for in the Belgian Company Code. The board of directors can exercise this power for a period of maximum three years starting as of the date of the publication of the relevant resolution of the extraordinary general shareholders' meeting in the Annexes to the Belgian Official Gazette.

The board of directors is authorized, with power of substitution, to amend the articles of association upon each capital increase realized within the framework of the authorized capital, in order to bring them in accordance with the new situation of the share capital and the shares.

At the date of this document, the Board of Directors has used the above described powers under the Authorized Capital as follows:

On July 4 2012, the Board of Directors used the Authorized Capital for a private placement of 6,891,113 new shares
with institutional investors at a price of EUR 1.45. This transaction reduced the available Authorized Capital by EUR
5,497,040.84.

#### **4.5 RIGHTS ATTACHED TO SHARES**

## **4.5.1 Dividend Rights**

All shares participate in the same manner in the Company's profits (if any). Pursuant to the Belgian Company Code, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the annual general shareholders' meeting, based on the most recent audited statutory financial statements, prepared in accordance with the generally accepted accounting principles in Belgium and based on a (non-binding) proposal of the Company's Board of Directors. The Company's articles of association also authorize the Board of Directors to issue interim dividends on profits of the current financial year subject to the terms and conditions of the Belgian Company Code.

Dividends can only be distributed if following the declaration and issuance of the dividends the amount of the Company's net assets on the date of the closing of the last financial year as follows from the statutory financial statements (i.e., the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all as prepared in accordance with Belgian accounting rules), decreased with the non-amortized costs of incorporation and extension and the non-amortized costs for research and development, does not fall below the amount of the paid-up capital, increased with the amount of non-distributable reserves. In addition, prior to distributing dividends, 5% of the net profits must be allotted to a legal reserve, until the legal reserve amounts to 10% of the share capital.

The right to payment of dividends on registered and dematerialized shares expires five years after the Board of Directors declared the dividend payable.

## 4.5.2. Preferential Subscription Rights

In the event of a capital increase in cash with issue of new shares, or in the event of an issue of convertible bonds or warrants, the shareholders have a preferential right to subscribe to the new shares, convertible bonds or warrants, pro rata of the part of the share capital represented by the shares that they already have. The general shareholders' meeting can decide to limit or cancel this preferential subscription right, subject to special reporting requirements. Such decision needs to satisfy the same quorum and majority requirements as the decision to increase the Company's share capital.

The shareholders can also decide to authorize the Board of Directors to limit or cancel the preferential subscription right within the framework of the Authorized Capital, subject to the terms and conditions set forth in the Belgian Company Code.

## 4.5.3. Voting Rights

Each shareholder of the Company is entitled to one vote per share. There are no different categories of shares. All shareholders have the same voting rights. Voting rights can be suspended in relation to shares:

- Which were not fully paid up, notwithstanding the request thereto of the Board of Directors of the Company;
- To which more than one person is entitled, except in the event a single representative is appointed for the exercise of the voting right;
- Which entitle their holder to voting rights above the threshold of 3%, 5%, or any multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Company on the date of the relevant general shareholders' meeting, except in the event where the relevant shareholder has notified the Company and the FSMA at least 20 days prior to the date of the general shareholders' meeting on which he or she wishes to vote of its shareholding exceeding the thresholds above; and
- Of which the voting right was suspended by a competent court or the FSMA.

### 4.5.4. Rights to Participate and Vote at Shareholder's Meetings

### Annual general shareholders' meeting

The annual general shareholders' meeting is held at the registered office of the Company or at the place determined in the notice convening the shareholders' meeting. The meeting is held every year on the last Friday of May at 10 a.m. At the annual general shareholders' meeting, the Board of Directors submits the audited statutory and consolidated financial statements and the reports of the Board of Directors and of the statutory auditor with respect thereto to the shareholders. The shareholders' meeting subsequently decides on the approval of the statutory financial statements, the proposed allocation of the Company's profit or loss, the discharge from liability of the directors and the statutory auditor, and, when applicable, the (re)appointment or resignation of the statutory auditor and/or of all or certain directors and their remuneration. In addition, as relevant, the annual general shareholders' meeting must also decide on the approval of provisions of service agreements to be entered into with Executive Directors, members of the management committee and other executives providing (as the case may be) for severance payments exceeding 12 months' remuneration (or, subject to a motivated opinion by the remuneration committee, 18 months' remuneration). As from the annual meeting held in 2012, the shareholders' meeting must also decide separately on the approval of the remuneration report included in the annual report.

#### Special and extraordinary general shareholders' meetings

The Board of Directors or the statutory auditor can, at any given time when the interest of the Company so requires, convene a special or extraordinary general shareholders' meeting. Such shareholders' meeting must also be convened every time one or more shareholders holding at least 20% of the Company's share capital so demand. Shareholders that do not hold at least 20% of the Company's share capital do not have the right to convene such special or extraordinary general shareholders' meeting.

### Notices convening the general meeting

The notice convening the general shareholders' meeting must indicate: (i) the agenda, place, date, and time of the meeting; (ii) the items to be discussed and the proposed resolutions that will be submitted to the meeting; (iii) a clear description of the formalities to be fulfilled by the shareholders in order to be entitled to participate to the general meeting and to exercise their voting right, including the period within which the shareholders should indicate to the Company their intention to participate to the meeting; (iv) a description of the procedure to vote by proxy (or at distance to the extent permitted by the articles of association); (v) details with regard to the right of shareholders to amend items of the agenda, require additional items/proposed resolutions to be put on the agenda, and ask questions;

(vi) the timeframe within which such rights may be exercised and an electronic address to which shareholders may send their queries; (vii) the registration date and explanations related thereto; and (viii) the place as well as the website on which all relevant documents can be obtained. The meeting cannot deliberate and vote on items that are not mentioned on the agenda, unless all shareholders are present or represented and decide unanimously to place such items on the agenda.

The notice convening the shareholders' meeting must be published (i) in the annexes to the Belgian Official Gazette, (ii) a newspaper with nationwide distribution in Belgium, (iii) via media as may reasonably be relied upon for the effective dissemination of information to the public throughout the European Economic Area and (iv) the website of the Company at least 30 calendar days prior to the general meeting (or, if a second meeting is required, if the date of the second meeting was mentioned in the notice convening the first meeting and if the agenda has not changed, at least 17 days prior to the second meeting).

A publication in the *Annexes* to the Belgian Official Gazette and on the website of MDxHealth suffices for notices convening the annual general shareholders' meeting if such meeting takes place in Liège and on the place, date and hour referred to above and if the agenda is limited to the submission of the financial statements, the reports of the Board of Directors and statutory auditor relating thereto, the discharge from liability of the directors and statutory auditor, the approval of provisions of service agreements and the approval of the remuneration report.

The holders of registered shares, warrants and bonds are personally notified by letter at least 30 days prior to the meeting.

#### Formalities to attend the general meeting

All holders of shares, warrants or bonds (if any) issued by the Company can attend shareholders' meetings. Only shareholders, however, can vote at shareholders' meetings. In order to attend the general shareholders' meeting, holders of securities issued by the Company should take into account the formalities and procedures described below.

#### Registration for the meeting

Firstly, the right for a holder of securities to participate to and, as applicable, to vote at a general meeting is only granted on the basis of the registration of the securities concerned, fourteen days prior to the general meeting (the "registration date") at midnight, via registration, in the applicable register book for the securities concerned (for registered securities) or in the accounts of a certified account holder or relevant settlement institution for the securities concerned. Secondly, in order to be admitted to the general shareholders' meeting, the holders of securities issued by the company must notify the company or a centralizing bank designated in the convening notice whether they want to participate to the meeting. The notice must reach the company by mail at its registered office or by e-mail at the latest on the sixth calendar day prior to the general shareholders' meeting. For the holders of dematerialized securities or securities in book-entry form, the notification should also include a certificate confirming the number of securities that have been registered in their name on the registration date. The certificate can be obtained by the holder of the dematerialized securities with his or her financial intermediary, the certified account holder or the applicable settlement institution for the securities concerned.

The registration procedure set forth here above is also applicable in the event where a second meeting needs to be convened, the required quorum not being present or represented at the first meeting.

#### **Power of attorney**

Each holder of securities has the right to attend a general shareholders' meeting and to vote at the general shareholders'

meeting in person or through a proxy holder, in conformity with applicable law. The proxy holder does not need to be a shareholder. The Board of Directors can request the participants to the meeting to use a model of power of attorney (with voting instructions). Such proxies must be in writing or via an electronic form, and must bear the shareholder's signature (which may be a digital signature as defined in article 1322, paragraph 2 of the Belgian Civil Code or as otherwise permitted by applicable law). In accordance with applicable law, the dated and signed proxy must be sent by letter, fax, email or any other means specified in article 2281 of the Belgian Civil Code to the company's registered office or the place indicated in the notice and must reach the company at the latest on the sixth calendar day prior to the general shareholders' meeting concerned. The holders of a proxy must comply with the provisions of the Belgian Company Code regarding proxies for general shareholders' meetings.

Holders of securities who wish to be represented by proxy must, in any case, comply with the formalities to register for the meeting, as explained under "—Registration for the meeting" above.

#### Amendments to the agenda and additional proposed resolutions

Shareholders who alone or together with other shareholders hold at least 3% of the outstanding shares of the company have the right to put additional items on the agenda of the annual and extraordinary general shareholders' meetings and to table draft resolutions in relation to items that have been or are to be included in the agenda. If the required quorum for the extraordinary general shareholders' meeting is not reached and a second extraordinary general shareholders' meeting is convened, this right will not apply in relation to the agenda of the second extraordinary general shareholders' meeting. Shareholders wishing to exercise this right must prove on the date of their request, that they own at least 3% of the outstanding shares. The ownership must be based, for dematerialized shares, on a certificate issued by the applicable settlement institution for the securities concerned, or by a certified account holder, confirming the number of securities that have been registered in the name of relevant shareholders and, for registered shares, on a certificate of registration of the relevant shares in the share register book of the company. In addition, the shareholder concerned must, in any case, comply with the formalities to register for the meeting (as explained under "—Registration for the meeting" above) with at least 3% of the outstanding shares. A request to put additional items on the agenda and/or to table draft resolutions must be submitted in writing, and must contain in the event of an additional agenda item, the text of the agenda item concerned and, in the event of a draft resolution, the text of the draft resolution. The request must also mention the mail or e-mail address to which the company will send the confirmation of receipt of the request. The request must reach the company by mail at its registered office or by e-mail at the e-mail address mentioned in the notice convening to the general meeting at the latest on the twenty second calendar day prior to the annual and extraordinary general shareholders' meeting. In case of amendments to the agenda and proposed additional resolutions as aforementioned, the company will publish an amended agenda with, as the case may be, additional agenda items and additional draft resolutions no later than on the fifteenth calendar day prior to the annual and/or extraordinary general shareholders' meeting. In addition, the company shall make amended forms available for votes by mail and votes by proxy. Proxies and votes by mail that reach the company prior to the publication of an amended agenda remain valid for the agenda items to which the proxies and votes by mail apply, subject, however, to applicable law and the further clarifications set out on the proxy forms and postal voting form.

### **Question right**

Every shareholder has the right to ask questions to the directors and statutory auditor related to items on the agenda of a general shareholders' meeting. Questions can be asked during the meeting or can be submitted in writing prior to the meeting. Written questions must reach the company by mail at its registered office or by e-mail at the latest on the sixth calendar day prior to the annual and extraordinary general shareholders' meeting. Written and oral questions

will be answered during the meeting concerned in accordance with applicable law. In addition, in order for written questions to be considered, the shareholders who submitted the written questions concerned must comply with the formalities to register for the meeting, as explained under "Registration for the meeting" above.

#### **Quorum and majorities**

In general, there is no quorum requirement for a general shareholders' meeting and decisions are generally passed with a simple majority of the votes of the shares present and represented. Capital increases not decided by the Board of Directors within the framework of the Authorized Capital, decisions with respect to the Company's dissolution, mergers, de-mergers and certain other reorganizations of the Company, amendments to the articles of association (other than an amendment of the corporate purpose), and certain other matters referred to in the Belgian Company Code do not only require the presence or representation of at least 50% of the share capital of the Company but also the approval of at least 75% of the votes cast. An amendment of the Company's corporate purpose, requires the approval of at least 80% of the votes cast at a general shareholders' meeting, which in principle can only validly pass such resolution if at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, are present or represented. In the event where the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second general shareholders' meeting can validly deliberate and decide regardless of the number of shares present or represented.

#### 4.6. ANTI-TAKEOVER PROVISIONS

#### 4.6.1. Takeover bids

Public takeover bids on the Company's shares and other voting securities (such as warrants or convertible bonds, if any) are subject to the supervision by the FSMA. Public takeover bids must be made for all of the Company's voting securities, as well as for all other securities that entitle the holders thereof to the subscription to, the acquisition of or the conversion in new voting securities. Prior to making a bid, a bidder must issue and disseminate a prospectus, which must be approved by the FSMA. The bidder must also obtain approval of the relevant competition authorities, where such approval is legally required for the acquisition of the Company.

In addition, as soon as a person or group of persons acting in concert, holding more than 30% of the voting securities issued by MDxHealth would (whether through an acquisition or a subscription etc.) be holding more than 30% of the voting right bearing securities, the outstanding voting rights bearing or voting rights conferring securities of MDxHealth will become subject to a takeover bid, at a price compliant with the provisions of the Belgian takeover legislation.

There are several provisions of Belgian company law and certain other provisions of Belgian law, such as the obligation to disclose important shareholdings (see under Section 4.7 below) and merger control, that may apply to MDxHealth and which may make an unfriendly tender offer, merger, change in management or other change in control, more difficult. These provisions could discourage potential takeover attempts that other shareholders may consider to be in their best interest and could adversely affect the market price of the Company's shares. These provisions may also have the effect of depriving the shareholders of the opportunity to sell their shares at a premium.

In addition, the Board of Directors of Belgian companies may in certain circumstances, and subject to prior authorization by the shareholders, deter or frustrate public takeover bids through dilutive issuances of equity securities (within the framework of the Authorized Capital – see Section 4.4 above) or through share buy-backs (i.e., purchase of own shares).

Normally, the authorization of the Board of Directors to increase the share capital of the Company within the

Authorized Capital through contributions in cash with cancellation or limitation of the preferential right of the existing shareholders is suspended as of the notification to the Company by the FSMA of a public takeover bid on the securities of the Company. The general shareholders' meeting can, however, authorize the Board of Directors to increase the share capital by issuing shares in an amount of not more than 10% of the existing shares of the Company at the time of such a public takeover bid. Such authorization has been granted to the Board of Directors of the Company by decision of the extraordinary shareholders' meeting on June 15, 2012.

The Board of Directors of MDxHealth was not granted the authorization to purchase own shares in case of a threatening serious disadvantage to the Company.

### 4.6.2. Squeeze out

Pursuant to article 513 of the Belgian Company Code, or the regulations promulgated thereunder, a person or entity, or different persons or entities acting alone or in concert, who, together with the Company, own 95% of the securities conferring voting rights in a public company, can acquire the totality of the securities conferring (potential) voting rights in that company following a squeeze-out offer. The shares that are not voluntarily tendered in response to such offer are deemed to be automatically transferred to the bidder at the end of the procedure. At the end of the offer, the Company is no longer deemed a public company, unless bonds issued by the Company are still spread among the public. The consideration for the securities must be in cash and must represent the fair value as to safeguard the interests of the transferring shareholders.

## 4.6.3. Sell-out Right

Holders of securities conferring (potential) voting rights may require an offeror who, acting alone or in concert, following a takeover bid, owns 95% of the voting capital or 95% of the securities conferring voting rights in a public company to buy their securities at the price of the bid, upon the condition that the offeror has acquired, through the bid, securities representing at least 90% of the voting capital subject to the takeover bid.

#### 4.7. NOTIFICATION OF IMPORTANT PARTICIPATION

The Belgian Company Code, applicable legislation and the Company's articles of association provide that every natural person or legal entity acquiring or transferring shares or other financial instruments of a listed company that entitle the holder thereof to voting rights, whether or not representing the Company's share capital (such as warrants, stock options, or automatic convertible bonds, if any), must, as soon as possible and at the latest four trading days following the transaction, notify the Company and the FSMA of the total number of financial instruments that he or she holds each time where, as a result of the acquisition or transfer, the total number of voting financial instruments exceeds or falls below a threshold of 3%, 5%, 10% or 15% (or every subsequent multiple of 5%) of the total number of financial instruments at the moment of the transaction.

All persons acting individually must make the notification. It must also be made by affiliated persons or persons acting in concert with respect to the holding, acquisition or transfer of voting financial instruments. In that event, the voting financial instruments of the affiliated persons or persons acting in concert must be combined for the purpose of determining whether a threshold is passed. The forms to make the aforementioned disclosures, as well as further explanations can be found on the website of the FSMA (www.FSMA.be).

The FSMA and the commercial court can suspend voting rights attached to voting financial instruments that have not been disclosed in accordance with the foregoing provisions. In addition, the president of the commercial court can

also order the sale of the financial instruments to a third party. In any event, shareholders cannot vote at shareholders' meetings with more voting rights than they have notified in accordance with the above rules at least 20 days prior to a shareholders' meeting.

#### 4.8. SHAREHOLDERSHIP

The table below provides an overview of the shareholders that have notified the Company of their ownership of MDxHealth securities. The overview is based on the most recent transparency declarations submitted to the Company.

Shareholder (or Party representing shareholders)	Number of shares	% of outstanding shares	Situation as of	Notification Received
IDInvest Partners	794,912	3.12%	Apr. 08, 2011	Apr. 14, 2011
Life Sciences Partners II BV	1,411,195	5.53%	Apr. 08, 2011	Apr. 12, 2011
Edmond de Rothschild Investment Partners	1,713,915	6.72%	Dec. 18, 2008	Dec. 18, 2008
ING Belgium NV/SA (private equity dept)	2,147,610	8.42%	Jul. 4, 2012	Jul. 4, 2012
Biovest Comm. VA.	3,729,341	14.62%	Jul. 4, 2012	Jul. 4, 2012
Valiance Asset Management	2,097,902	8.22%	Jul. 4, 2012	Jul. 4, 2012
<b>Total of Notified Shares</b>	11,897,875	46.62%		
Total Outstanding shares	25,513,440	100.00%		

Edmond de Rotschild Investment Partners is represented on the Board of Directors of MDxHealth by Mr. Raphaël Wiesnieski. Biovest Comm. VA is an investment company owned and managed by Mr. Rudi Mariën. Rudi Mariën also serves as a permanent representative of Gengest BVBA on the Board of Directors of MDxHealth.

#### 4.9. WARRANTS

This section provides an overview of the outstanding warrants as of December 31, 2012. The warrants were created within the context of stock based incentive plans for employees, directors and consultants of the Company.

On May 12, 2004, the shareholders' meeting of the Company issued 30,000 warrants pursuant to a stock option plan. According to this stock option plan, the warrants are granted for free to employees, directors and independent service providers of the Company and its subsidiaries. Each warrant entitles its holder to subscribe to one common share of the Company at a subscription price equal to the subscription price paid at the occasion of the most recent capital increase preceding the issuance of the warrants. The warrants have a term of 5 years. They become exercisable in cumulative tranches of 25% per year, i.e., 25% as of their issuance, 50% as of the first anniversary date, 75% as of the second anniversary date and 100% as of the third anniversary date of the issuance, provided that the beneficiary has provided at least one year of service. 29,750 of these warrants have been granted to the beneficiaries under the stock option plan. The 250 remaining warrants became null and void on June 30, 2004. In the course of 2006, 500 warrants (out of the 29,750 that were granted) were moreover cancelled (technically, have become definitively unexercisable) following the departure of an employee of OncoMethylome Sciences BV, bringing the total of outstanding warrants under this stock option plan to 29,250 at December 31, 2006. In the course of 2007, 12,617 of these warrants were exercised, bringing the total of outstanding warrants under this stock option plan to 16,633 at December 31, 2007. In the course of 2008, 8,125 of these warrants were exercised, bringing the total of outstanding warrants under this stock option plan to 8,508 at December 31, 2008. In the course of 2009, 4,508 of these warrants were exercised and 4,000 of these warrants expired without being exercised and were thus terminated. At December 31, 2008, all warrants under this plan have been exercised or terminated. No warrants remain exercisable or grantable under this stock option plan. On July 12, 2005, the Company's Board of Directors issued 15,000 warrants pursuant to a stock option plan in the framework of the Authorized Capital. All these warrants were granted for free to employees, directors and independent service providers of the Company and its subsidiaries. Each warrant entitles its holder to subscribe to one common share of the Company at a subscription price equal to the subscription price paid at the occasion of the most recent capital increase preceding the issuance of the warrants. The warrants have a term of 5 years. They become exercisable in cumulative tranches of 25% per year, i.e., 25% as of their issuance, 50% as of the first anniversary date, 75% as of the second anniversary date and 100% as of the third anniversary date of the issuance, provided that the beneficiary has provided at least one year of service. 15,000 of these warrants have been granted to the beneficiaries under the stock option plan. During the course of 2007, 9,900 of these warrants were exercised, bringing the total of outstanding warrants under this stock option plan to 5,100 at December 31, 2007. In the course of 2008, 2,500 of these warrants were exercised, bringing the total of outstanding warrants under this stock option plan to 2,600 at December 31, 2008. In the course of 2009, none of these warrants were exercised, bringing the total of outstanding warrants under this stock option plan to 2,600 at December 31, 2009. In the course of 2010, none of these warrants were exercised, and the non-exercised warrants expired bringing the total of outstanding warrants under this stock option plan to zero at December 31, 2010. No warrants remain exercisable or grantable under this stock option plan.

On March 8, 2006, the Board of Directors of the Company approved an additional stock option plan providing for the issuance of up to 66,700 warrants of the Company. The warrants are granted for free to employees, directors and independent service providers of the Company and its subsidiaries. Each warrant entitles its holder to subscribe to one common share of the Company at a subscription price equal to the subscription price paid at the occasion of the most recent capital increase preceding the issuance of the warrants. The warrants have a term of 10 years. They become exercisable in cumulative tranches of 25% per year, i.e., 25% as of their issuance, 50% as of the first anniversary date, 75% as of the second anniversary date and 100% as of the third anniversary date of the issuance, provided that the beneficiary has provided at least one year of service. The shareholders' meeting of the Company has issued 66,700 warrants pursuant to this stock option plan on March 22, 2006. All these 66,700 warrants have been granted to the beneficiaries under the stock option plan. During the course of 2007, 2,000 of these warrants were cancelled (technically, have become definitively unexercisable) following the departure of the beneficiaries prior to the vesting of the warrants. Also during the course of 2007, 24,100 of these warrants were exercised, bringing the total of outstanding warrants under this stock option plan to 40,600 at December 31, 2007. During the course of 2008, 1,337 additional warrants were cancelled and 5,474 were exercised, bringing the total of outstanding warrants under this stock option plan to 33,789 at December 31, 2008. During the course of 2009, 1,100 additional warrants were cancelled and 400 were exercised, bringing the total of outstanding warrants under this stock option plan to 32,288 at December 31, 2009. During the course of 2010, no warrants were exercised nor cancelled, bringing the total of outstanding warrants under this stock option plan to 32,288 at December 31, 2010. No warrants have been exercised, nor cancelled in 2011 and 2012. No warrants remain grantable under this stock option plan.

At the shareholders' meeting of <u>May 23, 2006</u>, it was decided that, as a result of the stock-split, each existing warrant at that date, upon the exercise thereof, would entitle the owner thereof to five (5) new shares.

On <u>November 8, 2006</u>, the Board of Directors issued 47,500 warrants under the framework of the Authorized Capital for the benefit of the employees of the Company and its subsidiaries. Each warrant entitles its holder to subscribe to one share of the Company. The warrants are granted for free and can be exercised at a price equal to the average closing price of the Company's shares as listed on Euronext Brussels during a term of 30 days prior to the date of their grant, or any other price determined by the Board of Directors. The exercise price can, however, never be lower than the fractional value of the shares. The warrants have a term of 10 years and become exercisable in cumulative tranches of 25% per year, provided that the beneficiary has provided at least one year of service. All 47,500 warrants

have been granted and accepted. During the course of 2007, 938 of these warrants were cancelled (technically, have become definitively unexercisable) following the departure of the beneficiaries prior to vesting of the warrants. Also during the course of 2007, 187 of these warrants were exercised, bringing the total of outstanding warrants under this stock option plan to 46,375 at December 31, 2007. During the course of 2008, no further warrants were cancelled nor exercised, leaving the total of outstanding warrants unchanged at 46,375 at December 31, 2008. During the course of 2009, no further warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants at 46,375 at December 31, 2009. During the course of 2010, 2,718 warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants at 43,657 at December 31, 2010. In 2011, 19,156 warrants were cancelled, leaving the total of outstanding warrants at 24,500. A further 14,000 warrants were cancelled in 2012, leaving the total of outstanding warrants at 10,500.No warrants remain grantable under this stock option plan.

On <u>April 18, 2007</u>, the Board of Directors issued 55,100 warrants under the framework of the Authorized Capital for the benefit of the employees of the Company and its subsidiaries. Each warrant entitles its holder to subscribe to one share of the Company. The warrants are granted for free and can be exercised at a price equal to the average closing price of the Company's shares as listed on Euronext Brussels during a term of 30 days prior to the date of their grant. The warrants have a term of 10 years and become exercisable in cumulative tranches of 25% per year, provided that the beneficiary has provided at least one year of service. All 55,100 warrants have been granted and accepted. During the course of 2007, 125 of these warrants were exercised, bringing the total of outstanding warrants under this stock option plan to 54,975 at December 31, 2007. During the course of 2008, 3,812 warrants were cancelled, bringing the total of outstanding warrants to 51,163 at December 31, 2008. During the course of 2009, 738 warrants were cancelled, bringing the total of outstanding warrants to 50,425 at December 31, 2009. During the course of 2010, 6,314 warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants at 44,111 at December 31, 2010. During the course of 2011, 19,936 warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants were exercised. No warrants were exercised, leaving the total of outstanding warrants were exercised. No warrants remain grantable under this stock option plan.

On May 25, 2007, the shareholders' meeting of the Company issued 50,000 warrants to directors and a consultant of the Company pursuant to a stock option plan. Each warrant entitles its holder to subscribe to one share of the Company. The warrants are granted for free and can be exercised at a price equal to the average closing price of the Company's shares as listed on Euronext Brussels during a term of 30 days prior to the date of their grant. The warrants have a term of 5 years and become exercisable in cumulative tranches of 25% per year, provided that the beneficiary has provided at least one year of service. All 50,000 warrants have been granted and accepted. The total outstanding warrants under this stock option plan were 50,000 at December 31, 2009. During the course of 2010, 10,313 warrants were cancelled and no warrants were exercised, leaving the total of outstanding warrants at 39,687 at December 31, 2010. No warrants were cancelled in 2011, leaving the total of outstanding warrants at 39,687 at December 31, 2011. During the course of 2012, 14,374 warrants were cancelled and no warrants were exercised, leaving the total of outstanding warrants at 15,000 at December 31, 2012. No warrants remain grantable under this stock option plan.

On <u>May 30, 2008</u>, the Board of Directors issued 61,000 warrants under the framework of the Authorized Capital for the benefit of the employees of the Company and its subsidiaries. Each warrant entitles its holder to subscribe to one share of the Company. The warrants are granted for free and can be exercised at a price equal to the average closing price of the Company's shares as listed on Euronext Brussels during a term of 30 days prior to the date of their grant. The warrants have a term of 10 years and become exercisable in cumulative tranches of 25% per year, provided that the beneficiary has provided at least one year of service. 49,000 warrants have been granted and accepted. The remaining 12,000 warrants became null and void on May 30, 2008. During the course of 2008, 875 of these warrants were cancelled,

bringing the total of outstanding warrants under this stock option plan to 48,125 at December 31, 2008. During the course of 2009, 8,625 of these warrants were cancelled, bringing the total of outstanding warrants under this stock option plan to 39,500 at December 31, 2009. During the course of 2010, 7,188 warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants at 32,312 at December 31, 2010. During the course of 2011, 4,874 warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants at 27,438 at December 31, 2011. In 2012, 938 warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants at 26,500 at December 31, 2012. No warrants remain grantable under this stock option plan.

On <u>January 27, 2009</u>, the Board of Directors issued 120,500 warrants under the framework of the Authorized Capital for the benefit of the employees of the Company and its subsidiaries. Each warrant entitles its holder to subscribe to one share of the Company. The warrants are granted for free and can be exercised at a price equal to the average closing price of the Company's shares as listed on Euronext Brussels during a term of 30 days prior to the date of their grant. The warrants have a term of 10 years and become exercisable in cumulative tranches of 25% per year, provided that the beneficiary has provided at least one year of service. 116,600 warrants have been granted and accepted. The remaining 3,900 warrants became null and void on January 27, 2009. During the course of 2010, 22,657 warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants at 93,943 at December 31, 2010. During the course of 2011, 34,692 warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants were cancelled and no further warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants at 59,251 at December 31, 2011. In 2012, 27,251 warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants at 32,000 at December 31, 2012. No warrants remain grantable under this stock option plan.

On June 21, 2010, the shareholders' meeting of the Company issued 145,000 warrants to directors of the Company pursuant to a stock option plan. Each warrant entitles its holder to subscribe to one share of the Company. The warrants are granted for free and can be exercised at a price equal to the average closing price of the Company's shares as listed on Euronext Brussels during a term of 30 days prior to the date of their grant. The warrants have a term of 5 years and become exercisable in cumulative tranches of 25% per year, provided that the beneficiary has provided at least one year of service. All 145,000 warrants have been granted and accepted. The total outstanding warrants under this stock option plan were 145,000 at December 31, 2010. During the course of 2011, 3,750 warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants at 141,250 at December 31, 2011. In 2012, 1,250 warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants at 140,000 at December 31, 2012. No warrants remain grantable under this stock option plan.

On May 27, 2011, the Board of Directors issued 225,000 warrants under the framework of the Authorized Capital for the benefit of the employees and consultants of the Company and its subsidiaries. Each warrant entitles its holder to subscribe to one share of the Company. The warrants are granted for free and can be exercised at a price equal to the average closing price of the Company's shares as listed on Euronext Brussels during a term of 30 days prior to the date of their issuance. The warrants have a term of 10 years and become exercisable in cumulative tranches of 25% per year, provided that the beneficiary has provided at least one year of service. The exception to this vesting rule for all beneficiaries of the warrant plan, is that the 30,000 warrants received by the CEO under this warrant plan, became fully and immediately vested on the date of grant, December 7, 2010. All 225,000 warrants under this plan have been granted and accepted. During the course of 2011, 15,000 warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants at 210,000 at December 31, 2011. In 2012, 36,875 warrants were cancelled and no further warrants were exercised, leaving the total of outstanding warrants at 173,125 at December 31, 2012. No warrants remain grantable under this stock option plan.

On March 15, 2012, the Board of Directors issued 195,000 additional warrants giving the beneficiaries the right to purchase common shares of the Company. The warrants were granted with an exercise price equal to the fair market price of the underlying common shares at the date of grant. The warrants were granted to selected beneficiaries by decision of the nomination and remuneration committee and the Board of Directors. Under this plan, 25% of the warrants become exercisable during each year following the date of the grant (on a straight-line basis, or 6.25% per quarter) it being understood however that no warrants are exercisable unless the beneficiary has provided as least 1 full year of services to the Company. Non-exercisable warrants become exercisable in case of a change of control of the Company. All warrants were granted for free. The duration of the warrants is 10 years from the date of the creation of the warrants. Warrants that have not been exercised within 10 years of their creation become null and void. In 2012, 18,125 warants were cancelled under this Plan leaving the total of outstanding warrants at 176,875 at December 31, 2012.

On June 15, 2012, by a decision of the extraordinary general shareholders' meeting, the Company issued 700,000 additional warrants giving beneficiaries the right to purchase common shares of the Company. The warrants are to be granted either to selected employees, with an exercise price determined by the board of directors and equal to at least the fair market price of the underlying common shares at the date of grant, or to selected non-employees, with an exercise price equal to the higher of (i) the average price of the shares on Euronext during the period of 30 days preceding the date of issuance of the stock options and (ii) the average price of the shares on Euronext during the 30 days preceding the date grant of the stock options. In total, 131,000 warrants were granted out of this pool in 2012. On the one hand, 95,000 warrants were granted to selected employees and consultants by decision of the nomination and remuneration committee and the Board of Directors, respectively on September 14, 2012 (85,000 warrants) and December 1, 2012 (10,000 warrants). On the other hand, 36,000 warrants were granted to selected directors on August 15, 2012. Under this plan, 25% of the warrants granted to selected participants who are not directors of the company become vested in instalments of 25% per year during a period of 4 years as of the date of grant (being it understood that during the first year after the date of grant, 25% of the stock options shall vest on the first anniversary date of the date of grant and that during the second, third and fourth years after the date of grant, the stock options granted shall vest on a quarterly basis). Warrants granted to selected participants who are directors are granted shall all vest on the date of the annual shareholders' meeting that takes place in the calendar year following the calendar year where the Stock Options were granted, provided that on the date preceding the date of the former annual shareholders' meeting the mandate of such (non executive) selected director has not terminated. Such warrants are exercisable in conformity with the exercisability and exercise period provisions defined in the May 2012 Stock Option Plan. Non-exercisable warrants become exercisable in case of a change of control of the Company. All warrants were granted for free. The duration of the warrants is 10 years from the date of issuance of the warrants. Warrants that have not been exercised within 10 years of their issuance become null and void.

The table below gives an overview (as at December 31, 2012) of the stock option plans described above. The table should be read together with the notes referred to below.

Issue date	Grant date	Term	Total potential shares from warrants created (1)	Total potential shares from warrants granted (1)	Total potential shares from warrants ter- minated (1)(3)	Exercise price per potential share (EUR) <sup>(2)</sup>	Total shares issued from exercised warrants (1)	Total potential shares from outstanding warrants
May 12, 2004	May 12, 2004	5	150,000	148,750	22,500	4.46	126,250	-
Jul. 12, 2005	Jul. 12, 2005	5	75,000	75,000	13,000	4.77	62,000	-
Mar. 22, 2006	Mar. 22, 2006	10	333,500	333,500	22,190	4.80	149,870	161,440

Issue date	Grant date	Term	Total potential shares from warrants created (1)	Total potential shares from warrants granted (1)	Total potential shares from warrants ter- minated (1)(3)	Exercise price per potential share (EUR) <sup>(2)</sup>	Total shares issued from exercised warrants (1)	Total potential shares from outstanding warrants
Nov. 08, 2006	Nov. 08, 2006	10	47,500	47,500	36,813	7.72	187	10,500
Apr. 18, 2007	Jan. 04, 2007	10	55,100	55,100	34,100	10.87	125	20,875
May 25, 2007	May 25, 2007	5	50,000	50,000	35,000	11.42	-	15,000
May 30, 2008	May 30, 2008	10	61,000	49,000	22,500	9.10	-	26,500
Jan. 27, 2009	Jan. 02, 2009	10	120,500	116,600	84,600	6.32	-	32,000
Jun. 21, 2010	Jun. 21, 2010	5	145,000	145,000	5,000	2.07	-	140,000
May 27, 2011	May 27, 2011	10	225,000	225,000	51,875	1.71	-	173,125
Mar. 15, 2012	Mar. 15, 2012	10	195,000	195,000	18,125	1.72	-	176,875
Jun. 15, 2012	Aug. 15, 2012	10	36,000	36,000	-	1.52	-	36,000
Jun. 15, 2012	Sep. 14, 2012	10	85,000	85,000	-	1.65	-	85,000
Jun. 15, 2012	Dec. 1, 2012	10	10,000	10,000	-	2.19	-	10,000
Total			1,588,600	1,571,450	345,703		338,432	887,315

#### Notes:

For easy reference, the number of warrants has already been multiplied by five (5) to take into account the 5-for-1stock split impacting only warrants granted and created before May 2006. As a consequence of the stock split, one (1) warrant will entitle the owner thereof to five (5) shares.

For easy reference, the exercise price has already been divided by five (5) to take into account the 5-for-1 stock split impacting only warrants granted and created before May 2006.

Cancelled due to non-grant of certain warrants or due to departure of beneficiary prior to vesting of warrants.

#### 4.10. OUTSTANDING FINANCIAL INSTRUMENTS

The table below provides an overview of the issued and outstanding voting financial instruments at December 31, 2012. The numbers below take into account the stock split (shares and warrants) decided upon by the shareholders' meeting of May 23, 2006.

		Number of voting rights
(A)	Actual voting rights attached to:	
	Shares issued prior to January 1, 2012	18,622,327
	Shares issued on July 4, 2012	6,891,113
	Total A	25,513,440
(B)	Potential future voting rights attached to shares representing the share capital to be issued upon the exercise of warrants that have already vested:	
	Warrants issued on May 12, 2004	0
	Warrants issued on July 12, 2005	0

		Number of voting rights
	Warrants issued on March 22, 2006	161,400
	Warrants issued on November 8, 2006	10,500
	Warrants issued on April 18, 2007	20,875
	Warrants issued on May 25, 2007	15,000
	Warrants issued on May 30, 2008	26,500
	Warrants issued on January 27, 2009	30,000
	Warrants issued on June 21, 2010	87,500
	Warrants issued on May 27,2011	120,313
	Warrants issued on March 15, 2012	43,125
	Warrants granted on August 15, 2012	2,250
	Warrants granted on September 14, 2012	0
	Warrants granted on December 1, 2012	0
	Total B	517,503
	Total(A) + (B)	26,030,943
(C)	Potential future voting rights attached to shares representing the share capital to be issued upon the exercise of warrants that have not yet vested and are still conditional:	
	Warrants issued on May 12, 2004	0
	Warrants issued on July 12, 2005	0
	Warrants issued on March 22, 2006	0
	Warrants issued on November 8, 2006	0
	Warrants issued on April 18, 2007	0
	Warrants issued on May 25, 2007	0
	Warrants issued on May 30, 2008	0
	Warrants issued on January 27, 2009	2,000
	Warrants issued on June 21, 2010	52,500
	Warrants issued on May 27,2011	52,812
	Warrants issued on March 15, 2012	133,750
	Warrants granted on August 15, 2012	33,750
	Warrants granted on September 14, 2012	85,000

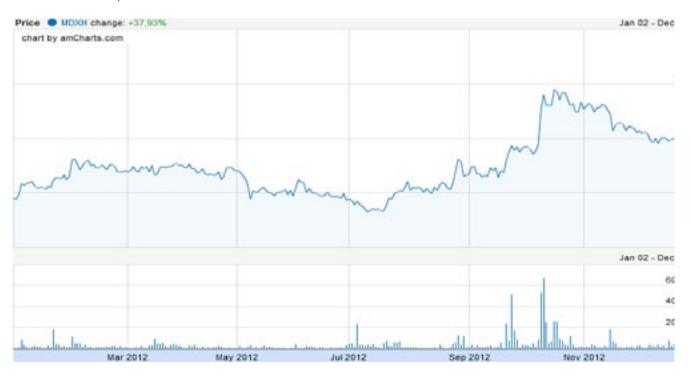
		Number of voting rights
	Warrants granted on December 1, 2012	10,000
	Total C	369,812
Total (A	A) + (B) + (C)	26,400,755

### **4.11. PAYING AGENT SERVICES**

The financial service for the shares of the Company is provided by ING Bank. Shareholders should inform themselves about the costs that other financial intermediaries may charge in connection with paying agency services.

### **4.12. SHARE PRICE EVOLUTION**

MDxHealth's share price evolution in 2012 is illustrated in the table below



The table below depicts the highest and lowest quarterly share price and the average daily volume in 2012.

MDxHealth (Euronext NYSE)	1Q12	2Q12	3Q12	4Q12	FY12
High Price	1.81 EUR	1.76 EUR	1.93 EUR	2.45 EUR	2.45EUR
Low Price	1.44 EUR	1.43 EUR	1.32 EUR	1.85 EUR	1.32 EUR



Audited Consolidated Financial Statements

### **5.1. CONSOLIDATED ANNUAL ACCOUNTS**

The following consolidated accounts are drawn up in accordance with International Financial Reporting Standards (IFRS) as adopted in the EU. The accounting policies and notes are an integral part of these consolidated financial statements. The following consolidated accounts differ from the statutory annual accounts of the Company, which have been prepared in accordance with Belgian GAAP.

The financial statements in this section 5 of the Registration Document have been approved and authorized for issue by the Board of Directors at its meeting of February 27, 2013. The financial statements have been signed by Dr. Jan Groen, Executive Director, on behalf of the Board of Directors. The financial statements will be submitted to the shareholders for their final approval at the annual general shareholders' meeting of May 31, 2013.

## 5.1.1. Consolidated statement of comprehensive income

Thousands of EUR except per share amounts / Years ended December 31	Notes	2012	2011	2010
Product and service income		3,719	1,838	1,968
Government grant income	5.1.5.21	883	849	568
Revenues		4,602	2,687	2,536
Cost of goods & services sold		903	266	370
Gross profit		3,699	2,421	2,166
Research and development expenses	5.1.5.3.	5,282	4,805	6,812
Selling, general and administrative expenses	5.1.5.3.	7,462	4,785	3,745
Other operating income		149	73	131
Other operating expenses		11	1	106
Total operating charges		12,606	9,518	10,532
Operating Profit (EBIT)		(8,907)	(7,097)	(8,366)
Financial income	5.1.5.5.	201	214	222
Financial expenses	5.1.5.5.	270	64	85
Profit/(Loss) before taxes		(8,976)	(6,947)	(8,229)
Income taxes		0	0	24
Net Profit/(Loss) for the year from continuing operations		(8,976)	(6,947)	(8,253)
Profit/(Loss) for the year from discontinued operations		0	0	0
Profit/(Loss) for the year from continuing operations		(8,976)	(6,947)	(8,253)
Other comprehensive income				
Exchange differences arising on translation of foreign operations		(57)	2	6
Other comprehensive income for the year (net of tax)		0	0	0
Total comprehensive profit/(loss) for the year (net of tax)		(9,033)	(6,945)	(8,247)
Basic earnings per share (EPS) EUR	5.1.5.7			
Using weighted average number of shares		(0.41)	(0.40)	(0.63)
Using end of period number of shares		(0.35)	(0.37)	(0.63)

## **5.1.2.** Consolidated statement of financial position

### **ASSETS**

Thousands of EUR / Years ended December 31	Notes	2012	2011	2010
ASSETS				
Intangible assets	5.1.5.8.	28	44	47
Property, plant and equipment	5.1.5.9.	800	727	579
Financial assets	5.1.5.10.	0	0	0
Grants receivable (> 1 year)	5.1.5.12.	0	0	483
Non-current assets		828	771	1,109
Grants receivable (< 1 year)	5.1.5.12.	348	827	771
Trade receivables	5.1.5.11.	1,694	1,267	1,058
Prepaid expenses and other current assets	5.1.5.11.	540	704	888
Cash and cash equivalents	5.1.5.13.	11,714	11,123	10,593
Current assets		14,296	13,921	13,310
TOTAL ASSETS		15,124	14,692	14,419

## LIABILITIES & SHAREHOLDERS' EQUITY

Thousands of EUR / Years ended December 31	Notes	2012	2011	2010
EQUITY AND LIABILITIES				
Share capital	5.1.5.15.	19,153	14,008	10,518
Issuance premium	5.1.5.15.	19,203	14,700	10,882
Accumulated profit/(loss)		(19,772)	(12,825)	(4,572)
Result of the year		(8,976)	(6,947)	(8,253)
Share-based compensation	5.1.5.19.	2,567	2,385	2,151
Translation reserves		(58)	(1)	(3)
Total equity		12,117	11,320	10,723
Grants payable (> 1 year)	5.1.5.12.	0	0	483
Advance on royalties		17	120	141
Long-term liabilities		0	160	0
Long-term lease debt	5.1.5.16.	0	0	2
Non-current liabilities		17	280	626
Current portion of lease debt	5.1.5.16.	0	0	2
Trade payables	5.1.5.17.	1,661	2,024	1,556
Grants payable (< 1 year)	5.1.5.12.	0	403	786
Other current liabilities	5.1.5.17.	1,329	665	726
Current liabilities		2,990	3,092	3,070
TOTAL EQUITY AND LIABILITIES		15,124	14,692	14,419

## 5.1.3. Consolidated cash flow statement

Thousands of EUR / Years ended December 31	Notes	2012	2011	2010
CASH FLOWS FROM OPERATING ACTIVITIES				
Operating Profit/(Loss)		(8,907)	(7,097)	(8,366)
Depreciation, amortization and impairment results	5.1.5.8/9	399	307	348
Share-based compensation	5.1.5.19	182	234	170
(Gain)/Loss on disposal of fixed assets		(16)	0	112
Interests paid		(13)	0	0
Income taxes		0	0	(24)
(Increase)/decrease in accounts receivable (1)		216	402	1,952
Increase/(decrease) in account payable (2)		(367)	(406)	(2,321)
Total adjustments		401	537	237
Net cash provided by/(used in) operating activities		(8,506)	(6,560)	(8,129)
CASH FLOWS FROM INVESTING ACTIVITIES				
(Purchase)/Sale of financial assets	5.1.5.10	0	0	635
Proceed from sale of fixed assets		37	0	58
Interest received	5.1.5.5	66	153	87
Other financial profit/(loss)	5.1.5.5	(15)	(3)	(23)
Purchase of property, plant and equipment	5.1.5.8	(486)	(348)	(48)
Purchase of intangible assets		0	(18)	(23)
Net cash provided by/(used in) investing activities		(398)	(216)	686
CASH FLOWS FROM FINANCING ACTIVITIES				
Payments on long-term leases		0	(4)	0
Proceeds from issuance of shares (net of issue costs)	5.1.5.15	9,648	7,308	0
Net cash provided by/(used in) financing activities		9,648	7,304	0
Net increase/(decrease) in cash and cash equivalents		744	528	(7,443)
Cash and cash equivalents at beginning of year		11,123	10,593	18,032
Effect on Exchange rate changes	5.1.5.13	(153)	2	4
Cash and cash equivalents at end of period		11,714	11,123	10,593

### Notes:

 $<sup>1) \,</sup> Long \, term \, grants \, receivable + short \, term \, grants \, receivable + trade \, receivables + prepaid \, expenses \, and \, other \, current \, assets.$ 

 $<sup>2) \ \</sup> Advance\ on\ royalties + long\ term\ grants\ payable + trade\ payables + short\ term\ grants\ payable + other\ current\ liabilities.$ 

## 5.1.4. Consolidated statement of changes in shareholders' equity

Thousands of EUR	Attributable to equity holders of the Company					
	Number of shares	Share capital & issuance premium	Retained earnings	Share-based compensation	Translation reserves	Total equity
Notes	5.1.5.15	5.1.5.15		5.1.5.19		
Balance at January 1, 2010	13,185,614	61,971	(45,143)	1,981	(9)	18,800
Total comprehensive income			(8,253)		6	(8,247)
Accumulated losses against capital		(40,571)	40,571			0
Share-based compensation				170		170
Balance at December 31, 2010	13,185,614	21,400	(12,825)	2,151	(3)	10,723
Balance at January 1, 2011	13,185,614	21,400	(12,825)	2,151	(3)	10,723
Total comprehensive income			(6,947)		2	(6,945)
Issuance of shares	5,436,713	8,155				8,155
Deduction of SPO costs		(847)				(847)
Share-based compensation				234		234
Balance at December 31, 2011	18,622,327	28,708	(19,772)	2,385	(1)	11,320
Balance at January 1, 2012	18,622,327	28,708	(19,772)	2,385	(1)	11,320
Total comprehensive income			(8,976)		(57)	(9,033)
Issuance of shares	6,891,113	10,000				10,000
Deduction of SPO costs		(352)				(352)
Share-based compensation				182		182
Balance at December 31, 2012	25,513,440	38,356	(28,748)	2,567	(58)	12,117

#### 5.1.5. Notes to consolidated financial statements

#### 5.1.5.1. General information

MDxHealth SA is a limited liability company incorporated in Belgium.

MDxHealth is a biotechnology company founded in 2003 which is focused on using a novel and proprietary molecular technology for developing and commercializing products and services for personalized oncology medicine to assist physicians with the diagnosis of cancer, prognosis of recurrence risk, and prediction of response to a specific therapy. The Company has in-licensed, discovered and patented an extensive portfolio of technologies and genetic markers which it uses to develop molecular diagnostic products and personalized medicine tests for the oncology market. The research and development work is done both in-house and through collaboration agreements with an extensive international network of leading oncology experts and medical centers. The molecular technology used by the Company is known as "DNA Methylation" and has been widely confirmed by the Company and many independent scientists, doctors, and journals throughout the world.

Since 2003, MDxHealth has licensed-out a number of methylation markers and its technology for specific applications to third-party commercial laboratories or diagnostic kit companies for them to distribute the product. These out-licensed products are primarily cancer screening applications. Starting in 2010, MDxHealth has retained the rights to certain

products (primarily personalized medicine applications) which it intends to commercialize itself via a commercial laboratory in the United States. MDxHealth also performs marker discovery, assay development, and clinical trial trials services for pharmaceutical companies in search of a potential companion diagnostic test for their oncology therapy.

The MDxHealth group of companies has its parent company, headquarters, and main laboratory in Belgium, but also operates in the United States, Belgium and The Netherlands. The operating activities of the Netherlands subsidiary were ceased in the third quarter of 2010 upon their transfer to the laboratory facilities in Belgium. The Dutch legal entity was liquidated in the course of 2012. MDxHealth's registered and main administrative office and assay development facility is based in Liège, Belgium (Tour 5 GIGA, Avenue de l'Hôpital 11, 4000 Liège). MDxHealth, Inc., the Company's U.S. subsidiary, is located at 15279 Alton Parkway – Suite 100 – Irvine, CA 92618, United States MDxHealth BVBA, the Company's Belgian subsidiary, was merged into MDxHealth SA in the course of 2012.

The consolidated financial statements are presented in Euro because that is the currency of the parent Company.

#### 5.1.5.2. Accounting policies

#### Use of estimates and judgments

MDxHealth's consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB), as adopted by the European Union up to December 31, 2012.

The preparation of financial statements in accordance with IFRSs as adopted by the EU requires the use of certain critical accounting estimates and management judgment in the process of applying the Company's accounting policies that affects the reported amounts of assets and liabilities and disclosure of the contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in the following Notes:

Note 5.1.5.6.: Taxes

Note 5.1.5.19: Warrant plans

#### Basis of preparation and statement of compliance

The principal accounting policies applied in the preparation of the above consolidated financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

All amounts are presented in thousands of Euros (EUR) unless otherwise indicated, rounded to the nearest EUR 1,000.

The financial statements have been prepared on the historical cost basis. Any exceptions to the historical cost convention are disclosed in the valuation rules described hereafter.

The financial statements have been established assuming the Company is a going concern. The Company has generated losses since its inception, which is inherent to the current stage of the Company's business life cycle as a biotech company. To date, the Company has ended each year with cash, investments available for sale or committed funding that exceeded more than one year of cash needs. Based on the current cash availability, the Company believes that the future research programs and company activities can be guaranteed for more than one year.

#### Changes in accounting policy and disclosures

#### 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 year starting on January 1, 2012. The Group has not applied any new IFRS requirements that are not yet effective as per December 31, 2012.

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

- IFRS 1 First-time Adoption of International Financial Reporting Standards (Amendment December 2010) Additional exemption for entities ceasing to suffer from severe hyperinflation
- IFRS 1 First-time Adoption of International Financial Reporting Standards (Amendment December 2010) Replacement of 'fixed dates' for certain exceptions with 'the date of transition to IFRSs'
- IAS 12 Income Taxes (Amendment December 2010) Limited scope amendment (recovery of underlying 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 annual 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 December 31, 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 1 First-time Adoption of International Financial Reporting Standards (Amendment May 2012) Amendments resulting from Annual Improvements 2009-2011 Cycle (repeat application, borrowing costs)
- IFRS 7 Financial Instruments: Disclosures (Amendment December 2011) Amendments related to the offsetting of assets and liabilities
- 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
- 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 1 Presentation of Financial Statements (Amendment May 2012) Amendments resulting from Annual Improvements 2009-2011 Cycle (comparative information)
- IAS 16 Property, Plant and Equipment (Amendment May 2012) Amendments resulting from Annual Improvements 2009-2011 Cycle (servicing equipment)
- 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 27 Consolidated and Separate Financial Statements (Amendment October 2012) Amendments for investment entities
- IAS 28 Investments in Associates Reissued as IAS 28 Investments in Associates and Joint Ventures (May 2011)
- IAS 32 Financial Instruments: Presentation (Amendment December 2011) Amendments relating to the offsetting of assets and liabilities
- IAS 32 Financial Instruments: Presentation (Amendment May 2012) Amendments resulting from Annual Improvements 2009-2011 Cycle (tax effect of equity distributions)
- IAS 34 Interim Financial Reporting (Amendment May 2012) Amendments resulting from Annual Improvements 2009-2011 Cycle (tax effect of equity distributions)
- IFRIC 20 Stripping Cost in the Production Phase of Surface Mine

None of the other new standards, interpretations and amendments, which are effective for periods beginning after 1st January 2013 and which have not been adopted early, are expected to have a material effect on the Group's future financial statements.

#### **Basis of consolidation**

The consolidated financial statements incorporate the financial statements of MDxHealth SA (Belgium legal entity), and MDxHealth Inc. (United States legal entity) made up to December 31, each year. Up to December 31, 2011 the consolidated financial statements also incorporated the financial statements of OncoMethylome Sciences BV (Netherlands legal entity) and MDxHealth PharmacoDx BVBA (Belgian legal entity). Both entities have either been liquidated or merged into MDxHealth SA as of December 31, 2012. MDxHealth SA (Belgium) incorporated MDxHealth Inc. (U.S.) as a wholly-owned subsidiary in 2003, OncoMethylome Sciences BV (Netherlands) in 2004, and MDxHealth PharmacoDx BVBA in 2007. The subsidiaries are included following the full consolidation method. All intra-group transactions, balances, income and expenses are eliminated in consolidation.

#### **Foreign currency translation**

#### **Functional and presentation currency**

Items included in the financial statements of each of the group's entities are measured using the currency of the primary economic environment in which the entity operates (functional currency). The consolidated financial statements are presented in Euro, which is the Company's functional and presentation currency.

#### **Transactions and balances**

Transactions in currencies other than Euro are recorded at the rates of exchange prevailing on the dates of the transactions. At each balance sheet date, the monetary assets and liabilities that are denominated in foreign currencies are translated at the rates prevailing on the balance sheet date. Non-monetary assets and liabilities carried at fair value that are denominated in foreign currencies are translated at the rates prevailing at the date when the fair value was determined. Gains and losses arising on translation are included in net profit or loss for the period, except for exchange differences arising on non-monetary assets and liabilities where the changes in fair value are recognized directly in equity.

On consolidation, the assets and liabilities of the group's foreign operations are translated at exchange rates prevailing on the balance sheet date. Income and expense items are translated at the average exchange rates for the period. Exchange differences arising, if any are classified as income or as expense in the period in which the operation is disposed of.

#### **Segment information**

The Company does not distinguish different segments, neither business nor geographical segments since at this time the majority of revenues are generated from clinical laboratory service testing or from grants in Belgium. In 2012, 81% of revenues were derived from testing/R&D services and 19% from grants. In 2012, the majority of product and service revenues were generated from the sale of clinical testing/R&D services to pharmaceutical companies evaluating the biomarkers of MDxHealth as potential companion diagnostic tests. These service testing revenues were primarily generated from the performance of testing in the Company's European ISO-certified commercial laboratory in Belgium. All of the grant revenues have been earned in Belgium by the parent company based in Liege. Almost all of the commercial revenues have been earned by the parent company, which performed services in Belgium on behalf of customers mainly based in Europe. Some minor revenues were generated from the United States via contracts between the Belgian parent-company and third party partners or customers in the United States.

All non-current assets (other than financial instruments, deferred tax assets, post-employment benefit assets, and rights arising under insurance contracts) in 2012 were located in Belgium, other than EUR 486,000 of equipment and leasehold improvements that were purchased in 2012 and which are located in the United States.

#### **Revenue recognition**

Substantially all of the Company's revenues are generated from technology out-licensing deals, product and service sales or royalties on such sales, research and development service fees, and government grants. Most commercial agreements include up-front fees, milestone fees, and royalty fees.

License fees are recognized when the Company has fulfilled all conditions and obligations. The license fee will not be recognized if the amount cannot be reasonably estimated and if the payment is doubtful. License up-front (signature fees) and non-refundable fees for access to prior research results and databases are recognized when earned, if the Company has no continuing performance obligations and all conditions and obligations are fulfilled (this means after the delivery of the required information).

If the Company has continuing performance obligations towards the fees, the fee will be recognized on a straight line basis over the contractual performance period.

Milestone fees are recognized as revenue when the amount of the milestone fee is determinable and the earning process and measures relative to the milestone have been fully completed.

Royalties will be generated by the sales by third parties of products or services which incorporate the Company's proprietary technology. Royalties are recognized as revenue once the amounts due can be reliably estimated based on the sale of the underlying products and services and when the collection of the royalties can be reasonably assured. In situations where there is adequate financial information on sales, royalties are recorded based on the reports received from the licensee or based on reliably estimated sales if the information has not been received.

Research and development service fees are recognized as revenue over the life of the research agreement as the required services are provided and costs are incurred. These services are usually in the form of a defined number of full-time equivalents (FTE) at a specified rate per FTE.

Government grants are recognized as revenue over the life of the grant as the required or planned activities are performed and the related costs incurred and when there is reasonable assurance that the Company will comply with the conditions of the grant. The grants are usually in the form of periodic progress payments. Grants related to assets are deducted from the assets acquired. The grants are recognized as income, over the useful life of the related asset, starting from the moment the asset is used by the Company, by way of a reduced depreciation charge.

Given the ConfirmMDx<sup>™</sup> for Prostate Cancer assay was recently introduced to the market in 2012, the company's revenue recognition policy has limited the amount of revenue recognized in 2012. Of the reported revenue for the ConfirmMDx<sup>™</sup> for Prostate Cancer assay in 2012, 80% is based on a cash collection basis. Given that the volume of billable cases is larger than the collection volumes, there exists unrecognized revenue potential not reflected in the financial statements. These unrecognized transactions will most likely impact revenues in future months as they either are collected or the payment pattern for given 3rd party payors warrants accrual accounting treatment for these 2012 transactions per the company's revenue recognition policy.

MDxHealth recognizes revenue for its CLIA laboratory services based on an accrual basis when test results are delivered and billed when the following criteria are met.

- 1) There is persuasive evidence that an agreement exists.
- 2) Test results have been delivered or services have been rendered and billed.
- 3) The fee is fixed or determinable.
- 4) Collection of the fee is reasonably assured.

The company assesses whether the fee is fixed or determinable based on an existing contractual arrangement for the nature of the fee charged for the products or services delivered or based on a historical analysis of each individual payor's payment patterns and history for each product or service, when no contractual arrangement exists. The determination of whether there is sufficient history to reliably estimate a payor's individual payment patterns is based on at least several months of payment history. The percentage of the number of tests paid relative to the number of tests billed must be at a consistently high percentage of tests billed and at a reliably consistent reimbursement rate. This reimbursement analysis will be updated at least each quarter to determine if the accrual method of revenue recognition will be applied or continued.

To the extent that all conditions and criteria set forth above are not met, including where there is no evidence of payment history at the time test results are delivered and billed, product and service revenues will be recognized on a cash basis when payment is received from the payor.

Deferred revenue represents amounts received prior to revenue being earned.

#### **Research & development costs**

The Company considers that the regulatory and clinical risks inherent to the development of its products preclude it from capitalizing development costs. Development costs are capitalized to the extent that all conditions for capitalization have been satisfied. In the consolidated IFRS financial statements of MDxHealth, no research and development costs have been capitalized.

#### Property, plant and equipment

Property, plant and equipment are stated at historical cost less accumulated depreciation and impairment. Repair and maintenance costs are charged to the income statement as incurred. Gains and losses on the disposal of property, plant and equipment are included in other income or expenses. Depreciation is charged so as to write off the cost or valuation of assets over their useful lives, using the straight-line method, on the following basis:

• Equipment: 5 years

• IT hardware and software: 3 years

Furniture: 5 years

Vehicles: 5 years

· Leasehold improvements: in line with the lease agreement period

#### **Intangible assets**

Acquired patents and software licenses are measured internally at purchase cost and are amortized on a straight-line basis over their estimated useful lives on the following basis:

- Patents: shorter of 5 years or the remaining patent life
- Software: shorter of 5 years or the software license period

Costs related to patents which are in-licensed are expensed as incurred. Costs related to the filing, maintenance and defense of patents are expensed as incurred. Internal and external research and development program costs are expensed as incurred.

#### Leases

Leases are classified as finance leases whenever the terms of the lease transfers substantially all the risks and rewards of ownership to the lessee. All other leases are classified as operating leases.

Assets held under finance leases are recognized as assets of the Company at their fair value or, if lower, at the present value of the minimum lease payments, each determined at the inception of the lease. The corresponding liability to the lessor is included in the balance sheet as a finance lease obligation so as to achieve a constant rate of interest on the remaining balance of the liability. Finance charges are expensed.

Rentals payable under operating leases are charged to income on a straight-line basis over the term of the relevant lease. Benefits received and receivable as an incentive to enter into an operating lease are also spread on a straight-line basis over the lease term.

#### Impairment of tangible and intangible assets

At each balance sheet date and at each interim reporting date, the Company reviews the carrying amount of its tangible and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss (if any). Where the asset does not generate cash flows that are independent from other assets, the Company estimates the recoverable amount of the cash-generating unit to which the asset belongs. An intangible asset with an indefinite useful life is tested for impairment annually and at each interim reporting date, and whenever there is an indication that the asset might be impaired. Recoverable amount is the higher of fair value less costs to sell and value in use. The estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

If the recoverable amount of an asset or cash generating unit is estimated to be less than the carrying amount, the carrying amount of the asset is reduced to its recoverable amount. An impairment loss is recognized as an expense immediately, unless the relevant asset is carried at re-valued amount, in which case the impairment is treated as a revaluation decrease. Where an impairment loss subsequently reverses, the carrying amount of the asset is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset in prior years. A reversal of an impairment loss is recognized as income, unless the relevant asset is carried at re-valuated amount, in which case the reversal of the impairment is treated as a revaluation increase.

#### **Inventories**

Inventories are stated at the lower of cost and net realizable value. Cost comprises merely purchase costs, as the inventory consists solely of raw materials. Raw materials are not ordinarily interchangeable and they are as such accounted for using the specific identification of their individual cost.

The Company does not account for work in progress and finished products, as the production process is very short and finished goods are shipped to customers immediately, thereafter resulting in no such items on the balance sheet at year-end for any of the periods reported.

#### **Trade receivables**

Trade receivables do not carry any interest and are stated at their minimal value as reduced by appropriate allowances for irrecoverable amount.

#### Grants receivable and grants payable

When a government grant is allocated, the Company books the full amount as both a receivable and a payable. No income is recognized when the grant is approved, but is fully deferred at that point. When it is received, the receivable is reduced by the amount. When the grant is recognized as income, the payable is reduced by the amount. The grant is only recorded as a payable/receivable when (i) the grant has been approved by the granting party, (ii) the amounts are measurable, and (iii) the Company believes it will meet the conditions necessary to be able to receive/use the grant.

### Cash and cash equivalents

Cash and cash equivalents are carried in the balance sheet at nominal value. For the purposes of the cash flow statements, cash and cash equivalents comprise cash on hand, deposits held on call with banks, other short highly liquid investments and bank overdrafts. In the balance sheet, bank overdrafts, if any, are included in borrowings in current liabilities.

#### **Taxation**

Deferred income tax is provided in full using the "balance sheet liability method", on temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes.

The amount of deferred tax provided is based on the expected manner or realization of settlement of the carrying amount of assets and liabilities, using tax rates enacted or substantially enacted at the balance sheet date. Deferred tax assets relating to tax losses carried forward are recognized to the extent that it is probable that the related tax benefits will be realized. Currently, no deferred tax asset is recognized on the balance sheet.

### **Trade payables**

Trade payables are not interest bearing and are stated at their nominal value.

#### **Equity instruments**

Equity instruments issued by the Company are recorded in the amount of the proceeds received, net of direct issue costs.

#### **Derivative instruments**

The Company has not used any derivative financial instruments.

#### **Financial Assets**

Investments classified as available for sale financial assets, are current and non-current investments comprising unlisted equity shares. They are stated at fair value, except where fair value cannot be established reliably in which case the

securities are carried at cost. Any resultant gain or loss on investments measured at fair value is recognized in a revaluation reserve in equity with the exception of impairment losses which are recognized directly in profit and loss. These investments are held with the objective of realizing a capital gain from a future sale. All purchase and sale of funds are recognized at the date of settlement. Investments are reviewed periodically and revalued by the Directors on a case by case basis.

Financial assets are assessed for indicators of impairment at each reporting period. Financial assets are impaired where there is objective evidence that as a result of one or more events that occurred after the initial recognition of the financial asset, the estimated future cash flows of the investment have been impaired. For unlisted shares classified as available for sale a significant or prolonged decline in the fair value of the security below its cost is considered to be objective evidence of impairment.

#### Retirement benefit schemes and employee savings schemes

Payments to defined contribution retirement benefit schemes are charged as an expense as they fall due. Payments to defined contribution employee savings schemes are charged as an expense as they fall due. The Company does not offer nor operate any defined benefit schemes for its employees.

#### Share-based compensation plans for personnel, directors and business associates

The Company has share-based compensation (stock option) plans for personnel, directors and business associates. The fair value of the employee services received for the granted compensation plans are measured as an expense. The corresponding credit is recorded directly into equity.

The total cost to be charged as an expense over the vesting period is measured at the fair value of the granted compensation plans. The estimate of the number of compensation plans which will be vested is revised at each reporting date. The change in estimates will be recorded as expense with a corresponding correction in equity.

The received amount, less directly attributable transaction costs, will be recorded as share capital and share premium when the compensation plans are exercised.

#### 5.1.5.3. Operating result

Result from operations has been arrived at after charging:

#### a. Research and development expenditures

Thousands of EUR / Years ended December 31	Notes	2012	2011	2010
Personnel costs	5.1.5.4.	2,449	1,985	3,619
Lab consumables		639	465	306
External research and development collaborator fees		1,526	1,462	1,667
Patent and license fees		0	0	347
Depreciation and amortization		343	276	338
Other expenses		325	617	535
Total		5,282	4,805	6,812

R&D expenditures increased in 2012 a a result of the setup of the CLIA laboratory in Irvine California in order to launch the Confirm MDx for Prostate product. Personnel costs were increased primarily as a result of the development of the United States laboratory facility in mid-2011 and to an increase of the number of personnel throughout the Group. External R&D collaborator fees decreased since 2009 as a result of the discontinuation of certain projects, such as cancer screening trials, but remain stable since 2011 Patent and license fees decreased in 2010 as a result of the discontinuation of certain projects and their associated IP while they were totally expensed under SG&A in 2011 and after. Depreciation and amortization expenses increased in 2012 as a result of large acquisition of capital expenditures in the United States.

# b. Selling, general and administrative expenses

Thousands of EUR / Years ended December 31	Notes	2012	2011	2010
Personnel costs	5.1.5.4.	3,815	2,311	1,847
Depreciation		54	39	37
Professional fees		1,363	1,345	1,211
Other expenses		1,869	727	476
Patent expenses		361	363	174
Total		7,462	4,785	3,745

SG&A expenses have continued to increase in 2012 as a consequence of the change in strategy in 2010 whereby the Company will pursue direct sales of certain of its products via a commercial laboratory in the United States. SG&A expenses include primarily costs for the general management of the Company, such as the finance, marketing, sales, and other similar activities.

# 5.1.5.4. Personnel costs

The number of employees at the end of the year was

Thousands of EUR / Years ended December 31	2012	2011	2010
The number of employees at the end of the year was:			
Management (headcount)	4	6	5
Laboratory staff (headcount)	37	23	23
SG&A staff (headcount)	29	10	9
Total	70	39	37
Their aggregate remuneration comprised:			
Wages and salaries	4,989	3,300	4,185
Social security costs	390	294	403
Pension costs	149	67	167
Other costs	736	635	711
Total	6,264	4,296	5,466

The personnel numbers in the table reflect year-end numbers. The year-end headcount in 2012 was higher than in 2011, and the total personnel costs increased significantly in 2012 for 2 reasons: (i (i) the new hires in 2011 were hired near year-end thus they did not add significantly to the 2011 personnel costs and (ii) the headcount increased by 31 in 2012.

# 5.1.5.5. Finance income/ (costs)

Thousands of EUR / Years ended December 31	2012	2011	2010
Interest on bank deposits	66	153	74
Interest on commercial paper	0	0	0
Gain on sales of liquid assets	0	0	13
Gain on sales of financial assets	0	0	135
Foreign exchange gain/(loss)	(107)	3	(62)
Other financial gain/(loss)	(28)	(6)	(23)
Net financial results	(69)	150	137

The largest portion of the financial results is composed of interest revenues from bank deposits. For the year ended December 31, 2010, the gain on sales of liquid assets arose from gains on a money-market account and on sales of tradable shares. The money-market account is invested in short-term interest bearing and publicly-traded obligations with high ratings. In 2010, the sale of the equity stake in Signature Diagnostics AG (formerly shown on the balance sheet as a financial asset) generated a gain of EUR 135 thousand. For accounting purposes, these liquid assets are considered as a cash equivalent on the balance sheet and in the cash flow statements as generating cash flows from investing activities in terms of interest income.

#### 5.1.5.6. Taxes

There is no current tax accounted for in any of the periods presented. The following table provides a reconciliation of the deferred taxes to the profit and loss statement.

	Balance at	Income Statement			Balance at
Thousands of EUR/ Years ended December 31	31-Dec-12	2012	2011	2010	01-Jan-10
Tax losses carried forward	93,208	10,375	9,170	10,369	63,294
Purchase of intangible assets	(7,035)	0	0	0	(7,035)
Depreciation of intangible assets	7,016	9	10	17	6,980
Total deductible temporary difference	93,189	10,384	9,180	10,386	63,239
Deferred taxes @ 34%	31,675	2,903	3,094	3,519	
Unrecognized opening balance of deferred tax asset		28,152	25,058	21,539	
Deferred tax of the year		3,523	3,094	3,519	
Deferred taxes at December 31	31,675	31,675	28,152	25,058	21,539

The Company has not recorded deferred net tax assets on the basis that at December 31, 2012, 2011 and 2010 no profits were realized and the lack of guarantees that it will generate profits in the future which could be offset against current losses.

The deferred taxes are calculated on the following items:

- Tax losses as per tax return. The financial figures under IFRS are not necessarily the same as the local GAAP financial figures used for tax declarations. Tax losses as per tax return refers to accounting rules of the tax authorities which in certain cases differ from IFRS accounting rules;
- In the statutory accounts, the costs related to certain research and development were capitalized and amortized on a straight-line basis over a period of 5 years, starting at January 1, 2003. In the IFRS statements development costs are capitalized to the extent that all conditions for capitalization have been satisfied (currently no R&D is capitalized in the Company's IFRS accounts). In 2009, the Company decided to consider these R&D costs as an expense and to align the statutory accounts with the IFRS accounts.

#### 5.1.5.7. Loss per share

Basic loss per share is calculated by dividing the net result attributable to shareholders by the weighted average number of shares outstanding during the year.

Thousands of EUR except per share amounts / Years ended December 31	2012	2011	2010
Result for the purpose of basic loss per share, being net loss	(8,976)	(6,947)	(8,253)
Number of shares Weighted average number of shares for the purpose of basic loss per share (assuming stock split in all periods)	22,071,704	17,207,292	13,185,614
Basic loss per share (in EUR)	(0.41)	(0.40)	(0.63)

At December 31, 2012, 2011, and 2010, the Company has dilutive potential shares in the form of warrants. Under IAS 33, no disclosure is required of the diluted result per share, since as long as the Company is reporting a net loss, the warrants have an anti-dilutive effect rather than a dilutive effect.

# 5.1.5.8. Intangible assets

Thousands of EUR / Years ended December 31	2012	2011	2010
Gross value			
At January 1	2,597	2,579	2,561
Additions	0	18	23
Disposals	0	0	(5)
Impairment			
Gross value at December 31	2,597	2,597	2,579
Accumulated amortization			
At January 1	(2,533)	(2,533)	(2,512)
Additions	(16)	(20)	(21)
Disposals	0	0	2
Related to subsidy	0	0	0
Impairment	0	0	0
Accumulated amortization at December 31	(2,569)	(2,553)	(2,533)
Net value at December 31	28	44	47

The intangible asset consists of intellectual property rights and software licenses.

These investments are being amortized on a straight-line basis over 3-5 years, unless impairment is noted during the periodic assessment of these assets.

# 5.1.5.9. Tangible assets

Thousands of EUR	Laboratory equipment	Furniture	IT equipment	Leasehold improvements	TOTAL
Gross value					
At January 1, 2010	2,345	198	576	172	3,291
Opening currency exchange rate	0	1	2	0	3
Additions	31	6	11	2	50
Disposals	(459)	(77)	(69)	(37)	(648)
Gross value at December 31, 2010	1,917	128	520	138	2,703
Accumulated amortization					
At January 1, 2010	(1,581)	(129)	(487)	(72)	(2,269)
Opening currency exchange rate	0	(1)	(2)	0	(3)
Additions	(248)	(20)	(48)	(9)	(325)
Disposals	363	45	51	14	473
Accumulated amortization at December 31, 2010	(1,466)	(105)	(486)	(67)	(2,214)
Net value at December 31, 2010	451	23	34	71	579
Thousands of EUR	Laboratory equipment	Furniture	IT equipment	Leasehold improvements	TOTAL
Gross value					
At January 1, 2011	1,917	128	520	138	2,703
Opening currency exchange rate	0	1	4	0	5
Additions	309	2	29	104	444
Disposals	(1)	0	(22)	0	(23)
Impairment	0	(16)	(57)	(7)	(80)
Gross value at December 31, 2011	2,225	115	474	235	3,049
Accumulated amortization					
At January 1, 2011	(1,466)	(105)	(486)	(67)	(2,123)
Opening currency exchange rate	0	(1)	(3)	0	(4)
Additions	(234)	(17)	(30)	(15)	(296)
Disposals	0	0	22	0	0
Impairment	0	16	57	7	80
Accumulated amortization at December 31, 2011	(1,700)	(107)	(440)	(75)	(2,322)

Net value at December 31, 2011	525	8	34	160	727
Thousands of EUR	Laboratory equipment	Furniture	IT equipment	Leasehold improvements	TOTAL
Gross value					
At January 1, 2012	2,225	115	474	235	3,049
Opening currency exchange rate	(4)	0	0	(2)	(6)
Additions	225	96	86	66	473
Disposals	(223)	(23)	(41)	(2)	(289)
Impairment	0	0	0	0	0
Gross value at December 31, 2012	2,223	188	519	297	3,227
Accumulated amortization					
At January 1, 2012	(1,700)	(107)	(440)	(75)	(2,322)
Opening currency exchange rate					
Additions	(227)	(24)	(19)	(115)	(385)
Disposals	219	23	36	2	280
Impairment	0	0	0	0	0
Accumulated amortization at December 31, 2012	(1,708)	(108)	(423)	(188)	(2,427)
Net value at December 31, 2012	515	80	96	109	800

# 5.1.5.10. Financial assets

On January 30, 2008, the Company took a minority equity stake in Signature Diagnostics AG (SD), a diagnostics start-up company using RNA-based technologies. In 2009 and 2008, the financial assets were recorded on the balance sheet at the price paid by MDxHealth for the shares issued by SD. SD is a privately-held company and there is no active market for its shares. In 2010, the equity stake in SD was sold and the related account balance has been reduced to zero. Since 2010, thus the Company no longer holds these financial assets.

#### 5.1.5.11. Trade and other receivables

# a. Trade receivables

Thousands of EUR / Years ended December 31	2012	2011	2010
Trade accounts receivable	1,694	1,267	1,058
Total trade accounts receivable	1,694	1,267	1,058

Trade receivables mainly consist of fees due from the customers of the Company.

The trade accounts receivable balances at end-2011 and end-2012 were composed mainly of services provided to pharmaceutical companies in the fourth quarter of those years. Out of the total trade receivable balance at the end of 2012, EUR 430 thousand are more than 60 days outstanding, whereas all the rest is outstanding for less than 60 days, out of which EUR 261 thousand were collected in early 2013. No provision for doubtful accounts has been made in 2012.

#### b. Other receivables

Thousands of EUR / Years ended December 31	2012	2011	2010
Prepayments	204	161	225
Deposits	13	20	27
Recoverable VAT	159	412	481
Inventories	93	63	108
Other	71	47	47
Total prepaid expenses and other current assets	540	703	888

The Company considers that the carrying amount of trade and other receivables approximates their fair value. The Recoverable VAT balance decreased in 2012 due to the 2010 closure of the lab facility in the Netherlands and the resulting reduced intercompany services between the parent company and the Dutch subsidiary that previously created significant recoverable VAT balances.

#### 5.1.5.12. Grants receivable

Thousands of EUR / Years ended December 31	2012	2011	2010
BE Wallonia: ETB bladder subsidy	144	339	770
BE Wallonia: Lung cancer subsidy Extension	102	0	0
BE Wallonia : BioWin	0	327	327
BE Wallonia: Eurostars - Cervix	102	162	
NL CTMM Airforce – Lung / Head & Neck	0	0	58
NL CTMM Decode – Colon	0	0	99
Total grants receivables	348	827	1,254
More than one year	0	0	483
Less than one year	348	827	771
Total grants receivables	348	827	1,254

In 2012, the Company was awarded one new grant, the Wallonia Lung cancer subsidy extension (3 program) which started retroactively in September 1, 2011 for a twelve months period.

In 2011, the Company was awarded two new grants, the Wallonia Eurostars grant for R&D on cervix cancer which started in September 1, 2011 and a lung subsidy extension from the Walloon region that was retroactive to September 2010 and finished in June 2011.

In 2010, the Company was awarded one new grant, the Wallonia/EuroTransBio grant for R&D on bladder cancer aggressiveness markers. No new grants were received in 2009. With the change in change in strategy announced in 2010, the Company has pursued fewer subsidized early-stage research projects. As a consequence the grant balances have decreased in 2010 and continues to decrease in 2011. Further detail on the grants is available in section 5.1.5.21(E) of this document.

# 5.1.5.13. Cash and cash equivalents

Thousands of EUR / Years ended December 31	2012	2011	2010
Cash at bank and in hand	11,714	11,123	10,593
Total cash and cash equivalents	11,714	11,123	10,593

The bank balances and cash held by the Company and short-term bank deposits have an original maturity of less than 3 months. The carrying amount of these assets approximates their fair value. These cash and cash equivalents have no restriction upon them.

# 5.1.5.14. Financial Risk Management

# **Capital management**

The company manages its capital with the aim of ensuring that the Company can continue to operate in continuity.

#### **Credit risk**

The limited number of the group's customers subjects the Company to concentrations of credit risk. In 2010, the Company generated 90% of its commercial turnover with sixteen customers, reducing the concentration of credit risk. In 2011, 87% of the commercial turnover is was generated by 10 customers. In 2012, the Company generated 74% of its commercial turnover with six customers, increasing its credit risk. In 2012, 2 individual customers each represented more than 9% of the total commercial revenues of the Company and together they accounted for 46% of total commercial revenues. The 2 largest customers in 2012 were Merck KGaA and Predictive Biosciences.

Customer's compliance with agreed credit terms is monitored regularly and closely. No major overdue trade accounts receivable are identified and the year-end 2012 balance was EUR 1.694 thousand.

Receivables related to research grants from the Belgian government (EUR 348 thousand at December 31, 2012) are recognized when there is a reasonable assurance that the Company will comply with the conditions attached to them and the grant will be received. The company considers the overall recognition criteria being met when an award letter has been received, the related project costs have been incurred, and grant specific milestones have been achieved or are assumed to be reliably achieved in the future.

The credit risk on cash and cash equivalents (EUR 11,714 thousand) is limited given that the counterparties are banks with high credit scores attributed by international rating agencies.

#### **Interest risk**

The group is not subject to material interest risk. All leases have fixed interest rates.

# **Currency risk**

The group is not currently exposed to material currency risk, but in the future this risk may increase with an expansion of the Company's U.S. activities. The group has cash outflows in U.S. Dollars for the operations of its U.S. wholly-owned subsidiary and for numerous external research and development projects it carries out with U.S.-based medical centers. In 2013, the Company will likely have material commercial revenues denominated in U.S. Dollars. The Company has not engaged in hedging of the foreign currency risk via derivative instruments. The Company has started in 2012 to sell products directly to treating physicians in the United States via its commercial laboratory. This new activity is likely to

increase the dollar-denominated costs and revenues of the Company as a percentage of the overall costs and revenues starting in 2012.

The monetary items at December 31, 2012 in U.S.D are composed of cash on hand of \$ 2,377 thousand.

For compliance with the IFRS 7 rule, the Company discloses a sensitivity analysis of an increase/decrease of exchange rate on operations in U.S.D of 10%.

The exposure of operations to the currency risk is limited to the net amount of \$ 8.1 million (\$ 2.3 million revenue and \$ 10.4 million costs), giving a potential loss of EUR 696 thousand in case of an increase of the U.S.D/EUR exchange rate by 10%, and a potential gain of EUR 570 thousand in case of an decrease of the exchange rate by 10%.

# **Liquidity risk**

The Group manages liquidity risk by maintaining adequate reserves and by continuously monitoring forecast and actual cash flows and matching the maturity profiles of financial assets and liabilities. The company has no borrowing arrangements at December 31, 2012 and has no derivative instruments.

#### Other risks

The Group subscribes to certain insurance policies to cover matters such as (i) fire, theft, and other damage to its assets, (ii) product liability insurance and clinical trial insurance, and (iii) D&O insurance. To date, no claims have been made under these insurance policies and there is no guarantee that the insurances will cover all damages if they should ever occur.

To date, the Company has received several government grants for various R&D projects. Some of these grant amounts can be re-claimed if the Company does not fulfill all the conditions of the grant agreements.

# 5.1.5.15. Share capital and reserves

At December 31, the Company's share capital was represented by the following number of shares (units). Only one class of shares (common shares) exists and they have no par value.

Years ended December 31	2012	2011	2010
Common shares	25,513,440	18,622,327	13,185,614
Total outstanding shares	25,513,440	18,622,327	13,185,614

The capital stock and the issuance premium at December 31 amounted to the following:

Thousands of EUR / Years ended December 31	2012	2011	2010
Share Capital as per statutory accounts	20,352	14,855	10,518
IPO Costs & Capital Increase costs	(1,199)	(847)	(0)
Share capital under IFRS	19,153	14,008	10,518
Issuance premium	19,203	14,700	10,882
Share capital and issuance premium	38,356	28,708	21,400

The share capital and issuance premium increased in 2012 as a result of the private placement with institutional investors of 6,891,113 new shares on July 4, 2012. The new shares were issued at EUR 1.45 per share.

The table below provides an overview of the history of the Company's share capital since its incorporation in 2003. The overview should be read together with the notes set out below the table.

Date	Transaction	Number (and class) of shares issued	Issue price per share (EUR)	Issue price per share (EUR) post-stock split	Capital increase (000 EUR)	Share capital after transaction (000 EUR)
Incorporation						
Jan.10, 2003	Incorporation	202,975	0.30	0.06	62	62
Phase I financing I	round December 20, 2002 (p	preferred A shares)				
Feb.07, 2003	Capital increase in cash	197,025 (preferred A)	20.00	4.00	3,941	4,002
Jun.30, 2003	Capital increase in cash	33,333 (preferred A)	20.00	4.00	667	4,669
Sep.30, 2003	Capital increase in cash	218,139 (preferred A)	22.31	4.46	4,867	9,535
Jun.30, 2004	Capital increase in cash	195,504 (preferred A)	23.87	4.77	4,667	14,202
Phase II financing	round October 19, 2005 (pre	eferred B shares)				
Oct.28, 2005	Capital increase in cash	375 (preferred B)	24.00	4.80	9,000	23,202
Mar. 31, 2006	Capital increase in cash	193,548 (preferred B)	31.00	6.20	6,000	29,202
Stock split and co	nversion of all shares to com	mon shares				
May 23, 2006		-	-	-	-	29,202
IPO						
Jun. 30, 2006	Capital increase in cash	2,933,334 (ordinary)	7.50	7.50	22,000	51,202
Absorption of loss	ses					
Jun. 30, 2006	Absorption of losses	-	-	-	(10,218)	40,984
Exercise of over-al	lotment warrants					
Jun. 30, 2006	Capital increase through exercise of over-allotment warrants	440,000 (ordinary)	7.50	7.50	1,817	42,801 (as per statutory accounts)
Deduction of IPO	costs (under IFRS)					
Jun. 30, 2006	Deduction of IPO costs	-	-	-	(2,174)	40,627 (under IFRS)
Exercise of warran	ts					
Apr. 18, 2007	Capital increase in cash	182,560 (ordinary)	4.70	4.70	748	41,375
Secondary offerin	<del></del>					
Oct. 19, 2007	Capital increase in cash	1,063,510 (ordinary)	10.00	10.00	4,355	45,730
Exercise of warran						
Oct. 25, 2007	Capital increase in cash	50,837 (ordinary)	4.73	4.73	208	45,938
Deduction of seco	ondary Offering Fees (Under	IFRS)				

Date	Transaction	Number (and class) of shares issued	Issue price per share (EUR)	Issue price per share (EUR) post-stock split	Capital increase (000 EUR)	Share capital after transaction (000 EUR)
Dec. 31, 2007	Deduction of SPO costs	-	-	-	(457)	45,481 (under IFRS)
Exercise of warrar	nts					
Apr. 24, 2008	Capital increase in cash	61,120 (ordinary)	4.59	4.59	250	45,731
Exercise of warrar	nts					
Nov. 05, 2008	Capital increase in cash	19,375 (ordinary)	4.73	4.73	80	45,811
Secondary offering	ng of shares					
Dec. 18, 2008	Capital increase in cash	1,332,877 (ordinary)	6.29	6.29	5,459	51,270
Deduction of second	ondary Offering Fees (Under	IFRS)				
Dec. 31, 2008	Deduction of SPO costs	-	-	-	(281)	50,989 (under IFRS)
Exercise of warrar	nts					
Apr. 17, 2009	Capital increase in cash	24,540 (ordinary)	4.49	4.49	100	51,089
Reduction of shar	re capital (with no change to	number of shares)				
Jun. 21, 2010	Reduction of Share Capital	-	-	-	-	10,518
Secondary Offerin	ng of shares					
Apr. 08, 2011	Capital increase in cash	5,436,713 (ordinary)	1.50	1.50	4,337	14,855
Secondary Offerin	ng of shares					
Jul. 4, 2012	Capital increase in cash	6,819,113 (ordinary)	1.45	1.45	5,497	20,352
Deduction of second	ondary Offering Fees (Under	IFRS)				
Jun. 30, 2011	Deduction of SPO costs	-	-	-	(847)	
Jul. 4, 2012	Deduction of SPO costs	-	-	-	(352)	19,153 (under IFRS)

At incorporation, on <u>January 10, 2003</u>, the Company issued 202,975 common shares in consideration for a contribution in cash of EUR 61,500. On January 30, 2003, 200,000 of these shares were transferred to the Company's management and consultants.

The extraordinary shareholders' meeting of February 7, 2003 approved the issuance of 197,025 new series A preferred shares in consideration for a contribution in cash of EUR 3,940,500. At the same occasion, two different classes of shares were created, i.e., the ordinary or common shares and the series A preferred shares. All shares issued at this occasion and 2,975 of the shares issued at incorporation were re-classified as series A preferred shares. The remaining 200,000 shares are ordinary or common shares. At the same shareholders' meeting 100 series A anti-dilution warrants were also issued to the owners of the existing series A preferred shares.

The extraordinary shareholders' meeting of <u>June 30, 2003</u> approved the issuance of 33,333 new series A preferred shares in consideration for a contribution in cash of EUR 666,660. At the same time, 20 new series A anti-dilution warrants were issued to the subscriber to the newly issued series A preferred shares.

The extraordinary shareholders' meeting of <u>September 30, 2003</u> approved the issuance of 218,139 new series A preferred shares in consideration for a contribution in cash of EUR 4,866,681.

The extraordinary shareholders' meeting of May 12, 2004 approved the issuance of 30,000 warrants and authorized the issuance of an additional 15,000 warrants by the Board of Directors in the framework of the Authorized Capital pursuant to the terms of the approved stock option plan for employees, consultants and directors. In May 2004, 29,750 warrants were granted to beneficiaries under the stock option plan and 250 warrants were never granted and became null and void on June 30, 2004 in accordance with the terms and conditions of the stock option plan.

The extraordinary shareholders' meeting of <u>June 30, 2004</u> approved the issuance of 195,504 new series A preferred shares in consideration for a contribution in cash of EUR 4,666,680.

On <u>July 12, 2005</u>, the Board of Directors approved the issuance of 15,000 warrants in the framework of the Authorized Capital pursuant to the terms of the stock option plan approved in 2004. All these warrants were granted to beneficiaries under the stock option plan.

The extraordinary shareholders' meeting of October 28, 2005 approved the issuance of 375,000 new series B preferred shares in consideration for a contribution in cash of EUR 9,000,000. At the same time, the 120 existing series A anti-dilution warrants were cancelled and 160 new series A anti-dilution warrants were issued to the owners of the series A and series B preferred shares.

The extraordinary shareholders' meeting of <u>March 31, 2006</u> approved the issuance of 193,548 new series B preferred shares in consideration for a contribution in cash of EUR 5,999,988.

The annual general shareholders' meeting of May 23, 2006 approved the split of all outstanding shares at a conversion rate of 5-for-1 and the conversion of all types of shares into a single class of common shares. On May 23, 2006, the general shareholders' meeting of the Company decided to increase the Company's share capital through issuance of new shares in connection with an initial public offering. The capital increase with an amount of EUR 22,000,005 was completed on June 30, 2006. At the same time, all existing shares of the Company were converted into ordinary shares.

On <u>May 23, 2006</u>, the general shareholders' meeting passed a resolution to make a formal capital reduction, upon the listing of the Company's shares on Euronext, through the incorporation of the Company's Belgian statutory account losses through the period ended December 31, 2005 (for a total amount of EUR 10,217,809) without cancellation of any shares. The capital decrease was completed on June 30, 2006.

On <u>May 23, 2006</u>, the general shareholders' meeting of the Company decided to create an over-allotment warrant. The over-allotment warrant was granted to ING Belgium NV/SA and Fortis Bank NV/SA to cover over-allotments in connection with the initial public offering by the Company. On June 30, 2006, the share capital was increased with an amount of EUR 1,817,200 through exercise of 440,000 over-allotment warrants and the issuance of 440,000 new ordinary shares. An amount of EUR 1,482,800 was allocated to the Company's issuance premium account.

In accordance with IFRS and general industry practice, the Company decided in 2006 to record the costs associated with the IPO in 2006 as direct reduction of the share capital in the equity account of the balance sheet rather than as an expense in the income statement.

On <u>April 18, 2007</u>, the share capital was increased through exercise of (i) 9,937 warrants issued by the extraordinary general shareholders' meeting of May 12, 2004 (Warrants 2004) at an exercise price of EUR 22.31 per warrant, (ii) 6,900 warrants issued by the Board of Directors on July 12, 2005 (Warrants 2005) at an exercise price of EUR 23.87 per warrant, and (iii) 19,675 warrants issued by the extraordinary general shareholders' meeting of March 22, 2006 (Warrants 2006) at an exercise price of EUR 24.00 per warrant. The issue share prices in the above table indicate the weighted average price of the exercised warrants. Pursuant to the stock split decided upon by the general shareholders' meeting of May 23, 2006,

each Warrant 2004, Warrant 2005 and Warrant 2006 entitles the holder thereof to five shares of the Company.

On <u>October 15, 2007</u>, the Board of Directors decided to increase the Company's share capital in connection with a private placement with qualified institutional investors. The capital increase with an amount of EUR 4,354,954.02 was completed on October 19, 2007.

On October 25, 2007, the share capital was increased through exercise of (i) 2,680 warrants issued by the extraordinary general shareholders' meeting of May 12, 2004 (Warrants 2004) at an exercise price of EUR 22.31 per warrant, (ii) 3,000 warrants issued by the Board of Directors on July 12, 2005 (Warrants 2005) at an exercise price of EUR 23.87 per warrant, (iii) 4,425 warrants issued by the extraordinary general shareholders' meeting of March 22, 2006 (Warrants March 2006) at an exercise price of EUR 24 per warrant, (iv) 187 warrants issued by the Board of Directors on November 8, 2006 (Warrants November 2006) at an exercise price of EUR 7.72 per warrant and (v) 125 warrants issued by the Board of Directors on April 18, 2007 (Warrants January 2007) at an exercise price of EUR 10.87 per warrant. The issue share prices in the above table indicate the weighted average price of the exercised warrants. Pursuant to the stock split decided upon by the general shareholders' meeting of May 23, 2006, each Warrant 2004, Warrant 2005 and Warrant 2006 entitles the holder thereof to five shares of the Company.

On <u>April 25, 2008</u>, the share capital was increased through exercise of (i) 7,500 warrants issued by the extraordinary general shareholders' meeting of May 12, 2004 (Warrants 2004) at an exercise price of EUR 22.31 per warrant, and (ii) 4,724 warrants issued by the extraordinary general shareholders' meeting of March 22, 2006 (Warrants 2006) at an exercise price of EUR 24.00 per warrant. The issue share prices in the above table indicate the weighted average price of the exercised warrants. Pursuant to the stock split decided upon by the general shareholders' meeting of May 23, 2006, each Warrant 2004, Warrant 2005 and Warrant 2006 entitles the holder thereof to five shares of the Company.

On <u>November 5, 2008</u>, the share capital was increased through exercise of (i) 625 warrants issued by the extraordinary general shareholders' meeting of May 12, 2004 (Warrants 2004) at an exercise price of EUR 22.31 per warrant, (ii) 2,500 warrants issued by the Board of Directors on July 12, 2005 (Warrants 2005) at an exercise price of EUR 23.87 per warrant, and (iii) 750 warrants issued by the extraordinary general shareholders' meeting of March 22, 2006 (Warrants 2006) at an exercise price of EUR 24.00 per warrant. The issue share prices in the above table indicate the weighted average price of the exercised warrants. Pursuant to the stock split decided upon by the general shareholders' meeting of May 23, 2006, each Warrant 2004, Warrant 2005 and Warrant 2006 entitles the holder thereof to five shares of the Company.

On <u>December 18, 2008</u>, the Board of Directors decided to increase the Company's share capital in connection with a private placement with qualified institutional investors. The capital increase for an amount of EUR 5,458,797.75 and the issuance of 1,332,877 new common shares was completed on December 18, 2008.

On <u>April 17, 2009</u>, the share capital was increased through exercise of (i) 4,508 warrants issued by the extraordinary general shareholders' meeting of May 12, 2004 (Warrants 2004) at an exercise price of EUR 22.31 per warrant, and (ii) 400 warrants issued by the extraordinary general shareholders' meeting of March 22, 2006 (Warrants 2006) at an exercise price of EUR 24.00 per warrant. The issue share prices in the above table indicate the weighted average price of the exercised warrants. Pursuant to the stock split decided upon by the general shareholders' meeting of May 23, 2006, each Warrant 2004 and Warrant 2006 entitles the holder thereof to five shares of the Company.

On <u>June 21, 2010</u>, the Extraordinary General Shareholders' meeting approved the formal reduction of the share capital in accordance with article 614 of the Belgian Company Code through the incorporation (and neutralization) of (accumulated) sustained losses as demonstrated from the approved annual accounts as per December 31, 2009,

without reducing the total number of issued and outstanding shares, in order to improve the ratio of the Company's net assets vis-à-vis its share capital. Therefore, the share capital was reduced by EUR 43,483,535.37, bringing the share capital per the statutory accounts from EUR 54,001,197.27 to EUR 10,517,661.90. This transaction caused the share capital under IFRS to be reduced from EUR 51,089,000 to EUR 10,518,000.

On <u>April 8, 2011</u>, the Board of Directors decided to increase the Company's share capital in connection with a private placement with qualified institutional investors. 5,436,713 new common shares were issued at EUR 1.50 per share, resulting in an increase of the share capital for an amount of EUR 4,336,865.96 (with the remaining balance allocated to issuance premium).

On <u>July 4, 2012</u>, the Board of Directors decided to increase the Company's share capital in connection with a private placement with qualified institutional investors. 6,819,113 new common shares were issued at EUR 1.45 per share, resulting in an increase of the share capital for an amount of EUR 5,497,040.84(with the remaining balance allocated to issuance premium).

<u>Voting rights</u> - Each share is entitled to one vote.

<u>Dividends</u> – The Company has never declared or paid any dividends on its shares and does not anticipate paying any dividends in the foreseeable future. Under Belgian law, the Company is required to allocate at least 5% of its net profits during each financial year to the legal reserve until such reserve has reached an amount equal to 10% of the Company's share capital. At December 31, 2012, there were no profits available for distribution under Belgian law.

<u>Preferential subscription rights</u> – On the occasion of any capital increase or issue of warrants, the Company's shareholders have a preferential subscription right. Such preferential subscription right is proportionate to the shareholder's participation in the Company's capital at the time of the capital increase or issue of warrants.

Authorized Capital – By virtue of the resolution of the extraordinary general shareholders' meeting held on June 15, 2012, the Board of Directors has been expressly authorized to increase the share capital in one or more transactions with an amount of up to EUR 14,854,527.86 (the "Authorized Capital"), subject to certain limitations and conditions described below. The Board of Directors can exercise this power for a period starting on the date of the publication of the relevant resolution of the extraordinary general shareholders' meeting in the Annexes to the Belgian Official Gazette and ending on the date of the annual general shareholders' meeting to be held in 2015 which shall resolve on the annual accounts relating to the accounting year ending on December 31, 2014. This authorization may be renewed in accordance with the relevant legal provisions.

The capital increases to which can be decided according to this authorization, can take place in accordance with the modalities as are to be decided by the board of directors, such as:

- by means of contribution in cash or in kind, within the limits as permitted by the Belgian Company Code,
- through conversion of reserves and issuance premiums,
- with or without issuance of new shares, with or without voting rights,
- through issuance of convertible bonds, subordinated or not,
- through issuance of warrants or bonds to which warrants or other tangible values are attached, and/or
- through issuance of other securities, such as shares in the framework of a stock option plan.

In the framework of the use of its powers within the framework of the authorized capital, the board of directors can limit or cancel the preferential subscription right of the shareholders in the interest of the company, subject to the limitations and in accordance with the conditions provided for by the Belgian Company Code.

This limitation or cancellation can also occur to the benefit of the employees of the company and its subsidiaries, and, to the extent permitted by law, to the benefit of one or more specific persons that are not employees of the company or its subsidiaries.

If, following a capital increase that has been decided within the framework of the authorized capital, an issuance premium is paid, the board of directors is authorized and obliged to book the amount of such issuance premium onto the account "Issuance Premiums", that shall serve as guarantee for third parties in the same manner as the company's share capital and which, apart from the possibility to convert this reserve into share capital, can only be disposed of in accordance with the rules provided by the Belgian Company Code for amendments to the articles of association.

By virtue of the resolution of the extraordinary general shareholders' meeting held on June 15, 2012, the board of directors has also been expressly authorized to increase the share capital in one or more transactions following a notification by the Belgian Financial Services and Markets Authority that it has been informed of a public takeover bid on the company's financial instruments, through contributions in cash with cancellation or limitation of the preferential subscription rights of the shareholders (including for the benefit of one or more well defined persons who are not employees of the company) or through contributions in kind, with issuance of shares, warrants or convertible bonds, subject to the terms and conditions provided for in the Belgian Company Code. The board of directors can exercise this power for a period of maximum three years starting as of the date of the publication of the relevant resolution of the extraordinary general shareholders' meeting in the Annexes to the Belgian Official Gazette.

The board of directors is authorized, with power of substitution, to amend the articles of association upon each capital increase realized within the framework of the authorized capital, in order to bring them in accordance with the new situation of the share capital and the shares.

At the date of this document, the Board of Directors has used the above described powers under the Authorized Capital as follows:

• On July 4, the Board of Directors used the Authorized Capital for a private placement of 6,891,113 new shares with institutional investors at a price of EUR 1.45. This transaction reduced the available Authorized Capital by EUR 5,497,040.84.

Externally imposed capital requirements – None of the current contracts of the Company impose any capital requirements on the Company. Article 633 of the Belgian Company Code requires that if in the statutory Belgian-GAAP accounts the net assets of a limited liability company (société anonyme) have fallen below 50% of its share capital as a result of sustained losses, a shareholders' meeting must be convened within two months as from the determination of such situation in order to deliberate and to resolve upon the dissolution of the Company or the continuation of its activities of the Company (and any other proposed measures to address the situation) upon proposal of the Board of Directors of the Company. Article 634 of the Belgian Company Code states that if in the statutory Belgian-GAAP accounts the net assets of a limited liability company (société anonyme) have fallen below EUR 61,500, any interested party can ask the courts to dissolve the Company. The courts may grant the Company time to rectify the situation. At the date of this document, the Company's financial situation is such that no action needs to be taken pursuant to either Article 633 or 634 of the Belgian Company Code.

# 5.1.5.16. Finance lease obligations and other lease obligations

Thousands of EUR / Years ended December 31	2012	2011	2010
Amounts payable under finance lease			
Within one year	0	0	2
In the second to fifth year	0	0	2
After five years	0	0	0
Total	0	0	4
Less future finance charges	0	0	0
Present value of lease obligations	0	0	0
Outstanding commitments for future minimum rent payments, which fall due as follows:			
Within one year	262	353	399
In the second to fifth year	182	267	418
After five years	0	0	0

The fair value of the Company's lease obligations approximated their carrying value. Outstanding commitments for future minimum rent payments include rental fees related to leased facilities and vehicles. These lease contracts can be terminated early with certain indemnity fees. All figures shown assume that the lease contracts will not be terminated early.

# 5.1.5.17. Accounts payable

# a) Trade accounts payable

Thousands of EUR / Years ended December 31	2012	2011	2010
Trade accounts payable	1,083	982	656
Accruals for invoices to be received	578	1,042	900
Total trade accounts payable	1,661	2,024	1,556

# b) Other current liabilities

Thousands of EUR/ Years ended December 31	2012	2011	2010
Payroll	1,152	568	375
Other accruals	177	97	351
Total other current liabilities	1,329	665	726

The trade accounts payable and other current liabilities balances have increased in 2012 mainly because MDxHealth incurred costs to set-up its CLIA lab facility in Irvine, California. CTMM is a Dutch research consortium MDxHealth has been working with for a number of years, primarily in colon cancer. The long-term liability to CTMM amounts EUR 160 thousand and is presented under the Non-Current liabilities section. In 2010, the trade payables balance was reduced versus the 2009 balance following the reduction of costs initiated at end-2009 and the change in strategy which has led to a focus on a smaller set of projects and products.

Payroll liabilities at year–end 2012 increased mainly due to the accrual of extra bonuses for certain managers and personnel, mainly for commercial operations.

#### 5.1.5.18. Retirement benefit schemes

The Company operates defined contribution systems for all its qualifying employees. The assets of the schemes are held separately from those of the Company in designated funds.

A total cost of EUR 182 thousand in 2012 (EUR 67,000 in 2011 and EUR 170,000 in 2010) represents contributions payable to these schemes by the Company at rates specified in the rules of the plans.

The employees of the Company in Belgium are members of a state-managed retirement benefit scheme operated by the government (i.e., legal pension) and are members of a bank-operated private pension scheme. The Company is required to contribute a specified percentage of payroll costs to the retirement benefit scheme to fund the benefits. The only obligation of the Company with respect to the retirement benefit scheme is to make the specified contributions.

# 5.1.5.19. Stock Option plans (warrants)

The Company has created several pools of warrants under stock option plans for grant to eligible employees, directors, and consultants.

When the annual general shareholders' meeting of May 23, 2006 decided to have a 5-for-1 stock split for all outstanding shares, it also decided to modify all warrants outstanding prior to that date. The exercise price of the warrants was left unchanged but each warrant became convertible into 5 common shares upon their exercise, rather than just 1 share.

The table below provides an overview as per December 31, 2012 of the warrants that have been created, granted and that are still exercisable. Terminated warrants are described below as cancelled warrants. Generally, those warrants described as cancelled are due to forfeitures. In future years, the term forfeited will be used in place of cancelled.

Warrant data as of December 31, 2012								
Date	Total number created	Total number granted	Total terminated	Total exercised	Total outstanding	Total exercisable	Exercise price (EUR)	
May 12, 2004	30,000	29,750	4,500	25,250	-	-	22.31	
Jul. 12, 2005	15,000	15,000	2,600	12,400	-	-	23.87	
Mar.22, 2006	66,700	66,700	4,438	29,974	32,288	32,288	24.00	
Nov.08, 2006	47,500	47,500	36,813	187	10,500	10,500	7.72	
Apr. 18, 2007	55,100	55,100	34,100	125	20,875	20,875	10.87	
May 25, 2007	50,000	50,000	35,000	-	15,000	15,000	11.42	
May 30, 2008	61,000	49,000	22,500	-	26,500	26,500	9.10	
Jan. 02, 2009	120,500	116,600	84,600	-	32,000	30,000	6.32	
Jun. 21, 2010	145,000	145,000	5,000	-	140,000	87,500	2.07	
May 27, 2011	225,000	225,000	51,875	-	173,125	114,688	1.71	
Mar. 15, 2012	195,000	195,000	18,125	-	176,875	43,125	1.72	
Aug. 15, 2012	36,000	36,000	-	-	36,000	2,250	1.52	
Sep. 14, 2012	85,000	85,000	-	-	85,000	-	1.65	
Dec. 1, 2012	10,000	10,000	-	-	10,000		2.19	
Total	1,141,800	1,125,650	299,551	67,936	758,163	382,726		

The table below presents the same data as the above table, except it provides the number of common shares and the exercise price of the warrants in order to obtain a single common share.

Warrant data as	of December 31,	2012 reflecting po	otential number	of common shar	es underlying the	e warrants	
Date	Total potential shares from warrants created	Total potential shares from warrants granted	Total potential shares from warrants terminated	Total shares issued from exercised warrants	Total potential shares from outstanding warrants	Total potential shares from exercisable warrants	Exercise price per potential share (EUR)
May 12, 2004	150,000	148,750	22,500	126,250	-	-	4.46
Jul. 12, 2005	75,000	75,000	13,000	62,000	-	-	4.77
Mar.22, 2006	333,500	333,500	22,190	149,870	161,440	161,440	4.80
Nov.08, 2006	47,500	47,500	36,813	187	10,500	10,500	7.72
Apr. 18, 2007	55,100	55,100	34,100	125	20,875	20,875	10.87
May 25, 2007	50,000	50,000	35,000	-	15,000	15,000	11.42
May 30, 2008	61,000	49,000	22,500	-	26,500	26,500	9.10
Jan. 02, 2009	120,500	116,600	84,600	-	32,000	30,000	6.32
Jun. 21, 2010	145,000	145,000	5,000	-	140,000	87,500	2.07
May 27, 2011	225,000	225,000	51,875	-	173,125	114,688	1.71
Mar. 15, 2012	195,000	195,000	18,125	-	176,875	43,125	1.72
Aug. 15, 2012	36,000	36,000	-	-	36,000	2,250	1.52
Sep. 14, 2012	85,000	85,000	-	-	85,000	-	1.65
Dec. 1, 2012	10,000	10,000	-	-	10,000		2.19
Total	1,588,600	1,571,450	345,703	338,432	887,315	511,878	

The table below presents the outstanding warrants and their exercise price at the end of December of each year:

	Warrants	Weighted average exercise price (EUR)	Potential shares from exercise of warrants	Weighted average exercise price per potential share (EUR)
Outstanding 31 December 2004	29,750	22.31	148,750	4.46
Granted in 2005	15,000	23.87	75,000	4.77
Outstanding 31 December 2005	44,750	22.83	223,750	4.57
Granted in 2006	114,200	17.23	381,000	5.16
Outstanding 31 December 2006	158,450	18.80	602,250	4.94
Granted in 2007	105,100	11.13	105,100	11.13
Outstanding 31 December 2007	213,683	14.01	463,015	6.47
Granted in 2008	49,000	9.10	49,000	9.10
Outstanding 31 December 2008	240,560	12.41	420,148	7.11
Granted in 2009	116,600	6.32	116,600	6.32
Outstanding 31 December 2009	337,788	10.10	477,340	7.14
Granted in 2010	145,000	2.07	145,000	2.07
Outstanding 31 December 2010	430,998	7.50	560,150	5.77
Granted in 2011	225,000	1.71	225,000	1.71

	Warrants	Weighted average exercise price (EUR)	Potential shares from exercise of warrants	Weighted average exercise price per potential share (EUR)
Outstanding 31 December 2011	558,589	5.29	687,741	4.30
Granted in 2012	326,000	1.60	326,000	1.60
Outstanding 31 December 2012	758,163	3.70	887,315	3.16
Exercisable at 31 December 2012	382,726	5.59	511,878	4.18

# A. Warrant Pool of 2004 for employees, directors, and consultants

By a decision of the extraordinary shareholders' meeting of May 12, 2004, the Company issued 30,000 warrants giving the beneficiaries the right to purchase common shares of the Company. The warrants were granted with an exercise price equal to the fair market price of the underlying common shares at the date of grant.

The warrants were granted to selected beneficiaries by decision of the nomination and remuneration committee and the Board of Directors. Under this plan, 25% of the warrants become exercisable during each year following the date of the grant, it being understood however that no warrants are exercisable unless the beneficiary has provided as least 1 full year of services to the Company. Non-exercisable warrants become exercisable in case of a change of control of the Company. All warrants were granted for free. The duration of the warrants is 5 years from the date of the creation of the warrants. Warrants that have not been exercised within 5 years of their creation become null and void.

29,750 of the 30,000 warrants in this warrant pool have been granted. The 250 non-granted warrants were cancelled. A further 500 of the granted warrants were terminated in 2006 and 4,000 in 2009. The annual general shareholders' meeting of May 23, 2006 modified the warrants of this pool so that they become convertible into 5 common shares upon exercise rather than just 1 share. This was done at the same time as all outstanding shares were split 5-for-1. No warrants remain outstanding or exercisable under this plan at December 31, 2012.

# B. Warrant Pool of 2005 for employees and directors

By a decision of the extraordinary shareholders' meeting of July 12, 2005, the Company issued 15,000 additional warrants giving the beneficiaries the right to purchase common shares of the Company. The warrants were granted with an exercise price equal to the fair market price of the underlying common shares at the date of grant. The warrants were granted to selected beneficiaries by decision of the nomination and remuneration committee and the Board of Directors. Under this plan, 25% of the warrants become exercisable during each year following the date of the grant, it being understood however that no warrants are exercisable unless the beneficiary has provided as least 1 full year of services to the Company. Non-exercisable warrants become exercisable in case of a change of control of the Company. All warrants were granted for free. The duration of the warrants is 5 years from the date of the creation of the warrants. Warrants that have not been exercised within 5 years of their creation become null and void.

All warrants in this warrant pool have been granted. The annual general shareholders' meeting of May 23, 2006 modified the warrants of this pool so that they become convertible into 5 common shares upon exercise rather than just 1 share. This was done at the same time as all outstanding shares were split 5-for-1. No warrants remain outstanding or exercisable under this plan at December 31, 2012.

# C. Warrant pool of March 2006 for employees, directors, and consultants

By a decision of the extraordinary shareholders' meeting of March 22, 2006, the Company issued 66,700 additional

warrants giving the beneficiaries the right to purchase common shares of the Company. The warrants were granted with an exercise price equal to the fair market price of the underlying common shares at the date of grant. The warrants were granted to selected beneficiaries by decision of the nomination and remuneration committee and the Board of Directors. Under this plan, 25% of the warrants become exercisable during each year following the date of the grant, it being understood however that no warrants are exercisable unless the beneficiary has provided as least 1 full year of services to the Company. Non-exercisable warrants become exercisable in case of a change of control of the Company. All warrants were granted for free. The duration of the warrants is 10 years from the date of the creation of the warrants. Warrants that have not been exercised within 10 years of their creation become null and void.

All warrants in this warrant pool have been granted. In 2007, 2,000 of these warrants were cancelled due to the fact that the warrant beneficiaries ceased providing services to the Company, a further 1,337 warrants were cancelled in 2008, and additional 1,101 warrants were also cancelled in 2009. The annual general shareholders' meeting of May 23, 2006 modified the warrants of this pool so that they become convertible into 5 common shares upon exercise rather than just 1 share. This was done at the same time as all outstanding shares were split 5-for-1. The number of outstanding and exercisable warrants under this Plan remains the same at December 31, 2012 as at December 31, 2011.

# D. Warrant pool of November 2006 for employees

By a decision of the Board of Directors' meeting of November 8, 2006, the Company issued 47,500 additional warrants giving the beneficiaries the right to purchase common shares of the Company. The warrants were granted with an exercise price equal to the fair market price of the underlying common shares at the date of grant. The warrants were granted to selected beneficiaries by decision of the nomination and remuneration committee and the Board of Directors. Under this plan, 25% of the warrants become exercisable during each year following the date of the grant (on a straight-line basis, or 6.25% per quarter) it being understood however that no warrants are exercisable unless the beneficiary has provided as least 1 full year of services to the Company. Non-exercisable warrants become exercisable in case of a change of control of the Company. All warrants were granted for free. The duration of the warrants is 10 years from the date of the creation of the warrants. Warrants that have not been exercised within 10 years of their creation become null and void. All warrants in this warrant pool have been granted. In 2007, 938 of these warrants were cancelled due to the fact that the warrant beneficiaries ceased providing services to the Company. A further 2,718 warrants were cancelled in 2010 and 19,156 warrants were cancelled in 2011. A futher 14,000 warrants were cancelled in 2012.

# E. Warrant pool of April 2007 for employees

By a decision of the Board of Directors' meeting of April 18, 2007, the Company issued 55,100 additional warrants giving the beneficiaries the right to purchase common shares of the Company. The warrants were granted with an exercise price equal to the fair market price of the underlying common shares at the date of grant. The warrants were granted to selected beneficiaries by decision of the nomination and remuneration committee and the Board of Directors. Under this plan, 25% of the warrants become exercisable during each year following the date of the grant (on a straight-line basis, or 6.25% per quarter) it being understood however that no warrants are exercisable unless the beneficiary has provided as least 1 full year of services to the Company. Non-exercisable warrants become exercisable in case of a change of control of the Company. All warrants were granted for free. The duration of the warrants is 10 years from the date of the creation of the warrants. Warrants that have not been exercised within 10 years of their creation become null and void. All warrants in this warrant pool have been granted. 10,864 of these warrants were cancelled due to the fact that the warrant beneficiaries ceased providing services to the Company in 2008,2009 and 2010. A further 19,936 warrants were cancelled in 2011, and a further 3,300 warrants were cancelled in 2012.

# F. Warrant pool of May 2007 for directors and consultants

By a decision of the extraordinary shareholders' meeting of May 25, 2007, the Company issued 50,000 additional warrants giving the beneficiaries the right to purchase common shares of the Company. The warrants were granted with an exercise price equal to the fair market price of the underlying common shares at the date of grant. The warrants were granted to selected beneficiaries by decision of the nomination and remuneration committee and the Board of Directors. Under this plan, 25% of the warrants become exercisable during each year following the date of the grant (on a straight-line basis, or 6.25% per quarter) it being understood however that no warrants are exercisable unless the beneficiary has provided as least 1 full year of services to the Company. Non-exercisable warrants become exercisable in case of a change of control of the Company. All warrants were granted for free. The duration of the warrants is 5 years from the date of the creation of the warrants. Warrants that have not been exercised within 5 years of their creation become null and void. In 2010, 10,313 warrants under this Plan were cancelled. In 2012, 14,374 warrants were cancelled.

# G. Warrant pool of May 2008 for employees

By a decision of the Board of Directors' meeting of May 30, 2008, the Company issued 61,000 additional warrants giving the beneficiaries the right to purchase common shares of the Company. The warrants were granted with an exercise price equal to the fair market price of the underlying common shares at the date of grant. The warrants were granted to selected beneficiaries by decision of the nomination and remuneration committee and the Board of Directors. Under this plan, 25% of the warrants become exercisable during each year following the date of the grant (on a straight-line basis, or 6.25% per quarter) it being understood however that no warrants are exercisable unless the beneficiary has provided as least 1 full year of services to the Company. Non-exercisable warrants become exercisable in case of a change of control of the Company. All warrants were granted for free. The duration of the warrants is 10 years from the date of the creation of the warrants. Warrants that have not been exercised within 10 years of their creation become null and void. All warrants in this warrant pool have been granted. In 2008, 2009 and 2010 respectively, 875, 8,625 and 7,188 of these warrants were cancelled due to the fact that the warrant beneficiaries ceased providing services to the Company. In 2011, 4,874 warrants were cancelled, and 938 further warrants were cancelled in 2012.

# H. Warrant pool of January 2009 for employees

By a decision of the Board of Directors' meeting of January 27, 2009, the Company issued 120,500 additional warrants giving the beneficiaries the right to purchase common shares of the Company. The warrants were granted with an exercise price equal to the fair market price of the underlying common shares at the date of grant. The warrants were granted to selected beneficiaries by decision of the nomination and remuneration committee and the Board of Directors. Under this plan, 25% of the warrants become exercisable during each year following the date of the grant (on a straight-line basis, or 6.25% per quarter) it being understood however that no warrants are exercisable unless the beneficiary has provided as least 1 full year of services to the Company. Non-exercisable warrants become exercisable in case of a change of control of the Company. All warrants were granted for free. The duration of the warrants is 10 years from the date of the creation of the warrants. Warrants that have not been exercised within 10 years of their creation become null and void. The 3,900 non-granted warrants were cancelled in 2009. In 2010, 22,657 warrants were cancelled under this Plan, and a further 34,692 warrants were cancelled in 2011. A further 27,251 warrants were cancelled in 2012.

# <u>I. Warrant pool of May 2010 for certain directors</u>

By a decision of the extraordinary general shareholders' meeting of June 21, 2010, the Company issued 145,000 additional warrants giving the beneficiaries the right to purchase common shares of the Company. The warrants were

granted with an exercise price equal to the fair market price of the underlying common shares at the date of grant. Under this plan, 25% of the warrants become exercisable during each year following the date of the grant (on a straight-line basis, or 6.25% per quarter) it being understood however that no warrants are exercisable unless the beneficiary has provided as least 1 full year of service (as director) to the Company. Non-exercisable warrants become exercisable in case of a change of control of the Company. All warrants were granted for free. The duration of the warrants is 5 years from the date of the creation of the warrants. Warrants that have not been exercised within 5 years of their creation become null and void. All 145,000 warrants were granted to a group of four new directors of the Company, including the CEO. In 2011, 3,750 warrants were cancelled and a further 1,250 warrants were cancelled in 2012.

# J. Warrant pool of April 2011 for employees

By a decision of the Board of Directors' meeting of May 27, 2011, the Company issued 225,000 additional warrants giving the beneficiaries the right to purchase common shares of the Company. The warrants were granted with an exercise price equal to the fair market price of the underlying common shares at the date of grant. The warrants were granted to selected beneficiaries by decision of the nomination and remuneration committee and the Board of Directors. Under this plan, 25% of the warrants become exercisable during each year following the date of the grant (on a straight-line basis, or 6.25% per quarter) it being understood however that no warrants are exercisable unless the beneficiary has provided as least 1 full year of services to the Company. The exception to this was that the CEO's 30,000 warrants under this Plan became immediately vested even though he had provided less than 1 year of service. Non-exercisable warrants become exercisable in case of a change of control of the Company. All warrants were granted for free. The duration of the warrants is 10 years from the date of the creation of the warrants. Warrants that have not been exercised within 10 years of their creation become null and void. All warrants were granted. In 2011, 15.000 warrants were cancelled under this Plan. A further 36,875 warrants were cancelled in 2012.

# K. Warrant pool of March 2012 for employees (mainly) and, in addition, to certain consultants.

By a decision of the Board of Directors' meeting of March 15, 2012, the Company issued 195,000 additional warrants giving the beneficiaries the right to purchase common shares of the Company. The warrants were granted with an exercise price equal to the fair market price of the underlying common shares at the date of grant. The warrants were granted to selected beneficiaries by decision of the nomination and remuneration committee and the Board of Directors. Under this plan, 25% of the warrants become exercisable during each year following the date of the grant (on a straight-line basis, or 6.25% per quarter) it being understood however that no warrants are exercisable unless the beneficiary has provided as least 1 full year of services to the Company. Non-exercisable warrants become exercisable in case of a change of control of the Company. All warrants were granted for free. The duration of the warrants is 10 years from the date of the creation of the warrants. Warrants that have not been exercised within 10 years of their creation become null and void. In 2012, 18,125 warants were cancelled under this Plan.

#### L. Warrant pool of May 2012 for employees (mainly) and, in addition for certain directors and consultants

By a decision of the extraordinary general shareholders' meeting of June 15, 2012, the Company issued 700,000 additional warrants giving beneficiaries the right to purchase common shares of the Company. The warrants are to be granted either to selected employees, with an exercise price determined by the board of directors and equal to at least the fair market price of the underlying common shares at the date of grant, or to selected non-employees, with an exercise price equal to the higher of (i) the average price of the shares on Euronext during the period of 30 days preceding the date of issuance of the stock options and (ii) the average price of the shares on Euronext during the 30 days preceding the date grant of the stock options. In total, 131,000 warrants were granted out of this pool in 2012. On the one hand, 95,000 warrants were granted to selected employees and consultants by decision of the nomination

and remuneration committee and the Board of Directors, respectively on September 14, 2012 (85,000 warrants) and December 1, 2012 (10,000 warrants). On the other hand, 36,000 warrants were granted to selected directors on August 15, 2012. Under this plan, 25% of the warrants granted to selected participants who are not directors of the company become vested in instalments of 25% per year during a period of 4 years as of the date of grant (being it understood that during the first year after the date of grant, 25% of the stock options shall vest on the first anniversary date of the date of grant and that during the second, third and fourth years after the date of grant, the stock options granted shall vest on a quarterly basis). Warrants granted to selected participants who are directors are granted shall all vest on the date of the annual shareholders' meeting that takes place in the calendar year following the calendar year where the Stock Options were granted, provided that on the date preceding the date of the former annual shareholders' meeting the mandate of such (non executive) selected director has not terminated. Such warrants are exercisable in conformity with the exercisability and exercise period provisions defined in the May 2012 Stock Option Plan. Non-exercisable warrants become exercisable in case of a change of control of the Company. All warrants were granted for free. The duration of the warrants is 10 years from the date of issuance of the warrants. Warrants that have not been exercised within 10 years of their issuance become null and void.

The following table provides an overview of the outstanding warrants per personnel category at December 31, 2012:

Category	Number of warrants
Executive Director	205,000
Non-Executive Directors	61,000
Management team (excluding the Executive Director)	215,000
Other employees, consultants, and former service providers	406,315
Total outstanding at December 31, 2012	887,315

# M. Accounting for share-based payment

The warrants have been accounted for in accordance with International Financial Reporting Standard 2 Share-based payment. IFRS 2 takes effect for all warrants.

The share-based compensation expense recognized in the income statements as such is given below as is the cumulated balance sheet amount:

Thousands of EUR / Years ended December 31	2012	2011	2010
Share-based compensation	182	234	170
Cumulated Share-based compensation	2,567	2,385	2,151

The Cumulated Share-based compensation amount is part of the Total Shareholders' Equity on the balance sheet. This amount is presented on the balance sheet for both exercised and non-exercised warrants.

The weighted average exercise price of all outstanding warrants (vested and non-vested warrants; assuming 1 warrant = 1 share) is EUR 3.16. The weighted average exercise price of all outstanding vested warrants (assuming 1 warrant = 1 share) is EUR 4.18. The weighted average remaining contractual life of all outstanding warrants at the end of 2012 is 6.40 years.

The fair value of each warrant is estimated on the date of grant using the Black-Scholes methodology with the following assumptions:

After stock split 5:1	Warrants 2006 granted March 21, 2006		·	Warrants 2005 granted July 12, 2005		Warrants 2004 granted May 12, 2004	
	to Belgian beneficiaries	to other beneficiaries	to Belgian beneficiaries	to other beneficiaries	to Belgian beneficiaries	to other beneficiaries	
Number of warrants granted	201,250	132,250	50,000	25,000	28,750	120,000	
Exercise price (EUR)	4.80	4.80	4.77	4.77	4.46	4.46	
Expected dividend yield	0%	0%	0%	0%	0%	0%	
Expected stock price volatility	51%	51%	51%	51%	51%	51%	
Risk-free interest rate	3.25%	3.25%	3.25%	3.25%	3.25%	3.25%	
Expected duration (months)	88.4	54.4	43.7	40.7	51.7	48.1	

After stock split 5:1	Warrants 2007 granted May 25, 2007			Warrants 2007 Granted January 4, 2007		Warrants 2006 granted October 2, 2006	
	to Belgian beneficiaries	to other beneficiaries	to Belgian beneficiaries	to other beneficiaries	to Belgian beneficiaries	to other beneficiaries	
Number of warrants granted	15,000	35,000	22,100	23,000	19,500	28,000	
Exercise price (EUR)	11.42	11.42	10.87	10.87	7.72	7.72	
Expected dividend yield	0%	0%	0%	0%	0%	0%	
Expected stock price volatility	65%	65%	65%	65%	65%	65%	
Risk-free interest rate	4.41%	4.41%	4.41%	4.41%	4.41%	4.41%	
Expected duration (months)	55.3	37.2	87.0	68.9	84.0	72.0	

After stock split 5:1	Warrants 2010 Granted June 21, 2010			Warrants 2009 Granted January 2, 2009		Warrants 2008 Granted May 30, 2008	
	to Belgian beneficiaries	to other beneficiaries	to Belgian beneficiaries	to other beneficiaries	to Belgian beneficiaries	to other beneficiaries	
Number of warrants granted	135,000	10,000	63,400	53,200	12,000	37,000	
Exercise price (EUR)	2.07	2.07	6.32	6.32	9.10	9.10	
Expected dividend yield	0%	0%	0%	0%	0%	0%	
Expected stock price volatility	76.17%	76.17%	57.24%	57.24%	52.30%	52.30%	
Risk-free interest rate	3.40%	3.40%	3.98%	3.98%	4.92%	4.92%	
Expected duration (months)	51.35	33.34	74.08	62.88	82.1	61.1	

After stock split 5:1	Gra	Warrants 2011 nted May 27, 2011	Warrants 201 Granted March 15, 201		
	to Belgian beneficiaries	to other beneficiaries	to Belgian beneficiaries	to other beneficiaries	
Number of warrants granted	100,000	125,000	75,000	120,000	
Exercise price (EUR)	1.71	1.71	1.72	1.72	
Expected dividend yield	0%	0%	0%	0%	
Expected stock price volatility	68.81%	68.81%	67.74%	67.74%	
Risk-free interest rate	4.15%	4.15%	3.43%	3.43%	
Expected duration (months)	76.21	58.19	78.57	60.56	

After stock split 5:1	Grante	Warrants 2012 d August 15, 2012	Granted Se	Warrants 2012 eptember 14, 2012
	to Belgian beneficiaries	to other beneficiaries	to Belgian beneficiaries	to other beneficiaries
Number of warrants granted	12,000	24,000	0	85,000
Exercise price (EUR)	1.52	1.52	1.65	1.65
Expected dividend yield	0%	0%	0%	0%
Expected stock price volatility	54.50%	54.50%	55.58%	55.58%
Risk-free interest rate	2.57%	2.57%	2.59%	2.59%
Expected duration (months)	73.54	61.54	72.56	60.56

After stock split 5:1	Granted	Warrants 2012 December 1, 2012
	to Belgian beneficiaries	to other beneficiaries
Number of warrants granted	0	10,000
Exercise price (EUR)	2.19	2.19
Expected dividend yield	0%	0%
Expected stock price volatility	57.13%	57.13%
Risk-free interest rate	2.19%	2.19%
Expected duration (months)	75.98	57.99

The weighted average risk-free interest rates used are based on Belgian Sovereign Strips at the date of grant with a term equal to the expected life of the warrants.

The expected volatility was determined using the average volatility of the stock over the last two years at the date of the grant date when sufficient data were available or using the average volatility of the sector when these data were not available.

# 5.1.5.20. Related parties

Transactions between MDxHealth SA, MDxHealth Inc., MDxHealth PharmacoDx BVBA and OncoMethylome Sciences BV, which are related parties, have been eliminated in consolidation and are not disclosed in this note. The intercompany services between the four 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. In 2012, the services charged by the subsidiaries to the parent company amounted to EUR 0.3 million.

Transactions between the Company and its employees, consultants or directors are disclosed below.

There were no other related party transactions.

Remuneration of key management personnel

At December 31, 2012, the executive management team comprised 4 members:

1. Chief Executive Officer and Executive Director, Dr. Jan Groen

- 2. Executive Vice President of Corporate and Legal Affairs, Mr. Joseph Sollee
- 3. Executive Vice President of Finance, Mr. Francis Ota
- 4. Excutive Vice-President of Commercial Operations, Mr. Christopher Thibodeau

Their combined remuneration package, including employer taxes, amounted to the following (all warrant and share data for all years reflect the May 23, 2006 5-for-1 stock split and related change to the warrant plans):

Thousands of EUR except per personnel, warrants & share amounts / Years ended December 31	2012	2011	2010
Number of management members and Executive Directors	4	4	5
Short-term employee benefits	1,296	1,181	742
Post-employment benefits	32	28	19
Other employment costs	70	58	115
Total benefits	1,398	1,267	876
IFRS share-based compensation expense	82	88	63
Outstanding receivables from persons	0	0	0
Outstanding payables to persons	0	0	8
Shares owned	0	0	10,000
Number of warrants offered	120,000	145,000	130,000
Cumulative outstanding warrants	395,000	317,190	172,190
Exercisable warrants	222,501	147,504	29,822
Exercised warrants	0	0	0

In 2012, as an aggregate for the group comprised by the 4 executive managers, no warrants were exercised, 120,000 new warrants were granted and accepted (for an annualized IFRS cost of EUR 48 thousand), and no shares were sold.

In 2011, as an aggregate for the group comprised by the 4 executive managers, no warrants were exercised, 145,000 new warrants were granted and accepted (for an annualized IFRS cost of EUR 57 thousand), and no shares were sold. The above table does not include the 100,000 new warrants that were granted by the Board of Directors to 3 of the 4 executive managers in December 2011 but which were only issued and created in March 2012.

In 2010, as an aggregate for the group comprised by the 5 executive managers, no stock options were exercised, 130,000 new stock options were granted and accepted by the CEO (for an annualized IFRS cost of EUR 9 thousand), and no shares were sold.

No loans, quasi-loans or other guarantees are outstanding with members of the executive management team.

# Transactions with Non-Executive Directors

Since 2012, The Non-Executive and non-independent directors do not receive a fee payment for attending and preparing for board meetings, for assisting the Company with Board matters. They receive reimbursement for expenses directly related to the board meetings for a total of EUR 4,000 in 2012.

In 2011 and 2010, respectively EUR 32,000, and EUR 34,000 were paid as fees and reimbursement for expenses to these

Non-Executive non-independent members of the Board of Directors for attending and preparing for board meetings, for assisting the Company with Board matters and for expenses reimbursement.

The independent directors receive a fee for attending and preparing meetings of the Board of Directors, for assisting the Company with Board matters, and they receive reimbursement for expenses directly related to the board meetings. In 2012, 2011, and 2010, respectively EUR 134,000, EUR 87,000 and EUR 128,000 were paid as fees and expense reimbursement to independent members of the Board of Directors.

36,000 warrants were granted to Non-Executive Directors in 2012. No warrants were exercised in 2012.

# 5.1.5.21. Significant agreements, commitments and contingencies

#### A. Collaborative research agreements and clinical research agreements

The Company has entered into numerous agreements with universities, medical centers and external researchers for research and development work and for the validation of the Company's technology and products. These agreements typically have durations of one to three years. The Company must pay fixed fees to the collaborators and in exchange receives access and rights to the results of the work.

# B. Intellectual property in-licensing agreements

The Company has entered into numerous agreements with universities and companies for in-licensing intellectual property. These agreements typically require the Company to pay an up-front fee, annual maintenance fees and/or minimum annual royalty fees, legal fees related to the patents, and certain milestone and royalty fees if the patents are eventually used in a commercialized product. In addition, the Company must provide the licensor with periodic reports.

# C. Commercial and intellectual property sub-licensing agreements

The Company has entered into numerous partnering and sub-licensing agreements.

#### PharmacoDx Partners

MDxHealth collaborates with a range of pharmaceutical companies in the identification and development of biomarkers for potential use as companion diagnostics for their therapeutic drugs or vaccines. MDxHealth usually derives revenues from providing R&D and clinical testing services to these partners. The identity of these partners is not always disclosed. In addition to the pharmaceutical collaborations described in detail below, MDxHealth has entered into collaborations in this manner with other pharmaceutical companies such as Abbott Laboratories, F. Hoffmann-La Roche Ltd., Pfizer and Merck/Schering-Plough.

# **Merck Serono**

In 2008, MDxHealth entered into a licensing and testing agreement with Merck KGaA of Darmstadt, Germany (now Merck Serono). Under the terms of the agreement, MDxHealth provided MGMT gene promoter methylation testing services for Merck's clinical trial program of Cilengitide. The MDxHealth MGMT test has been used in two Merck clinical trials together with its drug Cilengitide for patients with newly diagnosed brain tumors (glioblastomas), including a Phase III clinical trial (CENTRIC) and Phase II clinical trial (CORE). Patient selection for these Merck trials was based on the MGMT gene promoter methylation status of their tumor tissue.

In 2012, MDxHealth entered into an expanded collaboration agreement with Merck KGaA for the commercial development of MDxHealth's MGMT diagnostic test as a companion diagnostic to Merck's drug candidate Cilengitide.

However, Merck has recently announced that the Phase III trial for Cilengitide did not meet primary endpoints, and therefore it is unlikely that Merck will continue its development of Cilengitide or its support for the development and commercialization of the Company's MGMT test as an FDA-approved companion diagnostic to Cilengitide. Merck's discontinuation of its development support will have a material negative impact on the Company's potential revenues from this commercial project.

# Pfizer, Inc. (transferred to Clovis Oncology)

In 2010, MDxHealth entered into a collaboration agreement with Pfizer to pursue the identification and development of an MDxHealth biomarker predicting response to Pfizer's cancer drug candidate for PARP inhibition, PF-01367338. Newcastle University (UK) is also participating in the collaboration. The collaboration is assessing the potential to develop an MDxHealth test as a companion diagnostic test to guide treatment decisions in treatment of ovarian and breast cancers with the Pfizer drug candidate.

Under the terms of the agreement, MDxHealth is providing marker discovery, assay development and clinical trial testing services to Pfizer, and will retain rights to the eventual commercial companion diagnostic test. In addition, the partners have announced their mutual intention to ultimately set up a high throughput platform that is clinically validated to rapidly test for epigenetic defects in key DNA damage repair (DDR) genes to support the design and implementation of clinical trials to enable the development of optimized, targeted therapies.

During the course of 2011, Pfizer transferred the PARP program and the related companion diagnostic program to Clovis Oncology.

# GlaxoSmithKline Biologicals (GSK)

In 2010, MDxHealth expanded its existing relationship with GlaxoSmithKline Biologicals (GSK) to pursue the development and testing of new companion diagnostic tests that can potentially be used with GSK's immunotherapeutic oncology program. MDxHealth's collaboration with GSK was initiated in 2007 under a Wallonia-BioWin grant concerning mutual research in the immunotherapeutic oncology field. Under the expanded agreement signed in 2010, GSK is collaborating with MDxHealth to assess the potential use of one of MDxHealth's DNA methylation specific PCR biomarkers in GSK's immunotherapy development program.

# Molecular Diagnostics Partners

# **Exact Sciences**

In 2010, MDxHealth entered into an exclusive license agreement with Exact Sciences Corporation for stool-based screening of colorectal cancer. Under the terms of the agreement, Exact Sciences obtained exclusive, worldwide rights to use up to two of MDxHealth's DNA methylation biomarkers in stool-based detection of colorectal cancer, as well as non-exclusive access to MDxHealth's MSP platform technology for use with those biomarkers. In return, MDxHealth received an upfront license payment and is entitled to receive, subject to certain conditions, milestone payments and royalties on net sales.

In January 2011, following Exact Sciences' completion of preliminary studies, MDxHealth announced the election by Exact Sciences to include an MDxHealth methylation biomarker, together with MDxHealth's MSP platform technology, in Exact Sciences' ColoGuard stool-based DNA colon cancer screening test. This confirmation triggered a milestone payment to MDxHealth from Exact Sciences.

#### Veridex

In December 2010, MDxHealth entered into two non-exclusive licenses with Veridex LLC (a Johnson & Johnson Company) for the use of certain of MDxHealth's proprietary DNA methylation products in colorectal and prostate cancer screening. Under the agreements, Veridex licensed non-exclusive rights for the performance of service testing at its own laboratories worldwide using MDxHealth's DNA methylation biomarkers for use in blood-based detection of colorectal cancer, as well as tissue- and urine-based detection of prostate cancer. In return, MDxHealth is entitled to receive, subject to certain conditions, milestone payments and royalties on net sales. The new license agreements replace prior agreements first entered into with Veridex LLC in 2004 granting exclusive worldwide rights to prostate cancer testing services and kits. These license grants to Veridex were the result of an agreement between MDxHealth and Ortho-Clinical Diagnostics, Inc. (OCD, a Johnson & Johnson Company) that was entered into in 2003, when MDxHealth acquired certain methylation markers and technology from Tibotec-Virco (a Johnson & Johnson Company). Under the terms of this 2003 agreement, MDxHealth agreed to first offer to OCD the exclusive right to license, at commercially reasonable terms, any product in the human in vitro diagnostics field that contains those technology components that were once owned by Tibotec-Virco. Since 2003, MDxHealth has offered products under this first right to license option in the fields of prostate, lung, colon, cervical, brain and bladder cancer, of which Veridex has exercised its license rights only for Prostate and blood-based colon, each on a non-exclusive basis for service testing.

#### LabCorp

In 2008, MDxHealth granted to Laboratory Corporation of America (LabCorp) a royalty bearing sublicense to the MGMT test (exclusive license for the North American market only, of indefinite duration, and for service testing only) and entered into an agreement to supply reagents to LabCorp for its colorectal cancer screening test (ColoSure). In 2007, LabCorp obtained a non-exclusive license to perform laboratory-based diagnostic testing services in North America on prostate tissue samples using selected MDxHealth DNA methylation biomarkers. In 2008, LabCorp began to commercialize the three afore-mentioned tests in North America.

#### **Predictive Biosciences**

In 2010, MDxHealth entered into an exclusive license agreement with Predictive Biosciences for diagnostic applications in bladder cancer. Under the terms of the agreement, Predictive Biosciences obtained exclusive rights in the United States for the use of a number of MDxHealth's DNA methylation biomarkers in bladder cancer testing of urine, blood and other bodily fluids. MDxHealth retained exclusive worldwide rights to these markers in tissue-based bladder cancer tests. In return, MDxHealth received an upfront license payment and is entitled to receive, subject to certain conditions, milestone payments and royalties on net sales.

# **PLUS Diagnostics**

In April 2012, MDxHealth entered into an agreement to co-promote MDxHealth's *Confirm*MDx<sup>™</sup> for Prostate Cancer assay in the United States. PLUS Diagnostics, a leading U.S. anatomic pathology company that offers a full range of multi-specialty services will build awareness of *Confirm*MDx<sup>™</sup> for Prostate Cancer through its national network of urologists.

### **D.** Litigation

MDxHealth is not involved in any legal proceedings. To date, the only legal proceedings that MDxHealth has been

involved in was a case filed against MDxHealth, Inc. in 2011. This case involved a US employee whose employment contract was terminated in 2011. The case was resolved prior to commencement of any formal court proceedings and without any material financial impact on the Company.

#### E. Grants

Since its incorporation, MDxHealth has been awarded multiple grants from the Belgian regional governments, from the European Union, and from the Dutch government.

To date, MDxHealth has been approved for a total of EUR 9.3 million in grants and has received grant payments for a total of EUR 8.9 million. A total of EUR 9.3 million has already been recognized as revenues in the period 2004-2012. If the Company respects the conditions of the already approved grants, the Company stands to receive a further EUR 0.3 million in grant payments. The total revenue generated by the grants was EUR 883 thousand in 2012.

The main active grants are the following:

(1) Name (2) Source (3) Description (4) Applicability	Start Date	End Date	Amount Approved (EUR)	Amount Received (EUR)	Main Conditions
(1) <b>Lung 3 - extension</b> (2) Belgian government (Wallonia), (3) R&D for early detection of lung cancer (4) covers mainly personnel and sample collection costs	1/9/2011	31/08/2012	411,110	308,333	Respect plans and budget. Comments: Project full start-up only occurred in 2012, thus no revenue from project recognized in 2011
(1) <b>CTMM Decode</b> (2) Dutch government – SenterNovem (3) research and development into colon cancer detection test (4) covers part of personnel/lab costs, equipment costs, and sample collection costs	1/9/2008	31/08/2013	189,016	148,954	Respect plans and budget. Comments: Remainder of grant unlikely to be used
(1) CTMM Airforce (2) Dutch government – SenterNovem (3) research and development into lung cancer and head & neck cancer detection test (4) covers part of personnel/lab costs, equipment costs, and sample collection costs	1/10/2008	30/09/2013	100,000	42,184	Respect plans and budget. Comments: Remainder of grant unlikely to be used
(1) <b>Eurotransbio</b> (2) Belgian government (Wallonia), (3) R&D for biomarkers used for assessing aggressiveness of bladder cancer (4) covers mainly personnel and sample collection costs	1/9/2010	30/11/2012	770,000	626,423	Respect plans and budget. Comments: Project full start-up only occurred in Q1 2011, thus no revenue from project recognized in 2010
(1) <b>Eurostars</b> (2) Belgian government (Wallonia), (3) R&D for cervix cancer (4) covers mainly personnel and sample collection costs	1/9/2011	31/08/2012	162,015	60,756	Respect plans and budget.

In October 2008, the subsidiary of MDxHealth based in the Netherlands was approved for a 5-year project called CTMM AirForce for R&D into lung and head&neck cancer applications. MDxHealth needs to make certain contributions to the project and received certain grant payments. Since the project cannot be interrupted by request of the Dutch government and since MDxHealth does not believe the project will generate any positive results, MDxHealth decided

in 2010 and in 2011 to expense all the contributions MDxHealth must make to the project over its remaining term. Any grants MDxHealth may receive in the remaining term of the project will be recognized as income in the corresponding remaining term of the project.

The grants are subject to periodic reporting on the status of the projects and on the costs incurred to date by the project. The approved amounts are the maximum amounts the Company stands to receive. If the Company spends less on the projects than the original budget or deviates from the plans without consent, then it risks receiving lower grant payments than the amounts that were initially approved.

When a government grant is allocated, the Company books the full amount as both a receivable and a payable. No income is recognized when the grant is approved, but is fully deferred at that point. When it is received, the receivable is reduced by the amount. When the grant is recognized as income, the payable is reduced by the amount. The grant is only recorded as a payable/receivable when (i) the grant has been approved by the granting party, (ii) the amounts are measurable, and (iii) the Company believes it will meet the conditions necessary to be able to receive/use the grant.

# 5.1.5.22. Subsequent events

In 2013, through the date of this document, the Company made the following normal course of business announcements:

- MDxHealth announced the publication of results from a large clinical study on its epigenetic *Confirm*MDx<sup>™</sup> for Prostate Cancer test in the March 2013 issue of Journal of Urology. The blinded, multicenter study named MATLOC (Methylation Analysis To Locate Occult Cancer was conducted at University of Edinburgh Urological Cancer Group in the U.K., the University Hospital of Liege, Belgium, and the Institut de Genetique et Pathologie in Gossellies, Belgium. The result demonstrate the utility of the *Confirm*MDx<sup>™</sup> test as a powerful tool to address well-documented concerns over false-negative biopsy results.
- MDxHealth presented two important studies involving *Confirm*MDx<sup>™</sup> for Prostate Cancer at the ASCO Genitourinary Cancers Symposium 2013. The two studies were the "Epigenetic Field Effects for DNA Methylation Markers Extend Over Multiple Histological Benign Prostate Biopsy Cores" by Sandra M Gaston, PhD of New England Baptist Hospital, Harvard Medical School, and "Multi-gene Epigenetic MSP Assay Predicts Risk for Prostate Cancer in Histopathologically Negative Biopsies" by Leander van Neste PhD, MDxHealth SA, Liege, Belgium. Both these studies showed that *Confirm*MDx<sup>™</sup> for Prostate Cancer test provides very important personalized information that cannot be achieved with traditional procedures.
- MDxHealth announced the publication of results from a health economic study in the Journal of American Health & Drug Benefits. The budget impact analysis demonstrated achievable cost savings of MDxHealth's *Confirm*MDx™ for Prostate Cancer test, which is used by urologists to identify men who may avoid unnecessary repeat prostate biopsies, thereby reducing overall healthcare spending.
- Collections related to 2012 billings of *Confirm*MDx<sup>™</sup> for Prostate Cancer test received in 2013 through mid February were over \$150K, of which a portion was recorded as part of 2012 revenues as a subsequent event.
- A collections analysis completed in January 2013 identified six private insurance payors who presented a consistent pattern of payments and qualified under the company's revenue recognition policy to be treated under accrual revenue accounting.

• Merck KGaA announced in February 2013 that its Phase III clinical study with cilengitide in newly diagnosed glioblastoma did not meet its primary endpoints. MDxHealth had been providing an MGMT (methylguanine-DNA methyltransferase) diagnostic test, *Predict*MDx<sup>™</sup> for Glioblastoma, that was used in the clinical study to identify and stratify those glioblastoma patients who may be more likely to benefit from cilengitide treatment.

# 5.1.5.23. Reconciliation between the consolidated financial statements under local GAAP and IFRS

The Company presents the financial statements under IFRS for the previous three years. The date of transition for the Company is as such January 1, 2003. The Board of Directors decided to start preparing and filing the Company's consolidated financial statements under IFRS as of December 31, 2005 and thereafter.

The statutory annual accounts presented under section 6 are prepared on a non-consolidated basis and under local (Belgian) GAAP.

Equity reconciliation and profit & loss reconciliation between local GAAP and IFRS (on a consolidated basis)

		2012	2011			2010
Thousands of EUR / Years ended December 31	Equity	Loss of the year	Equity	Loss of the year	Equity	Loss of the year
Under Belgian GAAP	12,136	(9,394)	11,348	(7,570)	10,761	(8,100)
Purchase of intangible assets	(7,035)		(7,035)		(7,035)	
Depreciation of intangible assets	7,016	9	7,007	10	6,997	17
Share-based compensation		(182)		(234)		(170)
Deduction of IPO costs		352		847		
CTD adjustment		204				
Elim. of P/L liquidation		35				
Total restatements	(19)	418	(28)	623	(38)	(153)
Under IFRS	12,117	(8,976)	11,320	(6,947)	10,723	(8,253)

- In the statutory accounts the costs related to certain research and development had been previously capitalized and amortized on a straight-line basis over a period of 5 years, starting at January 1, 2003. In the IFRS statements development costs are capitalized to the extent that all conditions for capitalization have been satisfied (to date and currently no R&D is capitalized in the Company's IFRS accounts). To align the statutory accounts with those in the consolidated IFRS accounts, in 2009, the Company decided to fully expense the research and development costs that were previously capitalized in the statutory accounts. This change has no impact on the consolidated IFRS accounts.
- Under Belgian GAAP no employee benefit expense is recognized for stock offered to employees and other beneficiaries. Under IFRS 2 Share-based Payment, the entity shall measure a compensation expense for the fair value of the services received from employees and others providing similar services by reference to the fair value of the equity instruments granted. There is no net impact on equity as for equity-settled share-based payment transactions under IFRS 2, the compensation expense is recorded by a corresponding increase in equity.

#### 5.1.5.24. Disclosure under Article 114 of the Royal Decree dated January 30, 2001 implementing the Belgian Company Code

### **Subsidiaries**

The Company has one wholly-owned subsidiary, as follows:

MDxHealth Inc.	
Address	15279 Alton Parkway – Suite 100 – Irvine, CA 92618
Incorporation Date	April 14, 2003
Number of employees	50 at December 31, 2012, 13 at December 31, 2011, 6 employees at December 31, 2010

#### Remuneration of the board

The total remuneration of the Board of Directors (including the Executive Director) in 2012, 2011 and 2010 was EUR 597,000, EUR 645,000 and EUR 436,000 respectively (excluding VAT, stock-based compensation and expenses reimbursement). No advances or credits have been granted to any member of the Board of Directors. None of the members of the Board of Directors have received any non-monetary remuneration other than warrants as disclosed above.

# 5.2. MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion pertains to the consolidated financial statements of the Company which have been prepared in accordance with International Financial Reporting Standards (IFRS) as developed and published by the International Accounting Standards Board (IASB). The financial statements can be found in section 5.1 of this document.

# Results of Operations for the Year Ended December 31, 2012 compared to Year Ended December 31, 2011 Revenues

Total revenues increased from EUR 2,687,000 in 2011 to EUR 4,602,000 in 2012, an increase of 71%. Revenues are derived from commercial product sales, services, or royalties and from grants. Commercial revenues in 2012 increased by 102%, from EUR 1,838,000 in 2011 to EUR 3,719,000 in 2012 mainly as a result of milestones generated by pharmacogenomic activity. Grant revenue increased by 4% in 2012, from EUR 849,000 in 2011 to EUR 883,000 in 2012, as the Company was awarded 1 new grants in 2012 and completed the work on all current projects.

Substantially all of the Company's revenues have been derived from commercial license agreements, from pharmacogenomic contracts and from government grants. The commercial revenues include up-front fees and milestone fees (which are irregular in terms of the timing and amounts) and testing fees, contract research fees, and royalties on sales of products licensed to third parties.

Given the *Confirm*MDx<sup>™</sup> for Prostate Cancer assay was recently introduced to the market in 2012, the company's revenue recognition policy has limited the amount of revenue recognized in 2012, with *Confirm*MDx<sup>™</sup> for Prostate Cancer revenue representing a small portion (less than 10%) of the Company's total revenue. Of the reported revenue for the *Confirm*MDx<sup>™</sup> for Prostate Cancer assay in 2012, 80% is based on a cash collection basis. Given that the volume of billable cases is larger than the collection volumes, there exists unrecognized revenue potential not reflected in the financial statements. These unrecognized transactions will most likely impact revenues in future months as they either are collected or the payment pattern for given 3rd party payors warrants accrual accounting treatment for these 2012 transactions per the company's revenue recognition policy.

The Company has been awarded EUR 9.3 million in grants and subsidies since its inception of which EUR 883,000 have been recorded as revenues in 2012. Grants recorded in 2012 represent 19% of total revenues and were received from the Belgian government primarily for development work on lung cancers, bladder cancers and cervical cancers. Grants awarded generally take the form of refunds of specific expenses incurred in connection with approved scientific research activities.

# Cost of goods and services sold

The costs of goods include royalties MDxHealth must pay to third parties and the costs associated with providing testing services to third parties. The cost of goods was higher in 2012 than in 2011, as a result of the start of the CLIA activity generated by the launch of  $ConfirmMDx^{m}$  for Prostate Cancer.

# Research and development expenses

Research and development expenses were EUR 4,805,000 in 2011 compared to EUR 5,282,000 in 2012, an increase of 10%. The main reasons for the increase in the R&D expenditures in 2012 are the following: (i) ) the development of MGMT test as a companion diagnostic for Merck KGgA's Cilengitide cancer drug; (ii) enhancements to the *ConfirmMDx*™ for Prostate Cancer test; (iii) and other development work for pharmaceutical clients.

Thousands of EUR / Years ended December 31	2012	2011
Personnel costs	2,449	1,985
Lab consumables	639	465
External research and development collaborators	1,526	1,462
Patents and licenses	0	0
Depreciation & amortization	343	276
Other expenses	325	617
Total	5,282	4,805

# Selling, general and administrative expenses

In 2012, selling, general and administrative expenses amounted to EUR 7,462,000 compared to EUR 4,785,000 in 2011, an increase of 56%. The increase in costs is largely due to building U.S. the product development, marketing, quality, and administrative functions in relation to the set-up of the CLIA laboratory in California and the hiring of the direct sales force for the launch of the  $ConfirmMDx^{TM}$  for Prostate Cancer test in H1 2012. The detail of the administrative and selling expenses is as follows:

Thousands of EUR / Years ended December 31	2012	2011
Personnel costs	3,815	2,311
Depreciation	54	39
Professional fees	1,363	1,345
Other expenses	1,869	727
Patent expenses	361	363
Total	7,462	4,785

#### Financial results

In 2012, the Company ended the year with a net financial loss of EUR 69,000 while it recorded a net financial gain of EUR 150,000 in 2011. MDxHealth earned EUR 66 thousand of interest income and financial gains in 2012 compared to EUR 153 thousand in 2011. The net financial loss is also impacted by the currency exposure to USD.

#### **Net loss**

The net loss was EUR 8,976,000 in 2012 compared to EUR 6,947,000 in 2011, an increase of 29%. This increase is due primarily to a increase in operating costs caused by the set-up of the CLIA laboratory in California to support the commercial development of the company.

# Results of Operations for the Year Ended December 31, 2011 compared to Year Ended December 31, 2010

#### Revenues

Total revenues increased from EUR 2,536,000 in 2010 to EUR 2,687,000 in 2011, an increase of 6%. Revenues are derived from commercial product sales, services, or royalties and from grants. Commercial revenues in 2011 decreased by 7%, from EUR 1,968,000 in 2010 to EUR 1,838,000 in 2011 mainly as a result in the timing of one-time fees and milestones and the timing of certain trial of pharmaceutical partners. Grant revenue increased by 49% in 2011, from EUR 568,000 in 2010 to EUR 849,000 in 2011, as the Company was awarded 2 new grants in 2011.

Substantially all of the Company's revenues have been derived from commercial license agreements, from pharmacogenomic contracts and from government grants. The commercial revenues include up-front fees and milestone fees (which are irregular in terms of the timing and amounts) and testing fees, contract research fees, and royalties on sales of products licensed to third parties.

The Company has been awarded EUR 8.9 million in grants and subsidies since its inception of which EUR 849,000 have been recorded as revenues in 2011. Grants recorded in 2011 represent 32% of total revenues and were received from the Belgian government primarily for development work on lung cancers, bladder cancers and cervical cancers. Grants awarded generally take the form of refunds of specific expenses incurred in connection with approved scientific research activities.

# Cost of goods and services sold

The costs of goods include royalties MDxHealth must pay to third parties and the costs associated with providing testing services to third parties. The cost of goods was higher in 2010 than in 2011, as a result of more testing volume being sub-contracted to third-parties in 2010.

# Research and development expenses

Research and development expenses were EUR 4,805,000 in 2011 compared to EUR 6,812,000 in 2010, a decrease of 29%. The main reasons for the decrease in the R&D expenditures in 2011 are the following: (i) several projects and outside collaborations were discontinued in 2010 when they did not fit the new strategy with financial impact in 2011, (ii) several cost cutting and re-focusing efforts were launched at the end of 2009, and (iii) certain costs such as the CEO-related costs and patent costs have no longer been recorded as R&D costs starting in 2011. The detail of the research and development expenses is as follows:

Thousands of EUR / Years ended December 31	2011	2010
Personnel costs	1,985	3,619
Lab consumables	465	306
External research and development collaborators	1,462	1,667
Patents and licenses	0	347
Thousands of EUR / Years ended December 31	2011	2010
Depreciation & amortization	276	338
Other expenses	617	535
Total	4,805	6,812

# Selling, general and administrative expenses

In 2011, selling, general and administrative expenses amounted to EUR 4,785,000 compared to EUR 3,745,000 in 2010, an increase of 28%. The increase in costs is largely due to more general management personnel in relation to the set-up of the CLIA laboratory in California and the start of the hiring of the direct sales force for the launch of the *ConfirmMDx*™ for Prostate Cancer test in H1 2012. Also, certain costs such as CEO-related costs and patent costs which were previously recorded partly in R&D, are since 2011 entirely recorded as SG&A expenses. The detail of the administrative and selling expenses is as follows:

Thousands of EUR / Years ended December 31	2011	2010
Personnel costs	2,311	1,847
Depreciation	39	37
Professional fees	1,345	1,211
Other expenses	727	471
Patent expenses	363	179
Total	4,785	3,745

#### **Financial results**

In 2011, the Company ended the year with a net financial gain of EUR 150,000 while it recorded a net financial gain of EUR 137,000 in 2010. The net "financial income" slightly increased in 2011 due to a higher average cash balance. MDxHealth earned EUR 153 thousand of interest income and financial gains in 2011. In 2010, MDxHealth recognized a one-time gain of EUR 135 thousand on the sale of Financial Assets (shares bought in 2008 that were re-sold for a gain in 2010).

#### **Net loss**

The net loss was EUR 6,947,000 in 2011 compared to EUR 8,253,000 in 2010, a decrease of 16%. This decrease is due primarily to a decrease in operating costs following the cost-cutting and re-focus efforts launched in 2009 and 2010.

# **Financial results**

In 2010, the Company ended the year with a net financial gain of EUR 137 while it recorded a net financial gain of

EUR 430,000 in 2009. The net "financial income" decreased in 2010 due to a lower average cash balance and to lower interest rates on deposits. MDxHealth earned EUR 222K of interest income and financial gains in 2010, and this was decreased by foreign exchange differences of EUR 85K due to the fluctuation of the dollar throughout 2010. In 2010, MDxHealth recognized a one-time gain of EUR 135K on the sale of Financial Assets (shares bought in 2008 that were re-sold for a gain in 2010).

#### **Net loss**

The net loss was EUR 8,253,000 in 2010 compared to EUR 14,301,000 in 2009, a decrease of 42%. This decrease is due primarily to a decrease in operating costs following the cost-cutting and re-focus efforts launched in Q4 2009.

# Liquidity, working capital, and capital resources for the years ended December 31, 2012, 2011, and 2010

#### Year ended December 31, 2012

At December 31, 2012, the cash and cash equivalents of MDxHealth amounted to EUR 11.7 million compared to EUR 11.1 million at the end of 2011.

In 2012, net cash used in operating activities amounted to EUR 8.5 million and net cash used by investing activities was EUR 0.4 million. Excluding the net proceeds of EUR 9.6 million generated from the private placement of new shares with institutional investors in July 2012, the net cash consumption of the Company increased by EUR 2.5 million mainly driven by the set-up of the US-based CLIA lab launched in 2011 and accomplished in 2012.

#### Year ended December 31, 2011

At December 31, 2011, the cash and cash equivalents of MDxHealth amounted to EUR 11.1 million compared to EUR 10.6 million at the end of 2010.

In 2011, net cash used in operating activities amounted to EUR 6.6 million and net cash used by investing activities was EUR 0.2 million. Excluding the net proceeds of EUR 7.3 million generated from the private placement of new shares with institutional investors in April 2011, the net cash consumption of the Company was reduced from EUR 7.4 million in 2010 to EUR 6.8 million in 2011. The set-up of the US-based CLIA lab in 2011 caused the Company to experience an increase in cash used for investing activities.

### Year ended December 31, 2010

At December 31, 2010, the cash and cash equivalents of MDxHealth amounted to EUR 10.6 million compared to EUR 18 million at the end of 2009.

In 2010, net cash used in operating activities amounted to EUR 8.1 million and net cash provided by investing activities was EUR 0.7 million. The total net cash consumption of the Company was reduced from EUR 12.6 million in 2009 to EUR 7.4million in 2010. This cash consumption improvement of 41% is due primarily to the cost cuts initiated in Q4 2009, an improvement in working capital, and the sale of financial assets in 2010.

The operating cash flow was mainly impacted by the net result and an improvement in working capital.

# 5.3. REPORT OF THE BOARD OF DIRECTORS ON THE CONSOLIDATED FINANCIAL STATEMENTS

The following report has been established by the Board of Directors on February 27, 2013 for submission to the Annual

General Shareholders' Meeting of May 31st, 2013.

Dear MDxHealth Shareholder,

We are pleased to present to you the consolidated financial statements for the year ended December 31, 2012. The Board of Directors, represented by its directors, declares that, to the best of its knowledge, (i) the consolidated financial statements for the year ended December 31, 2012 give a fair view of the assets, liabilities, financial position and results of MDxHealth and of the entities included in the consolidation, and (ii) the consolidated board report of MDxHealth includes a fair view of the development and performance of the business and the position of the Company and of the undertakings included in the consolidation, as well as a description of the main risks and uncertainties that they face.

# 5.3.1. Discussion and analysis of the consolidated financial statements of 2012, 2011, and 2010

The consolidated financial statements have been prepared in accordance with IFRS and have been approved for issue by the Board of Directors on February 27, 2013.

#### **Revenues**

Substantially all of the Company's revenues have been derived from pharmaceutical company service agreements, commercial license agreements and from government grants. The commercial revenues are mainly up-front fees, milestone fees and service testing revenues, and thus are irregular in terms of the timing and amounts. Total revenues in 2012, 2011 and 2010 were EUR 4.6 million EUR 2.7 million, and EUR 2.5 million, respectively. The commercial revenues were primarily generated from deals with Merck Corporation, Veridex LLC (a Johnson & Johnson company), Abbott, GSK Biologicals, Pfizer, Exact Sciences, Predictive BioSciences, and Merck Serono. The government grants include primarily Belgian government grants for lung, bladder and cervix cancer R&D projects.

## **Operating charges**

Thousands of EUR / Years ended December 31	2012	2011	2010
Research & development expenses	5,282	4,805	6,812
Selling, general and administrative expenses	7,462	4,785	3,745
Other operating expenses/(revenues)	(138)	(72)	(25)
Total Operating Charges	12,606	9,518	10,532

Total operating charges increased by 32% from EUR 9.5 million in 2011 to EUR 12.6 million in 2012, mainly due to set-up of the CLIA lab in California.

As a consequence, R&D expenses increased by 10% from EUR 4.8 million in 2011 to EUR 5.3 million in 2012. SG&A expenses increased by 56% from EUR 4.8 million in 2011 to EUR 7.5 million in 2012, mainly due to the buildup of U.S. R&D, Marketing, Quality, and Administrative functions to support the development of the commercial operation in the US.

#### **Net results**

EBIT and net loss were EUR -7.1 million, and EUR -6.9 million in 2011 compared to EUR -8.9 million, and EUR -9.0 million in 2012.

#### **Cash Flow**

The net cash balance increased by EUR 0.6 million in 2012 due to capital increase inJuly compensated by the continuing losses of the Company.

#### **Balance Sheet**

The balance sheet at December 31, 2012 remained similar in terms of composition to previous years as evidenced by the following key ratios:

Thousands of EUR / Years ended December 31	2012	2011	2010
Cash & cash equivalents as a % of total assets	77%	76%	73%
Working capital as a % of total assets	75%	71%	70%
Solvency ratio (equity/total assets)	80%	77%	74%
Gearing ratio (Financial debt/equity)	0%	0%	0%

Cash and cash equivalents of EUR 11.7 million account for 77% of total assets at December 31, 2012. The other major assets are property, plant and equipment (EUR 0.8 million or 5 % of total assets), and grants awarded to the Company and receivable over the period 2012-2013 (EUR 0.4 million or 2 % of total assets).

Total equity of EUR 12.1 million accounts for 80% of the total balance sheet at December 31, 2012. The other major liabilities are trade payables (EUR 1.7million or 11 % of total assets).

#### **Taxation**

The losses of the Company in the last three years imply that no income taxes are payable for these years. On December 31, 2012, the Company had net tax losses carried forward amounting to EUR 93 million, implying a potential deferred tax asset of EUR 32 million. Due to the uncertainty surrounding the Company's ability to realize taxable profits in the near future, the Company did not recognize any deferred tax assets on its balance sheet.

# 5.3.2. Capital increases and issuance of financial instruments

On July 4, 2012, the Board of Directors decided to increase the Company's share capital in connection with a private placement with qualified institutional investors. The capital increase for an amount of EUR 10 million (net proceeds of EUR 9.6 million) and the issuance of 6,891,113 new common shares was completed on July 4, 2012.

By a decision of the Board of Directors' meeting of March 15, 2012, the Company issued 195,000 additional warrants to certain employees and consultants of the Company, giving the beneficiaries the right to purchase common shares of the Company. The warrants vest straight-line over 4 years (in quarterly installments), have a duration of 10 years, and have an exercise price of EUR 1.72.

By decision of the Extraordinary General Shareholders Meeting of June 15, 2012, the Company issued a pool of 700,000 additional warrants to certain employees and consultants of the Company, giving the beneficiaries the right to purchase common shares of the Company. Out of this pool, have already been granted in 2012 the following:

- 36,000 warrants granted on August 15, 2012 with an exercise price of EUR 1.52;
- 85,000 warrants granted on September 14, 2012 with an exercise price of EUR 1.65;
- 10,000 warrants granted on December 1, 2012 with an exercise price of EUR 2.19;

# 5.3.3. Risks

In 2012, the Company was potentially subjected to the following risks:

- The business model of MDxHealth has recently considerably changed and the Company may not be successful in accomplishing any of its new objectives
- The Company is at an early stage of development and may encounter difficulties in its growth and expansion of activities
- Losses have been incurred since the inception of the Company, further losses are expected in the foreseeable future, and further funding will be needed
- The Company is dependent on intellectual property rights which could be challenged and the Company could be affected by new patents of third parties
- The Company must comply with many conditions in order to maintain the intellectual property rights which it in-licenses from third parties
- The enforcement of the Company's intellectual property rights could involve significant costs and could impact the commercial freedom of the Company in certain areas
- The Company's performance could be hindered by the way its commercial partners utilize certain of its technologies
- The Company's success is dependent upon factors such as its ability to access samples, work with or obtain the support of certain scientific or medical partners, recruit and retain key personnel, generate positive clinical study results, obtain regulatory approval of its products and comply with ongoing regulations, partner with third parties for the manufacture and sale of its products, get the market to accept and use its products, and obtain reimbursement of its products for patients
- The Company operates in markets in which the competition and regulatory environment may change and thus impact the Company's products and strategy, such as in the United States, where the reimbursement for testing service from Medicare and 3rd party private insurance payors is in the early stages and still uncertain.
- The Company is subject to product liability risks
- Foreign exchange rate fluctuations could impact the results of the Company

In 2012, financial risk management involved primarily the following:

- <u>Credit risk:</u> The limited number of the group's customers subjects the Company to concentrations of credit risk. In 2010, the Company generated 90% of its commercial turnover with sixteen customers, reducing the concentration of credit risk. In 2011, 87% of the commercial turnover is was generated by 10 customers. In 2012, the Company generated 74% of its commercial turnover with six customers, increasing its credit risk. In 2012, 2 individual customers each represented more than 9% of the total commercial revenues of the Company and together they accounted for 46% of total commercial revenues. The 2 largest customers in 2012 were Merck KGaA and Predictive Biosciences.
- Interest risk: The Company is not currently subject to material interest risk since it has no financial debt.
- <u>Currency risk</u>: The Company is not currently subject to material currency risk. The Company reports in euros

and in 2012 generated the majority of its revenues and incurred the majority of its costs in Euros. No hedging instruments have been used so far. With the new strategic focus on the U.S. market, in future years the currency risk of the Company may increase.

• <u>Liquidity and investment risk</u>: The Company has invested all of its cash and cash equivalents in highly-rated and highly-liquid bank savings or money market accounts. The company has not invested in any derivative instruments or CDOs.

# 5.3.4. Services performed by the auditor

The Company expensed EUR 98 thousand in fees to the auditor in 2012. The fees are broken down as follows:

- · Statutory of EUR 35 thousand
- Audit fee for consolidated and stand-alone financials of EUR 12 thousand
- · Other audit missions for EUR 19 thousand
- · Other consulting missions for EUR 32 thousand

# 5.3.5. Subsequent events

In 2013, through the date of this document, the Company made the following normal course of business announcements:

- MDxHealth announced the publication of results from a large clinical study on its epigenetic *Confirm*MDx<sup>™</sup> for Prostate Cancer test in the March 2013 issue of Journal of Urology. The blinded, multicenter study named MATLOC (Methylation Analysis To Locate Occult Cancer was conducted at University of Edinburgh Urological Cancer Group in the U.K., the University Hospital of Liege, Belgium, and the Institut de Genetique et Pathologie in Gossellies, Belgium. The result demonstrate the utility of the *Confirm*MDx<sup>™</sup> test as a powerful tool to address well-documented concerns over false-negative biopsy results.
- MDxHealthpresented two important studies involving ConfirmMDx™ for Prostate Cancer at the ASCO Genitourinary Cancers Symposium 2013. The two studies were the "Epigenetic Field Effects for DNA Methylation Markers Extend Over Multiple Histological Benign Prostate Biopsy Cores" by Sandra M Gaston, PhD of New England Baptist Hospital, Harvard Medical School, and "Multi-gene Epigenetic MSP Assay Predicts Risk for Prostate Cancer in Histopathologically Negative Biopsies" by Leander van Neste PhD, MDxHealth SA, Liege, Belgium. Both these studies showed that ConfirmMDx™ for Prostate Cancer test provides very important personalized information that cannot be achieved with traditional procedures.
- MDxHealth announced the publication of results from a health economic study in the Journal of American Health & Drug Benefits. The budget impact analysis demonstrated achievable cost savings of MDxHealth's *Confirm*MDx™ for Prostate Cancer test, which is used by urologists to identify men who may avoid unnecessary repeat prostate biopsies, thereby reducing overall healthcare spending.
- Collections related to 2012 billings of *Confirm*MDx<sup>™</sup> for Prostate Cancer test received in 2013 through mid February were over \$150K, of which a portion was recorded as part of 2012 revenues as a subsequent event.
- A collections analysis completed in January 2013 identified six privator insurance payors who presented a
  consistent pattern of payments and qualified under the company's revenue recognition policy to be treated
  under accrual revenue accounting.

• Merck KGaA announced in February 2013 that its Phase III clinical study with cilengitide in newly diagnosed glioblastoma did not meet its primary endpoints. MDxHealth had been providing an MGMT (methylguanine-DNA methyltransferase) diagnostic test, *Predict*MDx<sup>™</sup> for Glioblastoma, that was used in the clinical study to identify and stratify those glioblastoma patients who may be more likely to benefit from cilengitide treatment.

# 5.3.6. Significant change in the issuer's financial or trading position

There has been no significant change in the financial or trading position of the group which has occurred since the end of the last financial period for which either audited financial information or interim financial information have been published.

# 5.3.7. Research & Development

In 2012, the Company conducted product development projects based on the discovery R&D performed in the prior years for both its clinical diagnostic product pipeline and pharmaceutical research and clinical trial customers. Extensive work was performed on the development of the Company's MGMT test and on the clinical diagnostic pipeline for Prostate Cancer. Also in 2012, work was completed to related to Bladder, Lung, and Cervix projects underwritten by the Wallonia regional government.

Prior to 2011, the Company primarily performed discovery R&D projects for a wide range of cancer applications so as to out-license biomarkers to 3rd party companies which would develop the products and eventually commercialize them. This strategy did not generate sufficient revenues for the Company and left the Company excessively dependent on external parties for its future.

At the end of 2009, MDxHealth announced that it would change its strategy. Today, the R&D activities are focused on the development of (i) Clinical Molecular Diagnostic products (*Clinical*MDx<sup>™</sup>) to assist physicians in the diagnosis of cancer, and (ii) Pharmaco Molecular Diagnostic products (*Pharmaco*MDx<sup>™</sup>) to assist pharmaceutical companies and physicians in getting the correct cancer treatment to the right patient. MDxHealth is now developing products which it intends to commercialize itself, primarily via a CLIA lab which the Company established in the United States in 2011.

With this new strategy the R&D is thus focused on "development" of products for its own commercialization.

#### **Research and Discovery**

MDxHealth maintains an internal R&D team specialized in new biomarker discovery and optimization. In addition, MDxHealth collaborates with several universities and medical centers throughout the world in new biomarker discovery. For example, MDxHealth collaborates with the Johns Hopkins University and the University of Gent in the area of methylation biomarker discovery using next generation sequencing. This approach has optimized its current assay development process by focusing on the DNA regions of interest, ensuring an "intelligent" and accelerated biomarker discovery process. MDxHealth also continues its discovery programs for both lung and colon cancer.

#### **Product Development**

MDxHealth's diagnostics business is focused on three clinical areas: prostate, lung and brain cancer. The products on which the most spending was done in 2012 are the following:

 Prostate cancer ConfirmMDx™: The Company is further validating an epigenetic ConfirmMDx™ for Prostate Cancer diagnostic test. The Company launched this test in the United States in mid-2012 via its new US-based CLIA laboratory.

- Prostate cancer InformMDx™: The Company is developing an epigenetic InformMDx™ for Prostate Cancer diagnostic
  test. The Company intends to launch this test in the United States via its new US-based CLIA laboratory.
- Brain Cancer Predict (MGMT for Glioblastoma): The Company is developing a test to predict brain cancer patient response to alkylating agent medication (MGMT). The test is being used by several pharmaceutical companies in clinical trials for brain cancer drugs.
- *Bladder cancer*: The Company performed R&D on a tissue-based test for the detection of bladder cancer and for the monitoring of recurrence.
- Lung cancer: The Company performed some R&D on a blood and a sputum-based test for the confirmation of lung cancer. This development work will form the basis of the Lung Confirm test. The Company also performed R&D work on its Lung Cancer Inform test. This test will provide a risk assessment of Stage I lung cancer patients with confirmation of whether the patient is either at low risk or high risk of recurrence.

The most advanced products include the following:

- ConfirmMDx<sup>™</sup> for Prostate Cancer: The Company launched this test in the United States in mid-2012 via its new US-based CLIA laboratory.
- InformMDx™ for Prostate Cancer tests: This prognostic test for prostate cancer is now being developed "in-house" and the Company intends to commercialize it as an LDT through its U.S. CLIA-accredited laboratory.
- Brain Cancer Predict™ (MGMT for Glioblastoma): The Company is developing a test to predict brain cancer patient response to alkylating agent medication (MGMT). The test is being used by several pharmaceutical companies in clinical trials for brain cancer drugs. The MGMT tissue-based test is currently being commercialized in North America via Laboratory Corporation of America (LabCorp).

In addition to the above R&D work, the Company is working on several tests to determine which patients will respond to certain drugs for particular cancers. This work is often done in partnership with pharmaceutical companies which have a drug in development.

# 5.3.8. Disclosures within the framework of the takeover directive (see also section 4.5 and 4.6 of the Registration Document)

# Justification to Continue using the accounting rules on the basis of going concern

Despite cumulated losses, the Board has decided to continue to apply the accounting rules on the basis of going concern. This decision is justified by (i) the success of the technology of the Company in various cancer applications and scientific publications, (ii) continued interest in the Company's technology, (iii) the continued industry growth in the field of molecular diagnostics and personalized medicine, and (iv) the fact that sufficient cash is available to support further development of the Company's products over the next 12 months period in function of the current business plan.

Considering the situation, the Board of Directors believes that there is enough cash to sustain the current projects of the Company at least until the date of the annual general shareholders' meeting scheduled for May 2014.

#### **Capital structure**

At the end of 2012, the issued capital of MDxHealth SA amounted to EUR 20,351,568.70 represented by 25,513,440

shares without nominal value. All shares have the same rights and obligations and participate equally in the profits of MDxHealth SA.

MDxHealth SA does not own any of the issued and outstanding shares of MDxHealth SA.

Shareholders holding more than 3% of the outstanding shares of the Company who make themselves known to the Company and to the FSMA are disclosed in section 4.8 of the 2012 Registration Document and on the Company's website at www.mdxhealth.com/investors/shareholder-information.

#### Restrictions concerning the transfer of securities

The Company's articles of association do not impose any restrictions on the transfer of securities in addition to the restrictions provided for in the Belgian Company Code.

#### Holders of securities with special control rights

The Company has not granted any special control rights to the holders of its securities.

## Mechanism for control of share plans for employees

There are no shares or similar plans for employees other than the stock option plans disclosed elsewhere in this document.

### Restrictions concerning the exercise of the voting right

Each shareholder of MDxHealth SA is entitled to one vote per share. There is only one category of shares (common shares). Voting rights can be suspended, amongst others, in relation to shares:

- · which were not fully paid up, notwithstanding the request thereto of the Board of Directors of the Company;
- to which more than one person is entitled, except in the event a single representative is appointed for the exercise of the voting right;
- which entitle their holder to voting rights above the threshold of 3%, 5%, or any multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Company on the date of the relevant general shareholders' meeting, except in the event where the relevant shareholder has notified the Company and the FSMA at least 20 days prior to the date of the general shareholders' meeting on which he or she wishes to vote of its shareholding exceeding the thresholds above; and
- of which the voting right was suspended by a competent court or the FSMA.

# Agreements between shareholders which are known to the issuer and may result in restrictions on the transfer of securities and/or exercise of voting rights

There are no declared or known agreements between shareholders.

#### Rules for the appointment and the replacement of directors and the amendment of the articles of association

Pursuant to the Company's articles of association, the Board of Directors of the Company is to be composed of at least 3 directors. The Company's corporate governance charter requires that the Board of Directors is, to the extent possible,

composed of at least five directors, of which at least 3 directors are independent directors, and to the extent possible, at least half of the directors are Non-Executive Directors. The directors of the Company are appointed by the general shareholders' meeting. However, in accordance with the Belgian Company Code, if the mandate of a director becomes vacant due to his death or resignation, the remaining directors have the right to appoint temporarily a new director to fill the vacancy until the first general shareholders' meeting after the mandate became vacant. The new director completes the term of the director whose mandate became vacant. The corporate governance charter provides that directors can be appointed for a maximum (renewable) term of four years. At the date of this document, the Board of Directors is composed of 7 members, 3 of whom are independent directors.

Amendments to the articles of association (other than an amendment of the corporate purpose) require the presence or representation of at least 50% of the share capital of the Company and the approval of at least 75% of the votes cast. An amendment of the Company's corporate purpose, requires the approval of at least 80% of the votes cast at a general shareholders' meeting, which in principle can only validly pass such resolution if at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, are present or represented. In the event where the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second general shareholders' meeting can validly deliberate and decide regardless of the number of shares present or represented.

#### Powers of Directors, in particular the power to issue or buy back shares

The Board of Directors of MDxHealth SA has the broadest powers to manage and represent the Company, except to the extent provided otherwise by applicable law or the Company's articles of association.

<u>Authorized Capital</u> – By virtue of the resolution of the extraordinary general shareholders' meeting held on June 15, 2012, the Board of Directors has been expressly authorized to increase the share capital in one or more transactions with an amount of up to EUR 14,854,527.86 (the "Authorized Capital"), subject to certain limitations and conditions described below. The Board of Directors can exercise this power for a period starting on the date of the publication of the relevant resolution of the extraordinary general shareholders' meeting in the Annexes to the Belgian Official Gazette and ending on the date of the annual general shareholders' meeting to be held in 2015 which shall resolve on the annual accounts relating to the accounting year ending on December 31, 2014. This authorization may be renewed in accordance with the relevant legal provisions.

The capital increases to which can be decided according to this authorization, can take place in accordance with the modalities as are to be decided by the board of directors, such as:

- by means of contribution in cash or in kind, within the limits as permitted by the Belgian Company Code,
- through conversion of reserves and issuance premiums,
- with or without issuance of new shares, with or without voting rights,
- through issuance of convertible bonds, subordinated or not,
- through issuance of warrants or bonds to which warrants or other tangible values are attached, and/or
- through issuance of other securities, such as shares in the framework of a stock option plan.

In the framework of the use of its powers within the framework of the authorized capital, the board of directors can

limit or cancel the preferential subscription right of the shareholders in the interest of the company, subject to the limitations and in accordance with the conditions provided for by the Belgian Company Code.

This limitation or cancellation can also occur to the benefit of the employees of the company and its subsidiaries, and, to the extent permitted by law, to the benefit of one or more specific persons that are not employees of the company or its subsidiaries.

If, following a capital increase that has been decided within the framework of the authorized capital, an issuance premium is paid, the board of directors is authorized and obliged to book the amount of such issuance premium onto the account "Issuance Premiums", that shall serve as guarantee for third parties in the same manner as the company's share capital and which, apart from the possibility to convert this reserve into share capital, can only be disposed of in accordance with the rules provided by the Belgian Company Code for amendments to the articles of association.

By virtue of the resolution of the extraordinary general shareholders' meeting held on June 15, 2012, the board of directors has also been expressly authorized to increase the share capital in one or more transactions following a notification by the Belgian Financial Services and Markets Authority that it has been informed of a public takeover bid on the company's financial instruments, through contributions in cash with cancellation or limitation of the preferential subscription rights of the shareholders (including for the benefit of one or more well defined persons who are not employees of the company) or through contributions in kind, with issuance of shares, warrants or convertible bonds, subject to the terms and conditions provided for in the Belgian Company Code. The board of directors can exercise this power for a period of maximum three years starting as of the date of the publication of the relevant resolution of the extraordinary general shareholders' meeting in the Annexes to the Belgian Official Gazette.

The board of directors is authorized, with power of substitution, to amend the articles of association upon each capital increase realized within the framework of the authorized capital, in order to bring them in accordance with the new situation of the share capital and the shares.

At the date of this document, the Board of Directors has used the above described powers under the Authorized Capital as follows:

• On July 4, the Board of Directors used the Authorized Capital for a private placement of 6,891,113 new shares with institutional investors at a price of EUR 1.45. This transaction reduced the available Authorized Capital by EUR 5,497,040.84.

# Significant agreements which take effect, alter or terminate upon a change of control of the issuer following a takeover bid

According to the terms and conditions of the warrants issued by MDxHealth, non-vested warrants become exercisable in case of a change of control of the Company (see also Section 5.1.5.19 of the Registration Document). In addition, material agreements with EXACT Sciences (as further described in Section 5.1.5.21 of the Registration Document) include change of control clauses.

Agreements with directors or employees providing for compensation if they resign or are made redundant without valid reason or if their employment ceases because of a public takeover bid

There are individual agreements between the Company and certain Members of the Management Committee that

provide a severance payment of up to 12 months, should this agreement be terminated due to the Company's change of control.

#### **Corporate Governance**

The Company's corporate governance charter was adopted in accordance with the recommendations set out in the Belgian Corporate Governance Code 2009 (the "2009 Code"), issued on March 12, 2009 by the Belgian Corporate Governance Committee (replacing the 2004 edition). Section 3 of the 2012 Registration Document summarizes the main rules and principles of MDxHealth's Corporate Governance Charter. The complete charter is available on the MDxHealth website, at <a href="https://www.mdxhealth.com">www.mdxhealth.com</a>

MDxHealth has adopted the 2009 Belgian Corporate Governance Code as its reference code. It complies to a large extent with the provisions of this Code, but believes that certain deviations are justified in view of the Company's specific situation. In line with the "comply-or-explain" principle of said Code, it should be noted that MDxHealth does not fully comply with the following provisions:

- Given the size of the Company, no internal audit function exists at this time.
- Given the size of the Company, the board will strive to include a majority of independent board members on the audit committee and on the nomination and remuneration committee, but may deviate from such a majority of independents on such committees if, in the reasonable opinion of the board, a different composition can bring more relevant experience and expertise to such committee. In 2012, the audit committee was composed of the following non-executive directors (amongst which two are independent directors); Mrs. Ruth Devenyns who is also the chairman of the committee; Mr. Edward L. Erickson; and Dr. Karin Dorrepaal.
- Although, according to the 2009 Code, Non-Executive Directors should not be entitled to performance-related remuneration such as bonuses, stock related long-term incentive schemes, fringe benefits or pension benefits, the Board of Directors is however of opinion that, for a company of the size of MDxHealth, it may be necessary to issue warrants to Non-Executive Directors, with a view to attracting directors with the relevant expertise and experience.
   All Non-Executive independent directors nominated before the May 2012 annual general shareholders' meeting have been awarded warrants.

The performance and functioning of the Board of Directors, its' committees, and of the Executive Management team are explained in section 3 of the 2012 Registration Document. Section 3.2.4 of the 2012 Registration Document also includes the 2012 Remuneration Report as prepared by the Board of Directors.

The Company's board of directors strives to maintain a well-balanced general diversity at the board of directors. Currently, there are 2 female directors among a total of 7 board members (representing a ratio of 29% female directors against 71% male directors). The Company is using its best efforts to ensure that the board of directors will meet the 2/3 gender diversity requirement by January 1, 2018.

Section 3.4 of the 2012 Registration Document provides a summary of MDxHealth's internal control and risk management systems.

Done on February 27, 2013

On behalf of the Board of Directors

# **5.4. STATUTORY AUDITOR'S REPORT**

# 5.4.1. Statutory auditor's report to the general meeting of shareholders of MDxHealth SA on the consolidated financial statements for the year ended December 31, 2012

In accordance with the legal requirements, we report to you on the performance of the engagement of statutory auditor, which has been entrusted to us. This report contains our opinion on the consolidated balance sheet as at 31 December 2012, the consolidated profit and loss statement for the year ended 31 December 2012 and the explanatory notes, as well as the required additional information.

## Report on the consolidated financial statements - unqualified opinion

We have audited the consolidated financial statements of the company MDxHealth SA for the year ended 31 December 2012, prepared in accordance with International Financial Reporting Standards as adopted by the European Union, which show a balance sheet total of 15.124 kEUR and a consolidated loss for the year of 8.976 kEUR.

Management's responsibility for the consolidated financial statements

Management is responsible for the preparation of the consolidated financial statements that give a true and fair view in accordance with International Financial Reporting Standards as adopted by the European Union, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatements, whether due to fraud or error.

#### Auditor's responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with International Standards on Auditing. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatements.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation of the consolidated financial statements that give a true and fair view in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We have obtained from management and the company's officials the explanations and information necessary for our audit.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for the audit opinion.

## **Unqualified** opinion

In our opinion, the consolidated financial statements of the company MDxHealth SA as of 31 December 2012 give a true and fair view of the net assets and financial position of the group as at 31 December 2012, as well as its consolidated results and cash flows for the year then ended, in accordance with International Financial Reporting Standards as adopted by the European Union.

## Report on other legal and regulatory requirements

Management is responsible for the preparation and the content of the consolidated Directors' report.

As part of our engagement, it is our responsibility, for all significant aspects, to ascertain the compliance of certain legal and regulatory requirements. Based on that requirement we report the following additional statement, which does not modify our audit opinion on the consolidated financial statements:

• The consolidated Directors' report includes the information required by law, is consistent, in all material aspects, with the consolidated financial statements and does not include any obvious inconsistencies with the information that we became aware of during the performance of our engagement.

Zaventem, 27 February 2013

BDO Réviseurs d'Entreprises Soc. Civ. SCRL

Statutory auditor

Represented by Bert Kegels

# 5.4.2. Statutory auditor's report to the general meeting of shareholders of MDxHealth SA on the consolidated financial statements for the year ended December 31, 2011

In accordance with the legal requirements, we report to you on the performance of the mandate of statutory auditor, which has been entrusted to us. This report contains our opinion on the true and fair view of the consolidated financial statements as well as the required additional statement.

#### Unqualified audit opinion on the consolidated financial statements

We have audited the consolidated financial statements of MDxHealth SA for the year ended 31 December 2011, prepared in accordance with International Financial Reporting Standards as adopted by the European Union, which show a balance sheet total of 14.692 EUR'000 and a consolidated loss of EUR 6.947 thousands.

Management is responsible for the preparation and the fair presentation of these consolidated financial statements. This responsibility includes: designing, implementing and maintaining internal control relevant to the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting principles and making accounting estimates that are reasonable in the circumstances.

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with the legal requirements and the Auditing Standards applicable in Belgium, as issued by the Institut des Réviseurs d'Entreprises. Those standards require that we plan and perform the audit to obtain reasonable assurance as to whether the consolidated financial statements are free from material misstatement, as to whether due to fraud or error.

In accordance with the above-mentioned auditing standards, we have carried out procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The selection of these procedures is a matter for our judgment, as is the assessment of the risk that the consolidated financial statements contain material misstatements, whether due to fraud or error. In making those risk assessments, we have considered the company's internal control relating to the preparation and fair presentation of the consolidated financial statements, in order to design audit procedures that were appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control. We have also assessed the appropriateness of the accounting

principles and consolidation principles, the reasonableness of accounting estimates made by management, as well as the overall presentation of the consolidated financial statements. Finally, we have obtained from management and the company's officials the explanations and information necessary for our audit. We believe that the audit evidence we have obtained provides a reasonable basis for our opinion.

In our opinion the consolidated financial statements for the year ended 31 December 2011 give a true and fair view of the group's assets and liabilities, its financial position, the results of its operations and cash flow in accordance with International Financial Reporting Standards as adopted by the European Union.

#### **Additional statement**

The preparation of the consolidated Directors' report and its content are the responsibility of management.

Our responsibility is to supplement our report with the following additional statement, which do not modify our audit opinion on the consolidated financial statements:

The consolidated Directors' report includes the information required by law and is consistent with the consolidated financial statements. We are, however, unable to comment on the description of the principal risks and uncertainties which the consolidated group is facing, and of its financial situation, its foreseeable evolution or the significant influence of certain facts on its future development. We can nevertheless confirm that the matters disclosed do not present any obvious inconsistencies with the information that we became aware of during the performance of our mandate.

Zaventem, 14 March 2012

BDO Réviseurs d'Entreprises Soc. Civ. SCRL

**Statutory Auditor** 

Represented by Bert Kegels

# 5.4.3. Statutory auditor's report to the general meeting of shareholders of MDxHealth SA on the consolidated financial statements for the year ended December 31, 2010

In accordance with the legal requirements, we report to you on the performance of the mandate of statutory auditor, which has been entrusted to us. This report contains our opinion on the true and fair view of the consolidated financial statements as well as the required additional statements.

#### Unqualified audit opinion on the consolidated financial statements

We have audited the consolidated financial statements for the year ended 31 December 2010, prepared in accordance with International Financial Reporting Standards as adopted by the European Union, which show a balance sheet total of EUR 14,419,000 and a consolidated loss of EUR 8,253,000.

Management is responsible for the preparation and the fair presentation of these consolidated financial statements. This responsibility includes: designing, implementing and maintaining internal control relevant to the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies and making accounting estimates that are reasonable in the circumstances.

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with the legal requirements and the Auditing Standards applicable in Belgium, as issued by the

Institut des Réviseurs d'Entreprises. Those standards require that we plan and perform the audit to obtain reasonable assurance as to whether the consolidated financial statements are free from material misstatement, as to whether due to fraud or error.

In accordance with the above-mentioned auditing standards, we considered the group's accounting system, as well as its internal control procedures. We have obtained from management and the Company's officials, the explanations and information necessary for executing our audit procedures. We have examined, on a test basis, the evidence supporting the amounts included in the consolidated financial statements. We have assessed the appropriateness of the accounting policies and consolidation principles, the reasonableness of the significant accounting estimates made by the Company, as well as the overall presentation of the consolidated financial statements. We believe that these procedures provide a reasonable basis for our opinion.

In our opinion the consolidated financial statements for the year ended 31 December 2010 give a true and fair view of the group's assets and liabilities, its financial position and the results of its operations in accordance with International Financial Reporting Standards as adopted by the European Union.

#### **Additional statements**

The preparation of the consolidated Directors' report and its content are the responsibility of management.

Our responsibility is to supplement our report with the following additional statements, which do not modify our audit opinion on the consolidated financial statements:

The consolidated Directors' report includes the information required by law and is consistent with the consolidated financial statements. We are, however, unable to comment on the description of the principal risks and uncertainties which the consolidated group is facing, and of its financial situation, its foreseeable evolution or the significant influence of certain facts on its future development. We can nevertheless confirm that the matters disclosed do not present any obvious inconsistencies with the information that we became aware of during the performance of our mandate.

Zaventem, 18 February, 2011

BDO Réviseurs d'Entreprises Soc. Civ. SCRL

**Statutory Auditor** 

Represented by Bert Kegels



Statutory Financial Statements

The statutory financial statements to be filed with the Belgian National Bank are based upon Belgian GAAP. An unqualified audit opinion will be issued by the statutory auditor.

The information included in this section is an extract from the statutory accounts that will be filed with the Belgian National Bank and do not include all information as required by articles 98 and 100 of the Company laws. The full statutory accounts have not yet been filed with the Belgian National Bank as of the date of this document. Once filed with the Belgian National Bank, the full statutory accounts will also be made available in the investors section of MDxHealth's website (www.mdxhealth.com).

# **6.1. STATUTORY INCOME STATEMENT**

#### STATUTORY INCOME STATEMENT

Thousands of EUR / Years ended December 31	2012	2011	2010
I. Operating income	4,580	3,022	2,827
A. Turnover	3,437	1,892	1,931
D. Other operating income	1,143	1,130	896
II. Operating charges	6,987	8,655	11,854
A. Purchase of goods and materials	537	639	537
B. Services and other goods	3,895	5,314	8,455
C. Remuneration, social security costs, pensions	2,237	2,274	2,200
D. Depreciation & amounts written off fixed assets	333	427	660
G. Other operating charges	(15)	1	2
III. Operating profit/(loss)	(2,407)	(5,633)	(9,027)
IV. Financial income	261	212	297
B. Income from current assets	261	211	76
C. Other	0	1	221
V. Financial charges	465	65	143
A. Debt charges	13	1	0
C. Other	452	64	143
VI. Current profit/(loss) before taxes	(2,611)	(5,486)	(8,873)
VII. Extraordinary income	49	0	0
VIII. Extraordinary charges	93	1,289	2
A. Extraordinary depreciations & amounts written off fixed assets	0	0	2
B. Extraordinary depreciation on financial assets	93	1,289	0
IX. Profit/(loss) before taxes	(2,655)	(6,775)	(8,875)
X. Income taxes	0	0	0
XI. Profit/(loss) for the year after taxes	(2,655)	(6,775)	(8,875)

# APPROPRIATION ACCOUNT

Thousands of EUR / Years ended December 31	2012	2011	2010
A. Loss to be appropriated			
A1. Loss for the period available for appropriation	(2,655)	(6,775)	(8,875)
A2. Loss brought forward	(15,650)	(8,875)	(43,483)
B. Transfer from capital and reserves			
B1. From capital and share premium account	0	0	43,483
C. Transfer to equity			
D. Result to be carried forward			
D2. Loss to be carried forward	18,305	15,650	8,875

# **6.2. STATUTORY BALANCE SHEET**

# **STATUTORY BALANCE SHEET AFTER APPROPRIATIONS**

Thousands of EUR / Years ended December 31	2012	2011	2010
ASSETS	3,729	6,176	4,699
I. Formation expenses	0	0	0
II. Intangible assets	48	72	85
III. Tangible fixed assets	257	384	544
B. Plant, machinery and equipment	203	318	457
C. Furniture and vehicles	54	65	87
IV. Financial assets	3,424	5,720	4,070
A. Affiliated enterprises	3,424	5,715	4,065
A1. Investments	3,422	5,715	4,065
A2. Amounts receivable	0	0	0
C. Other financial assets	0	5	5
C1. Investments	0	0	0
C2. Amounts received and cash guarantee	2	5	5
CURRENT ASSETS	19,267	12,629	13,347
V. Amounts receivable after one year			
VI. Stocks and contracts in progress	43	63	108
VII. Amounts receivable within one year	7,491	2,460	2,521
A. Trade debtors	6,923	1,203	941
B. Other amounts receivable	568	1,257	1,580
VIII. Investments	11,608	8,918	9,678
B. Other investments and deposits	310	8,918	9,678
IX. Cash at bank and in hand	11,298	1,060	834
X. Deferred charges and accrued income	125	128	206
TOTAL ASSETS	22,996	18,805	18,046

#### STATUTORY BALANCE SHEET AFTER APPROPRIATIONS

Thousands of EUR / Years ended December 31	2012	2011	2010
CAPITAL AND RESERVES	21,248	13,905	12,524
I. Capital	20,351	14,855	10,517
A. Issued capital	20,351	14,855	10,517
II. Share premium account	19,202	14,700	10,882
III. Revaluation surpluses			
IV. Reserves			
V. Accumulated profit/(loss)	(18,305)	(15,650)	(8,875)
VI. Investment grants	0	0	0
VII. Provisions and postponed taxes			
A. Provisions for liabilities and charges			
A4. Other liabilities & charges			
AMOUNTS PAYABLE	1,748	4,900	5,522
VIII. Debts payable after 1 year	0	160	0
A. Financial debts			
A4. Credit institutions			
IX. Debts payable within 1 year	1,748	4,492	4,499
A. Current portion of debts after one year			
B. Financial debts			
B1. Credit institutions			
C. Trade debts	1,341	4,012	4,196
C1. Suppliers	1,341	4,012	4,196
D. Advances received on contracts in progress	17	120	141
E. Taxes, remuneration & social security	375	360	162
E1. Taxes	48		
E2. Remuneration & social security	327	360	162
X. Accrued charges and deferred income	15	408	1,023
TOTAL LIABILITIES	22,966	18,805	18,046

# **6.3. ACCOUNTING POLICIES (BELGIAN GAAP)**

The valuation rules have been prepared in accordance with the provisions of Chapter II of the Royal Decree of January 30, 2001 relating to the implementation of the Belgian Company Code.

# Formation expenses and costs relating to capital increases

These are recognized as assets and are amortized 20% annually. During the financial year, the costs related to capital increases are recognized as expenses in the profit and loss statement.

## **Intangible assets**

Research and development costs

The Company applies the same recognition criteria for Research and Development costs for Belgian GAAP as for IFRS.

Certain external Research costs are capitalized and depreciated in the same financial year. These assets are capitalized at purchase price or at actual costs incurred or, if lower, at their useful value.

Certain external Development costs are capitalized if the project is already likely to generate a profitable product. These assets are capitalized at purchase price or at actual costs incurred or, if lower, at their useful value.

These assets are amortized on a straight-line basis over a period of 5 years. In the event that Development costs are exceptionally depreciated over a period exceeding 5 years, this will be justified.

Patents, licenses and similar rights

These assets are capitalized at purchase price or, if lower, at their useful value. These assets are depreciated on a straight-line basis over a period of 5 years.

## **Tangible fixed assets**

These assets (which are detailed below on a line-by-line basis) are capitalized as follows:

· At purchase price

Depreciation	Method	Basis NR/R**	Depreciation Rate		
	L/D* Other		Principal Min - Max	Accessory Costs Min - Max	
Industrial, administrative     or commercial buildings <sup>(a)</sup>	L	NR			
2. Other buildings	L	NR			
3. Installations and equipment (a)	L	NR	20% – 33.33%	20% - 33.33%	
4. Vehicles <sup>(a)</sup>	L	NR	20% - 20%	20% - 20%	
5. Offic e equipment and furniture (a)	L	NR	10% – 20%	10% - 20%	

\* L: Linear D: Digressive

\*\* NR : Not revalued R : Revalued

#### (a): including leased assets

In the event where the accounting value exceeds the useful value (or the realized value for the assets that are no longer used), the Company should perform additional or exceptional depreciations.

The Company applies an accelerated depreciation plan in agreement with the relevant tax authorities. In such a case, the amount of the tax deductible and excessive accelerated depreciation compared to the economically justifiable depreciations is to be mentioned.

- · Excessive amount of the financial year;
- Excessive cumulated amount.

The tangible fixed assets, of which the life-time is not limited in time, are reduced in value in case of depreciation or lasting value reduction.

#### Financial assets

These assets are capitalized at purchase price excluding any miscellaneous fees.

The shares and participations are reduced in value in case of depreciation or lasting reduction in value, as a result of the situation, the profitability or perspective of the Company in which the shares or the participations are held.

Reductions in value of amounts receivable included in the financial fixed assets are recorded when the payment thereof or part thereof at their due date is uncertain or has become compromised.

#### Amounts receivable (after one year – within one year)

The amounts receivable that are represented by fixed revenue instruments are capitalized at purchase price excluding any miscellaneous fees.

Other amounts receivable (commercial and other amounts receivable that are not represented by fixed revenue instruments) are capitalized at their nominal value.

This capitalization is accompanied by the recording thereof in the regularization accounts on the liabilities side and of the pro rata temporis booking of the results of:

- · The interests contractually included in the nominal value of the amounts receivable;
- The difference between the purchase cost and the nominal value of the amounts receivable;
- The advances of payable amounts receivable at a date of more than 1 year, that are not subject to interest or that are subject to an interest rate that is abnormally low. These advances are calculated at the applicable market rate for such amounts receivable at the time they enter into the Company's estate.

#### Treasury placements and available cash

Placements with financial institutions are capitalized at their nominal value. The titles are capitalized at purchase cost excluding miscellaneous fees.

Reductions in value are recorded in the event where the realization value at the date of the closing of the financial year is below the purchase cost.

## **Provisions for risks and charges**

The provisions for risks and charges are individualized taking into account the corresponding risks and charges they are intended to cover.

The provisions for risks and charges can only be maintained provided that they exceed, as per the date of the closing of the financial year, an actual appreciation of depreciations, charges and risks for which they have been established.

#### Debts (payable after one year - payable within one year)

All debts are capitalized at their nominal value at the date of the closing of the financial year.

The valuation rules applicable to amounts receivable are also applicable for debts, with the difference however that the implicit pro rata interests are recorded in the regularization accounts on the assets side.

At the date of the closing of the financial year, all charges to be paid in relation to the financial year concerned and the previous financial years are taken into account.

#### **Regularization accounts**

Regularization accounts on the assets side

These accounts include:

- The pro rata parts of the charges incurred during the financial year or during a previous financial year but that are related to one or more subsequent financial years.
- The pro rata parts of the proceeds that will only be received during a subsequent financial year but that relate to a previous financial year.

Regularization accounts on the liabilities side

These accounts include:

- The pro rata parts of the charges that will only be paid during a subsequent financial year but that relate to a previous financial year.
- The pro rata parts of the proceeds received during the financial year or a previous financial year but that relate to one or more subsequent financial years.

The commercial contract revenue fees which are not linked to a completed or unique event are spread over the remaining term of the agreement.

## **Currencies**

The amounts receivable and debts in currencies are converted at the applicable exchange rate at the date of the closing of the financial year.

Currency losses are recorded in the statement of results.

Unrealized currency gains are reported as proceeds to be recorded on the regularization accounts on the liabilities side.

## 6.4. REPORT OF THE BOARD OF DIRECTORS ON THE STATUTORY FINANCIAL STATEMENTS

The following report has been established by the Board of Directors on February 27, 2013 for submission to the Annual General Shareholders' Meeting of May 31, 2013.

Dear MDxHealth Shareholder,

We are pleased to present to you the statutory financial statements for the year ended December 31, 2012.

Pursuant to the provisions of the Belgian Company Code (C.C.) and the articles of association of the Company, we report on the situation of your company for the fiscal year of the Company closed on 31 December 2012.

## 6.4.1. Comments on the annual accounts

We submit for your approval the annual accounts for the fiscal year closed on 31 December 2012. The annual accounts give a true and fair view of the course of affairs of the Company during the past fiscal year. From the annual accounts you can derive the following:

a) Results of the fiscal year

The company has closed its annual accounts with respect to the past fiscal year with a loss of EUR 2,655,000

This loss results mainly from the costs related to the development of new products which have not yet generated significant revenues and to the set-up of the US CLIA laboratory and team to support direct sales of tests since mid-2012. Overall costs decreased in 2012 mainly due to the reduction in the number of projects and personnel, and the out-licensing of cancer screening applications to third parties.

b) Statutory and non-distributable reserves

The company has a corporate capital of EUR 20,351,568.70. The company has no statutory reserve.

As the Company has closed its annual accounts with respect to the past fiscal year with a loss, the Company is not legally obliged to reserve additional amounts.

c) Allocation of the results

We propose to carry forward the loss to the next fiscal year.

# 6.4.2. Material events that took place since the end of the fiscal year

In 2013, through the date of this document, the Company made the following normal course of business announcements:

- MDxHealth announced the publication of results from a large clinical study on its epigenetic *ConfirmMDx*™ for Prostate Cancer test in the March 2013 issue of Journal of Urology. The blinded, multicenter study named MATLOC (Methylation Analysis To Locate Occult Cancer was conducted at University of Edinburgh Urological Cancer Group in the U.K., the University Hospital of Liege, Belgium, and the Institut de Genetique et Pathologie in Gossellies, Belgium. The result demonstrate the utility of the *ConfirmMDx*™ test as a powerful tool to address well-documented concerns over false-negative biopsy results.
- MDxHealth presented two important studies involving *Confirm*MDx<sup>™</sup> for Prostate Cancer at the ASCO Genitourinary Cancers Symposium 2013. The two studies were the "Epigenetic Field Effects for DNA Methylation Markers Extend Over Multiple Histological Benign Prostate Biopsy Cores" by Sandra M Gaston, PhD of New England Baptist Hospital, Harvard Medical School, and "Multi-gene Epigenetic MSP Assay Predicts Risk for Prostate Cancer in Histopathologically Negative Biopsies" by Leander van Neste PhD, MDxHealth SA, Liege, Belgium. Both these studies showed that *Confirm*MDx<sup>™</sup> for Prostate Cancer test provides very important personalized information that cannot be achieved with traditional procedures.
- MDxHealth announced the publication of results from a health economic study in the Journal of American Health & Drug Benefits. The budget impact analysis demonstrated achievable cost savings of MDxHealth's *Confirm*MDx<sup>™</sup> for Prostate Cancer test, which is used by urologists to help identify men who may avoid unnecessary repeat prostate biopsies, thereby reducing overall healthcare spending.

- Collections related to 2012 billings of *Confirm*MDx<sup>™</sup> for Prostate Cancer test received in 2013 through mid February were over \$150K, of which a portion was recorded as part of 2012 revenues as a subsequent event.
- A collections analysis completed in January 2013 identified six private insurance payors who presented a consistent pattern of payments and qualified under the company's revenue recognition policy to be treated under accrual revenue accounting.
- Merck KGaA announced in February 2013 that its Phase III clinical study with cilengitide in newly diagnosed glioblastoma did not meet its primary endpoints. MDxHealth had been providing an MGMT (methylguanine-DNA methyltransferase) diagnostic test, *Predict*MDx™ for Glioblastoma, that was used in the clinical study to identify and stratify those glioblastoma patients who may be more likely to benefit from cilengitide treatment.

# 6.4.3. Significant change in the issuer's financial or trading position

There has been no significant change in the financial or trading position of the group which has occurred since the end of the last financial period for which either audited financial information or interim financial information have been published.

# 6.4.4. Activities in the field of research and development

In 2012, the Company conducted product development projects based on the discovery R&D performed in the prior years for both its clinical diagnostic product pipeline and pharmaceutical research and clinical trial customers. Extensive work was performed in development of the Company's clinical diagnostic pipeline for Prostate Cancer, as well as on behalf of Merck KGga in connection with the development of the Company's MGMT assay as a potential companion diagnostic for Merck's drug candidate. Also in 2012, work was completed to related to Bladder, Lung, and Cervix projects underwritten by the Wallonia regional government.

Prior to 2011, the Company primarily performed discovery R&D projects for a wide range of cancer applications so as to out-license biomarkers to 3rd party companies which would develop the products and eventually commercialize them. This strategy did not generate sufficient revenues for the Company and left the Company excessively dependent on external parties for its future.

At the end of 2009, MDxHealth announced that it would change its strategy in 2010 and focus its R&D activities on a smaller set of core products. Today, the R&D activities are focused on the development of (i) Clinical Molecular Diagnostic products (*Clinical*MDx™) to assist physicians in the diagnosis of cancer, and (ii) Pharmaco Molecular Diagnostic products (*Pharmaco*MDx™) to assist pharmaceutical companies and physicians in getting the correct cancer treatment to the right patient. MDxHealth is now developing products which it intends to commercialize itself, primarily via a CLIA lab which the Company established in 2011 in the United States.

With this new strategy the R&D is thus focused on "development" of products for its own commercialization.

#### **Research and Discovery**

MDxHealth maintains an internal R&D team specialized in new biomarker discovery and optimization. In addition, MDxHealth collaborates with several universities and medical centers throughout the world in new biomarker discovery. For example, MDxHealth collaborates with the Johns Hopkins University and the University of Gent in the area of methylation biomarker discovery using next generation sequencing. This approach has optimized our current assay development process by focusing on the DNA regions of interest, ensuring an "intelligent" and accelerated biomarker

discovery process. In 2011, the Company performed validation trials leading to the launch of its Prostate *Confirm*MDx™ test in the US in H1 2012.

#### **Product Development**

On October 2010, MDxHealth announced a re-focusing of its diagnostics business. The Company currently focuses its diagnostics business on three clinical areas: prostate, brain, and lung cancer.

The products on which the most spending was done in 2012 are the following:

- Prostate cancer ConfirmMDx™: The Company is further validating an epigenetic ConfirmMDx™ for Prostate Cancer diagnostic test. The Company launched this test in the United States in mid-2012 via its new US-based CLIA laboratory.
- Prostate cancer InformMDx™: The Company is developing an epigenetic InformMDx™ for Prostate Cancer diagnostic test. The Company intends to launch this test in the United States via its new US-based CLIA laboratory.
- Brain Cancer (MGMT for Glioblastoma): The Company is developing a test to predict brain cancer patient response to alkylating agent medication (MGMT). The test is being used by several pharmaceutical companies in clinical trials for brain cancer drugs.
- *Bladder cancer*: The Company performed R&D on a tissue-based test for the detection of bladder cancer and for the monitoring of recurrence.
- Lung cancer: The Company performed some R&D on a blood and a sputum-based test for the confirmation of lung cancer. This development work will form the basis of the Lung Confirm test. The Company also performed R&D work on its Lung cancer Inform test. This test will provide a risk assessment of Stage I lung cancer patients with confirmation of whether the patient is either at low risk or high risk of recurrence.

The most advanced products include the following:

- ConfirmMDx<sup>™</sup> for Prostate Cancer: The Company launched this test in the United States in mid-2012 via its new US-based CLIA laboratory.
- InformMDx™ for Prostate Cancer test: This prognostic test for prostate cancer is now being developed "in-house" and the Company intends to commercialize it as an LDT through its U.S. CLIA-accredited laboratory.
- Brain Cancer Predict (MGMT for Glioblastoma): The MGMT tissue-based test is currently being commercialized as an LDT in North America via Laboratory Corporation of America (LabCorp). The Company has been further developing the MGMT test to predict brain cancer patient response to alkylating agent medication. The test is being used by several pharmaceutical companies in clinical trials for brain cancer drugs. MDxHealth had been providing MGMT testing for Merck KGaA's Phase III clinical study of its drug candidate cilengitide. However, Merck recently announced that this trial did not meet primary endpoints, and therefore it is unlikely that Merck will continue its development of Cilengitide or its support for the development and commercialization of the Company's MGMT test as an FDA-approved companion diagnostic to Cilengitide.

In addition to the above R&D work, the Company is working on several tests to determine which patients will respond to certain drugs for particular cancers. This work is often done in partnership with pharmaceutical companies which have a drug in development.

# 6.4.5. Obligations not reflected in the 2012 financial statements

In December 2012, the Board of Directors of the Company agreed to grant warrants under the existing warrant pool issued at the Extraordinary General Shareholder's meeting of June 15, 2012. These warrants are not reflected in the financial statements of 2012.

# 6.4.6. Branches of the Company

The company has no branch.

# 6.4.7. Justification to continue using the accounting rules on the basis of going concern

Despite cumulated losses, the Board has decided to continue to apply the accounting rules on the basis of going concern. This decision is justified by (i) the success of the technology of the Company in various cancer applications and scientific publications, (ii) continued interest in the Company's technology, (iii) the continued industry growth in the field of molecular diagnostics and personalized medicine, and (iv) the fact that sufficient cash is available to support further development of the Company's products over the next 12 months period in function of the current business plan.

Considering the situation, The Board of Directors believes that there is enough cash to sustain the current projects of the Company at least until the date of the annual general shareholders' meeting scheduled for May 2014.

# 6.4.8. Financial risks (article 96 8° C.C.)

Virtually all of the Company's currency risk currently relates to U.S. Dollars. The Company reports in euros, and in 2012 generated the majority of its revenues and incurred the majority of its costs in Euros. With the new strategic focus on the U.S. market, in future years the currency risk of the Company may increase. At this time, the Company does not use hedging instruments to cover the exchange rate risk.

# 6.4.9. Risk factors (article 96 1° C.C.)

In 2012, the Company was potentially subjected to the following risks:

- The business model of MDxHealth has recently considerably changed and the Company may not be successful in accomplishing any of its new objectives
- The Company is at an early stage of development and may encounter difficulties in its growth and expansion of activities
- Losses have been incurred since the inception of the Company, further losses are expected in the foreseeable future, and further funding will be needed
- The Company is dependent on intellectual property rights which could be challenged and the Company could be affected by new patents of third parties
- The Company must comply with many conditions in order to maintain the intellectual property rights which it in-licenses from third parties
- The enforcement of the Company's intellectual property rights could involve significant costs and could impact the commercial freedom of the Company in certain areas

- The Company's performance could be hindered by the way its commercial partners utilize certain of its technologies
- The Company's success is dependent upon factors such as its ability to access samples, work with or obtain the support of certain scientific or medical partners, recruit and retain key personnel, generate positive clinical study results, obtain regulatory approval of its products and comply with ongoing regulations, partner with third parties for the manufacture and sale of its products, get the market to accept and use its products, and obtain reimbursement of its products for patients
- The Company operates in markets in which the competition and regulatory environment may change and thus impact the Company's products and strategy, such as in the United States, where the reimbursement for testing service from Medicare and 3rd party private insurance payors is in the early stages and still uncertain.
- The Company is subject to product liability risks
- Foreign exchange rate fluctuations could impact the results of the Company

In 2012, financial risk management involved primarily the following:

- <u>Credit risk:</u> The limited number of the group's customers subjects the Company to concentrations of credit risk. In 2010, the Company generated 90% of its commercial turnover with sixteen customers, reducing the concentration of credit risk. In 2011, 87% of the commercial turnover is was generated by 10 customers. In 2012, the Company generated 74% of its commercial turnover with six customers, increasing its credit risk. In 2012, 2 individual customers each represented more than 9% of the total commercial revenues of the Company and together they accounted for 46% of total commercial revenues. The 2 largest customers in 2012 were Merck KGaA and Predictive Biosciences.
- Interest risk: The Company is not currently subject to material interest risk since it has no financial debt.
- <u>Currency risk</u>: The Company is not currently subject to material currency risk. The Company reports in Euros, and in 2012 generated the majority of its revenues and incurred the majority of its costs in Euros. No hedging instruments have been used so far. With the new strategic focus on the U.S. market, in future years the currency risk of the Company may increase.
- <u>Liquidity and investment risk:</u> The Company has invested all of its cash and cash equivalents in highly-rated and highly-liquid bank savings or money market accounts. The company has not invested in any derivative instruments or CDOs.

# 6.4.10. Internal control and risk management systems

The company has implemented a number of standard control and management systems for a company of its size and industry sector.

For the reporting of financial information, the Company has specifically implemented the following controls and procedures:

- The Audit Committee reviews all financial information before it is released
- The Board of Directors reviews internal monthly financial information
- The financial auditors not only audit the year-end financial statements, but at the request of the Company they

also perform a limited review of the Interim half-year financial statements

- The Company managers and finance department personnel explain all material variances in historical figures and between the budget and actual figures
- The Board of directors, the Company managers and finance department personnel perform reviews and controls of the key financial figures at each reporting period, some of which are described below

At the Board of Directors level, there is a periodic review and approval of the following main topics:

- Overall strategy and strategic options
- 5-year business plan and company goals
- Ensuing year budget and targets
- · Comparison of actual results and budgeted figures
- Material in-licensing and out-licensing opportunities and deals
- Material supplier, contractor, and partnership opportunities and deals
- · Hiring, motivation, and retention of key talent
- · Remuneration and benefits
- Review and approval of press releases
- Financial statements
- Internal controls

Management of the Company is organized on the basis of plans, departments, projects, and corresponding budgets and targets. Progress on the core projects, budgets, and plans are reviewed on a periodic basis. The management has clearly aligned responsibilities as described in the job descriptions which are prepared for all employees of the Company.

A set of measures has been taken to assure the quality of the financial and management information, amongst others:

- The appointment of qualified personnel in key positions with all entities of the Company
- The definition of a set of standard procedures for key activities such as steps for the approval, purchasing and payment of services and goods
- The request for the external auditors to pay special attention to areas with specific company and industry risk
- The request for specialized consultants to assist in designing and/or reviewing key procedures, systems, or reports
- The audit committee or individual directors periodically review and are consulted on key matters and procedures and when needed external specialist assistance is sought

A significant part of the Company's funds are spent on research and development projects. To ensure control and management of such projects, the Company has a number of measures, amongst others:

- Use of design-control procedures in the development of all products
- · Each project has its specific development plan which is periodically updated and reviewed
- R&D and commercial services are performed in an ISO-certified laboratory
- External experts are used for advising on the projects (market research studies, scientific advisory board, clinical advisors, etc.)
- Both in-house and external intellectual property specialists manage the IP portfolio
- Audits of its laboratory facilities are performed by external specialists and by big pharmaceutical companies using the Company's services
- Environmental, safety, and security permits are obtained where necessary and staff is trained on relevant procedures

The legal department of MDxHealth under supervision of the CEO, together with the management team has set up internal procedures in order to ensure that acts performed within or by the Company are in compliance with the existing laws and external regulations. The management is also responsible to comply with internal regulations and the Board of Directors is ensuring that the management is respecting the general policies and the corporate plans.

The risks, which the Company is subject to, have been discussed at the start of this document. Risks with respect to infrastructure – such as fire, unwanted access and power failures - have been minimized by taking appropriate measures. For assets which are crucial for the continuity of the Company, being it equipment for R&D or stored human samples, measures have been taken to minimize the risk of loss or destruction of such assets. Next to avoiding risks in this respect, where possible, insurance has been taken to cover loss of these assets, always based however on an economical justification whereby the risk is evaluated against the price to insure the risk. With respect to complying with regulations concerning safety at work, working with biotechnological material and environmental matters in general, appropriate measures were taken within the Company to guarantee compliance with these regulations and to operate with and within the required permits in this respect.

The IT department is responsible for the continuity of the platforms used by the Company to support its operations as well as for the implementation of system access controls and safely storing data. Appropriate measures were taken to assure the continuity of the operations of the Company taking into account the requirements of the different departments.

All employees of the Company are instructed on the rules and policies of the Company via a booklet of work rules, the terms of their employment contracts, standard operating procedures defined by task/area, and by numerous documents (such as the Dealing Code) that are distributed and explained to the personnel. The directors and key consultants are subjected to the same standard procedures and rules when and where appropriate.

The IP-portfolio, for the protection of knowledge and proprietary technology, is actively managed by evaluating on a regular basis the costs to maintain such protection versus the benefits of doing this. Furthermore it is clearly communicated to employees on how to deal with confidential information (and rules are in place on how to share such information with third parties.

The Board periodically reviews and provides instructions to the management team on how to manage credit risks, interest risks, exchange risks, and liquidity risks. As an example, the Board has given instructions on what type of

financial instruments the Company can place its cash and on which it is not allowed to do so. The management also seeks external specialized advice on managing such risks.

# **6.4.11. Corporate Governance**

The Company's corporate governance charter was adopted in accordance with the recommendations set out in the Belgian Corporate Governance Code 2009 (the "2009 Code"), issued on March 12, 2009 by the Belgian Corporate Governance Committee (replacing the 2004 edition). The complete Corporate Governance Charter of MDxHealth is available on the MDxHealth website, at www.mdxhealth.com. Also, Section 3 of the 2012 Registration Document summarizes the main rules and principles of MDxHealth's Corporate Governance Charter. The Corporate Governance Charter forms an integral part of this Report of the Board of Directors.

MDxHealth has adopted the 2009 Belgian Corporate Governance Code as its reference code. It complies to a large extent with the provisions of this Code, but believes that certain deviations are justified in view of the Company's specific situation. In line with the "comply-or-explain" principle of said Code, it should be noted that MDxHealth does not fully comply with the following provisions:

- Given the size of the Company, no internal audit function exists at this time
- Although, according to the 2009 Code, Non-Executive Directors should not be entitled to performance-related remuneration such as bonuses, stock related long-term incentive schemes, fringe benefits or pension benefits, the Board of Directors is however of opinion that, for a company of the size of MDxHealth, it may be necessary to issue warrants to Non-Executive Directors, with a view to attracting directors with the relevant expertise and experience.
   All Non-Executive independent directors nominated before the May 2012 annual general shareholders' meeting have been awarded warrants.

The performance and functioning of the Board of Directors, its' committees, and of the Executive Management team are summarized below and are also explained in section 3 of the 2012 Registration Document.

#### **Board of Directors**

The Board of Directors' role is to pursue the long-term success of the Company by providing entrepreneurial leadership and enabling risks to be assessed and managed. The Board of Directors acts as a collegiate body. Pursuant to the Belgian Company Code and the articles of association of the Company, the Board of Directors should be composed of at least three directors. In accordance with the principles of corporate governance, the Board of Directors will, to the extent possible, be composed of at least five directors of which at least three directors are independent directors. To the extent possible, at least half of the board shall consist of Non-Executive Directors. Currently, the Board of Directors comprises 7 directors, of which 3 are independent directors and 6 are Non-Executive Directors. The directors of the Company are appointed by the general shareholders' meeting.

The Company's board of directors strives to maintain a well-balanced general diversity at the board of directors. Currently, there are 2 female directors among a total of 7 board members (representing a ratio of 29% female directors against 71% male directors). The Company is using its best efforts to ensure that the board of directors will meet the 2/3 gender diversity requirement by January 1, 2018.

The Board of Directors is a collegial body, and deliberates and makes decisions as such. Excluding the board committee meetings, throughout 2012 the Board of Directors met 9 times. All directors were present or represented for these 9 meetings.

#### Chairman

The chairman of the Board of Directors is responsible for the leadership of the Board of Directors. The chairman takes the necessary measures to develop a climate of trust within the Board of Directors, contributing to open discussion, constructive dissent and support for the decisions of the Board of Directors. The chairman promotes effective interaction between the board and the executive management. The chairman establishes a close relationship with the CEO, providing support and advice, while fully respecting the executive responsibilities of the CEO.

The Board of Directors appoints a chairman amongst the Non-Executive Directors. Currently, Mr. Edward L. Erickson is the chairman of the Board of Directors.

## **Independent Directors**

Effective as of January 8, 2009, new rules entered into force for Belgian publicly-listed companies with respect to the criteria for the independence of directors (article 526ter of the Belgian Company Code). The three independent MDxHealth directors meet these new definitions for independence. Composition of the Board of Directors.

Two directors resigned from MDxHealth in the course of 2011: (i) Hilde Windels BVBA, represented by Mrs. Hilde Windels, and (ii) ING Belgium NV, represented by Mr. Denis Biju-Duval. Mrs. Hilde Windels (an independent director and chair of the Audit Committee) was replaced by Mrs. Ruth Devenyns (an independent director who was also named chair of the audit committee). Mrs. Devenyns filled the seat vacated by Mrs. Windels based on a decision of the Board of Directors. Mrs. Devenyns' membership on the Board was confirmed by a decision of the annual general shareholders meeting in May 2012. Gengest BVBA, represented by its permanent representative Mr Rudi Mariën, filled the seat vacated by ING based on a decision of the Board of Directors, and became a non-independent director of MDxHealth. Mr. Marien's membership on the Board was confirmed by a decision of the annual general shareholders meeting in May 2012.

The table below describes the composition of the Board of Directors as of the date of this Registration Document.

Name	Age on Dec 31, 2012	Position	Term Start <sup>(1)</sup>	Term End <sup>(2)</sup>	Professional Address
Mr. Edward L. Erickson	66	Chairman, Non-Executive Independent director	2010	2013	Tour 5 GIGA, Av. de l'Hôpital 11, 4000 Liège, Belgium
Dr. Jan Groen	53	Executive, Director	2010	2013	Tour 5 GIGA, Av. de l'Hôpital 11, 4000 Liège, Belgium
Dr. Karin L. Dorrepaal	51	Non-Executive Director (Independent prior to Q4 2009)	2007	2013	Tour 5 GIGA, Av. de l'Hôpital 11, 4000 Liège, Belgium
Mr. Mark Myslinski	57	Non-Executive Independent Director	2010	2013	Tour 5 GIGA, Av. de l'Hôpital 11, 4000 Liège, Belgium
Edmond de Rothschild Investment Partners, rep- resented by Mr. Raphaël Wisniewski	42	Non-Executive Director	2005	2013	47, Rue du Faubourg St-Honoré, 75401 Paris Cedex 8, France
Gengest BVBA, represented by Mr. Rudi Mariën	67	Non-Executive Director	2011	2013	Karel van de Woestijnestraat 1-3, 9000 Gent, Belgium
Mrs. Ruth Devenyns	48	Non-Executive Independent Director	2011	2015	Kardinaal Sterckxlaan 47 1860 Meise, Belgium

#### Notes:

- 1) With the exception of Mrs. Ruth Devenyns, whose mandate was confirmed at the annual general shareholders' meeting held in May 2012, all directors were appointed or re-appointed by the ordinary general shareholders' meeting held on May 28, 2010 for a term of three years.
- 2) The term of the mandates of all directors will expire immediately after the annual general shareholders' meeting held on May 31, 2013.

## Litigation statement concerning the directors or their permanent representatives

At the date of this registration document, none of the directors, or in case of corporate entities being director, none of their permanent representatives, of the Company, other than those indicated in the paragraph below, has for at least the previous five years:

- any conviction in relation to fraudulent offenses
- held an executive function in the form of a senior manager or a member of the administrative, management or supervisory bodies of any company at the time of or preceding any bankruptcy, receivership or liquidation, or has been subject to any official public incrimination and/or sanction by any statutory or regulatory authority (including any designated professional body), except for:
  - (i) Mr. Edward Erickson who was CEO, chairman, and also held other executive and Non-Executive positions through June 2007 at the company Immunicon Corporation prior to its filing for bankruptcy in June 2008, for which the bankruptcy trustee has initiated legal proceedings against Mr. Erickson and other directors and managers of the bankrupt company
  - (ii) Mrs. Ruth Devenyns was a director of 2 US companies that filed for bankruptcy, PR Pharmaceuticals in 2008 and Altea Therapeutics in 2011
  - (iii)Mr. Raphaël Wisniewski who was a director at 2 companies which were liquidated in 2008, Nautilus Biotech and Androclus Therapeutics
- has ever been disqualified by a court from acting as a member of the administrative, management or supervisory bodies of any company or from acting in the management or conduct of affairs of any company.

#### **Committees of the Board of Directors**

The Board of Directors of MDxHealth has set up two permanent committees, the audit committee and the nomination and remuneration committee. The committees are advisory bodies only and the decision-making remains within the collegial responsibility of the Board of Directors.

#### **Audit Committee**

Effective as of January 8, 2009, new rules entered into force for Belgian publicly-listed companies with respect to (i) the establishment and tasks of the audit committee, (ii) the criteria for the independence of directors (see section 3.1.3), and (iii) the appointment of and dismissal of statutory auditors (see section 3.6).

With respect to the new rules covering the establishment of the audit committee, the following is applicable to MDxHealth:

• MDxHealth has had an Audit Committee in place since the Company's inception.

- According to the new rules, MDxHealth would meet the size criteria in order to operate without a separate audit committee, but the Company has chosen to continue operating with a separate audit committee.
- The new rules require that the audit committee be composed of Non-Executive Directors, which is and has always been the case for MDxHealth's audit committee.
- The new rules require that the audit committee be composed of at least one independent director with the
  necessary competence in auditing and accounting, which is and has always been the case for MDxHealth's audit
  committee.

MDxHealth's audit committee must be composed of at least three members and is limited to Non-Executive Directors. The committee appoints a chairman amongst its members. The chairman of the Board of Directors should not chair the committee.

The role of the audit committee is to assist the Board of Directors in fulfilling its financial, legal and regulatory monitoring responsibilities. The committee reports regularly to the Board of Directors on the exercise of its duties, identifying any matters in respect of which it considers that action or improvement is needed, and making recommendations as to the steps to be taken. The audit review and the reporting on that review cover the Company and its subsidiaries as a whole. The specific tasks of the audit committee are outlined in the Company's governance charter.

The following directors are currently members of the audit committee: Ruth Devenyns (chairperson), Edward Erickson and Dr. Karin Louise Dorrepaal, Non-Executive Directors.

The audit committee is a collegial body, and deliberates and makes decisions as such. The audit committee met 2 times in 2012. All members of the audit committee were present or represented at all meetings.

#### **Nomination and Remuneration Committee**

The Belgian Act of April 6, 2010 relating to the improvement of the corporate governance for publicly listed companies and autonomous governmental companies, and amending the regulation relating to professional prohibitions in the banking and financial sector ("Loi visant à renforcer le gouvernement d'entreprise dans les société cotées et les entreprises publiques autonomes et visant à modifier le régime des interdictions professionnelles dans le secteur bancaire et financier" / "Wet tot versterking van het deugdelijk bestuur bij de genoteerde vennootschappen en de autonome overheidsbedrijven en tot wijziging van de regeling inzake het beroepsverbod in de bank- en financiële sector") introduced a new article 526 quater in the Belgian Company Code requiring qualifying publicly listed companies to establish a remuneration committee as from the first accounting year started after the date of publication of said Act (i.e. April 23, 2010).

With respect to these new rules covering the establishment of the remuneration committee, the following is applicable to MDxHealth:

- Although this legal obligation to establish a remuneration committee would only apply for MDxHealth as from the accounting year started on January 1, 2011, MDxHealth has had a nomination and remuneration committee in place since the Company's IPO in June 2006.
- According to the new rules, MDxHealth would meet the size criteria in order to operate without a separate nomination and remuneration committee, but the Company has chosen to continue operating with a separate nomination and remuneration committee.

• The new rules require that the nomination and remuneration committee be composed of Non-Executive Directors, which is and has always been the case for MDxHealth's nomination and remuneration committee.

MDxHealth's nomination and remuneration committee must be composed of at least three members and must be composed exclusively of Non-Executive Directors. The committee appoints a chairman amongst its members. The chairman of the Board of Directors can chair the committee, but should not chair the committee when dealing with the designation of his successor. The CEO should participate to the meetings of the committee when it deals with the remuneration of other executive managers.

The role of the nomination and remuneration committee is to make recommendations to the Board of Directors with regard to the election of directors, the remuneration policy for Non-Executive Directors and the resulting proposals to be submitted to the shareholders' meeting, the remuneration policy for executive management, and to review and periodically update an overall remuneration policy for all personnel and directors of the Company. The committee's tasks are further described in the Company's corporate governance charter.

The following directors are members of the nomination and remuneration committee: Edward Erickson, independent director, Mark Myslinski (chairman of the committee) independent director, and Rudi Mariën, non-independent director.

The nomination and remuneration committee is a collegial body, and deliberates and makes decisions as such.

The nomination and remuneration committee met 6 time in 2012. All of the committee members attended all of the committee meetings.

## Process for Evaluating the Board, its Committees, and its Individual Directors

Every year the Board of Directors will, under the lead of its Chairman, assess its size, composition, performance and those of its committees, as well as the contribution of each director.

### **Executive Management**

The Board of Directors has appointed the executive management of the Company. The terms of reference of the executive management have been determined by the Board of Directors in close consultation with the CEO.

#### **Composition of the Management Team**

The composition of the Management Team is set out below and reflects the situation at the date of this report.

Name	Position	Age on Dec 31, 2012
Dr. Jan Groen	Chief Executive Officer (CEO)	53
Mr. Joseph Sollee	Executive Vice-President of Corporate Development and Legal Affairs	48
Mr. Christopher Thibodeau	Executive Vice President of Commercial Operations	42
Mr. Francis Ota	Executive Vice President of Finance	60

## Litigation statement concerning the management

The Company is not aware of any conviction of any member of the executive management in the previous five years for fraud or indictable offences, or of any involvement in bankruptcy, late payment, or forced liquidation. Each executive management team member has represented that he or she has not been convicted in the previous five years for fraud or indictable offences, or of any involvement in bankruptcy, late payment, or forced liquidation.

# 6.4.12. 2012 Remuneration Report

The following report has been prepared by the nomination and remuneration committee and approved by the board of directors of MDxHealth. This report contains the remuneration report as referred to in Article 96, §3 of the Belgian Company Code (Code des Sociétés/ Wetboek van Vennootschappen), as amended by the Law of April 6, 2010 (the "Remuneration Report").

The Remuneration Report has been prepared by the nomination and remuneration committee and has been approved by the board of directors of the Company on February 27, 2013.

The Company has reviewed the remuneration policy of its management, executive and Non-Executive Directors in light of article 96 of the Belgian Company Code (Code des Sociétés/ Wetboek van Vennootschappen), as amended by the Law of April 6, 2010 and as supplemented by the relevant provisions of the Belgian Corporate Governance Code and the Law of November 7, 2011 modifying the Belgian Company Code in relation with the share-based remuneration of Non-Executive Directors of listed companies, and has prepared this Remuneration Report in accordance with the requirements contained therein.

### **Procedure adopted in 2012**

#### Procedure adopted to develop a remuneration policy

During 2012, MDxHealth has continued to apply widely the remuneration policy applied in 2011. In conformity with the applicable legislation, the nomination and remuneration committee of the Board of Directors, composed of non-executive members of the board, has the tasks (i) to formulate proposals on the remuneration policy applicable to directors, managers and other executives, as well as on the determination of their remuneration on an individual basis, and (ii) to prepare the remuneration report to be inserted in the corporate governance statement of the annual report.

The remuneration report is submitted to a vote by the annual general shareholders' meeting.

The nomination and remuneration committee met on December 6, 2011 and made recommendations to the Board of Directors, which were approved by the same on December 7, 2011 and by the annual general shareholders' meeting on May 25, 2012.

The main recommendations implemented in 2012, which aim at better aligning the interests of the board members with the goal of the Company, can be summarized as follows:

- the setting in place of an equity incentive program, including a general pool of stock options in the form of warrants, for management and other personnel;
- the non granting of fees to non-independent directors for serving on the Board;
- the demand (but not the request) to independent directors serving as representatives of investors that own an amount of Company shares greater than the five percent (5%) transparency filing threshold to waive their board fees;
- the change from the variable component of Board remuneration to a fixed annual compensation scheme;
- the annual grant of six thousand (6,000) stock warrant to each non-executive board member, under the terms of a Company warrant program.

These recommendations, as reflected in the remuneration policy, were implemented in 2012 and are still applicable for the accounting year 2013.

#### Procedure adopted to determine the level of remuneration

#### a) Directors

Annually, the nomination and remuneration committee reviews the fee levels paid to directors and compares them to fee levels paid at other comparable companies.

Grants of warrants to directors are recommended by the non-conflicted members of the nomination and remuneration committee, reviewed by the Board of Directors and submitted to the general shareholders' meeting for approval. Non-executive directors may be entitled to warrants. Such warrants must be approved by a general shareholders' meeting. The warrants are used to attract, motivate, and retain key talents at the director level. The number of warrants granted to non-executive directors has remained low compared to the number of total outstanding security instruments. Non-executive directors are not entitled to bonuses, fringe benefits or pension benefits.

Non-executive board members who provide services to the Company outside of the formal board meetings or board committee meetings, must have their work and fees pre-approved by the non-conflicted members of the nomination and remuneration committee. These fees are then submitted for approval at the ensuing annual general shareholders' meeting.

For the executive director position, the nomination and remuneration committee proposes remuneration changes and bonuses, if any to the Board of Directors for approval.

## b) CEO and managers

The remuneration of the executive management is designed to attract, retain and motivate executive managers. The level and structure of the remuneration are subject to an annual review by the nomination and remuneration committee to take into account market practice. The annual review does not provide mechanisms for automatic adjustments, except for changes that are legally required.

The fixed remuneration level, the variable bonus, and the objectives of the CEO are reviewed by the nomination and remuneration committee, compared to industry and market levels, and confirmed by the Board of Directors. The Board of Directors sets the Company objectives and the personal objectives of the CEO.

The CEO sets the personal objectives of the other executive managers. He recommends grants of warrants, bonuses and changes, if any, in the fixed remuneration of executive managers to the nomination and remuneration committee. The nomination and remuneration committee reviews these recommendations and compares them to industry and market practices. It then proposes the warrant grants, bonuses and remuneration changes, if any, to the Board of Directors, and to the extent required by applicable law, to the general shareholders' meeting, for approval.

#### **Declaration on the remuneration policy**

## **Remuneration policy in 2012**

The Board of Directors determines, upon recommendation of the nomination and remuneration committee, the remuneration policy for directors and managers.

#### a) Directors

The remuneration policy for non-executive and executive directors was modified at the annual shareholders' meeting of May 25, 2012.

#### Non-executive directors

The non-executive directors are remunerated on the basis of a pre-defined fixed annual retainer fee. The fee level is the applicable fixed annual retainer fee approved at the last annual general shareholders' meeting concerning this matter, i.e.:

- EUR 35,000 for the Chair of the Board of Directors;
- EUR 30,000 for the Chair of the Audit Committee;
- EUR 28,000 for the Chair of the Nomination and Remuneration Committee; and
- EUR 25,000 for any other director.

A record of board attendance is maintained by the secretary to the Board of Directors. This record is then reviewed by the Board of Directors and confirmed by the approval of the board minutes. Regular attendance at scheduled meeting of the board of directors, including committee meetings, is expected. In the event that that a director fails to attend at least 75% of the scheduled meeting of the board of directors during a calendar year, the board may reduce such director's applicable annual retainer fee by a pro rata amount to reflect actual attendance.

Apart from the above remuneration, directors will be entitled to a reimbursement of out of pocket expenses actually incurred to participate to board meetings.

Although all non-executive directors have the right to receive the foregoing applicable annual retainer fee, the board suggests that each non-independent director elect, in his or her discretion, to waive its right to receive such fees. In calendar year 2012, the two non-independent directors, who have not held an executive position within the Company, agreed to waive their director' fees.

The mandate of non-executive directors can be terminated at any time without any compensation. Non-executive directors do not receive any form of pension plan benefits from the Company.

The Company has not made any loans to the members of the board of directors.

#### Executive directors

Executive directors do not receive any remuneration for their position as a director. Executive directors are only remunerated for their role as executive managers. These individuals receive a fixed remuneration plus a variable bonus that is linked to their personal achievements and the achievements of the Company. They do not receive any additional remuneration for the exercise of their board mandate. The mandate of executive directors may be terminated at any time without any form of compensation. Their remuneration package is approved by the general shareholders' meeting. The CEO is the only executive director of the Board of Directors of the Company and he does not earn any remuneration in respect of his executive director position.

• Relative importance of the components of remuneration.

The relative importance of the various components of remuneration as referred to in article 96, §3, al. 2, c) of the

Belgian Company Code, is provided under section C. (i) of this Remuneration Report.

#### b) CEO and managers

Each member of the executive management is entitled to a basic fixed remuneration designed to fit responsibilities, relevant experience and competences, in line with market rates for equivalent positions. The majority of the annual remuneration is a fixed compensation amount. There is no minimum nor maximum variable bonus.

The CEO has a fixed remuneration, a fixed bonus and a variable bonus linked to the performance of the Company and to his capacity to manage remuneration costs.

The management team members receive a fixed remuneration plus a variable bonus that is linked to their personal achievements (i.e. experience, know-how, education, skills, responsibilities, and performance) and the achievements of the Company. The remuneration is closely linked to performance. Bonuses, if any, are linked to identifiable objectives and to special projects and are set and measured on a calendar-year basis. Non performers are not retained in the Company. The performance objectives of the management team members are primarily evaluated with regard to the following criteria: (i) respect of the board-approved annual budget, (ii) share value, and (iii) meeting measurable operational targets. The various objectives and their weighting may differ for the individual managers. The nomination and remuneration committee of the board of directors meets annually to review the performance of the managers, to compare the actual measurable results to the objectives that were pre-defined by the committee, and to establish the measurable objectives for the ensuing calendar year.

Each member of the executive management who is a salaried employee may be entitled to a number of fringe benefits, which may include participating in a defined contribution pension or retirement scheme, disability insurance, a company car, a mobile telephone, internet access and/or a laptop computer according to general Company policy, and other collective benefits (such as hospitalization insurance and meal vouchers).

In 2012, all the members of the executive management (excluding the former CFO) were engaged on the basis of an employment contract. The employment contracts are generally for an indefinite term, with a trial period. The employment contracts may be terminated at any time by the company, subject to a severance payment in line with market standards. The employment contracts include, where appropriate, non-competition undertakings, as well as confidentiality and IP transfer undertakings (that will try to seek maximum protection of the Company's interests, under applicable laws and subject to the employee's agreement).

Executive members who are engaged on the basis of a services contract do not receive fringe benefits, except that they may be provided with a mobile phone and laptop computer according to General Company policy, and they qualify for reimbursement of expenses incurred while carrying out their professional responsibilities.

Executive managers of the Company that are employed under employee contracts are entitled to enroll in defined-contribution type pension plans (such as 401K plans in the United States). The assets of these pension plans are held and managed by third-party organizations and the Company only makes contributions to these plans during the term of service of the employee. Executive managers of the Company that are engaged on the basis of a service agreement are not entitled to any pension plans or pension plan contributions from the Company.

#### Warrants

Stock Options granted by the Company generally take the form of warrants in the sense of article 496 et seq. of the Belgian Company Code.

Warrants can periodically be awarded to managers, directors, employees, or even certain consultants, primarily as a retention and motivation tool. Warrants typically vest over time (subject to the beneficiary remaining with the Company) and can only be exercised after a specific period of time, except where the Company decides otherwise. There was no significant change in the remuneration policy in 2012.

#### Expected changes with respect to accounting year 2013 and the following accounting year

No significant change to the remuneration policy of Directors and Executive managers is envisaged for 2013 and 2014.

The bonuses of the management team members for 2013-2014 will be primarily linked to the following objectives:

- respect of the board-approved annual budget, with a focus on revenue growth and cash-flow management
- share value measured against a relevant industry index
- · meeting measurable operational targets, including specific product development and commercialization goals
- Remuneration earned by the Non-Executive Directors for the reported year

The following table provides the 2012 compensation of the Non-Executive Directors in function at the date of this document

Name	Position <sup>1</sup>	Pro-rata of annual retainer fee <sup>2</sup> (EUR K)	Other services (EUR K)	Total <sup>3</sup> (EUR K)
Edward Erickson	NED – Board Chair, member AC & NRC	35	0	35
Karin Dorrepaal	NED – member AC	25	0	25
Raphaël Wisniewski	NED	0	0	0
Rudi Mariën	NED - member NRC	0	0	0
Mark Myslinski	NED – NRC Chair	28	0	28
Ruth Devenyns	NED – AC Chair	30	0	30
TOTAL for current non-executive Board members		118	0	118

#### Notes:

During the course of 2012, the composition of the Board of Directors did not change.

During the course of 2012, the Company has not deviated from its remuneration policy for the non-executive directors. The total remuneration and benefits paid to the all directors (both executive and non-executive directors, and including the CEO remuneration) in 2012, 2011 and 2010 was EUR 640,000, 645,000 and EUR 436,000 respectively (gross amount, excluding VAT and stock based compensation).

On May 23, 2006, the Board of Directors decided, with application of Article 523 of the Belgian Company Code, that the Company will indemnify the directors against any claim by a third party based on directors' liability, except in the event of gross negligence and willful misconduct. Therefore the Company has taken out directors' liability insurance. The insurance policy was renewed in 2012. Additionally, on August 1, 2012, the Company's U.S. subsidiary, MDxHealth, Inc.,

<sup>1: &</sup>quot;NED" = Non-Executive Director, "ED" = Executive Director, "AC" = Audit Committee, "NRC" = Nomination & Remuneration Committee

<sup>2:</sup> Fixed annual retainer fees were paid for calendar year 2012 based on shareholder approval of the new remuneration policy for directors

<sup>&</sup>lt;sup>3</sup>: Excludes expense reimbursement and warrants. No other form of remuneration exists for directors.

entered into indemnification agreements directly with each of its directors, as well as each director of the Company, to indemnify each such person for liabilities to the extent that they may arise from, or claims therefor which are based on, U.S.-associated activities of the U.S. subsidiary or of the Company, including any claims based on a theory of derivative liability in the right of the U.S. subsidiary.

#### Remuneration earned by the Executive Director for the reported year

Dr. Jan Groen is not remunerated for his position as an Executive Director of the Company. Neither is he entitled to any severance pay in case of termination his mandate as an Executive Director of the Company.

#### Remuneration earned by the CEO for the reported year

Dr. Jan Groen was hired as CEO starting April 26, 2010. He is remunerated on the basis of his executive management position. The CEO has a variable bonus linked to the performance of the Company, which can amount to a maximum of 30% of his annual compensation, and a fixed annual bonus of maximum EUR 22,000, linked to its capacity to manage human resources costs. Excluding the value of warrants, the remuneration and benefits provided to the CEO in 2012 were comprised as follows:

	Euro (EUR)
Fixed gross remuneration <sup>1</sup> :	377,000
Bonuses paid and awarded <sup>2</sup> (gross)	85,000
Pension benefits:	13,000
Other benefits <sup>3</sup> :	30,000
Total	505,000

#### Notes:

- 1: Total cost to the Company, including employer social security contributions and vacation pay accrual.
- 2: Excludes value of 45,000 warrants the Board of Directors has agreed to issue to the CEO as a bonus for 2012 performance (see below). Excludes value of 130,000 warrants already created, issued, and accepted in 2010, 30,000 warrants already created, issued, and accepted in 2011, and the IFRS cost of the 45,000 warrants already created, issued, and accepted in 2012.
- 3: Includes Company-paid housing, Company car, meal vouchers, and other similar benefits. Excludes reimbursement of normal professional expenses such as telephone and Company travel expenses.

The total service fees paid to the CEO in 2012, 2011 and 2010 were EUR 505,000, EUR 524,000 and EUR 317,000, respectively (gross amount, excluding VAT and stock based compensation). It is to be noted that the present CEO was hired in and as from April 2010. Previously, the CEO was Herman Spolders BVBA, represented by its permanent representative Mr. Herman Spolders.

Dr. Jan Groen holds no shares in the Company. However, upon being hired in April 2010 he was granted 130,000 new warrants in the Company. The warrants were granted at the extraordinary general shareholders' meeting of June 21, 2010 and have the following characteristics:

- Exercise price of EUR 2.07 (one stock option (warrant) gives right to buy one share)
- Vesting: straight-line on a quarterly basis over 4 years (no vesting if less than one year of service or employment is provided)
- Duration of options: 5 years

The IFRS share-based compensation of the above 130,000 warrants granted in 2010 amounts to EUR 162,000.

Dr. Groen was granted an additional 30,000 new warrants in the Company at the Board of Directors' meeting of May 27, 2011 and have the following characteristics:

- Exercise price of EUR 1.71 (one stock option (warrant) gives right to buy one share)
- Immediate and full vesting of all stock options on the date of grant (December 7, 2010)
- Duration of options: 10 years

The IFRS share-based compensation of the above 30,000 warrants granted in 2011 amounts to EUR 26,000.

At the board meeting of December 7, 2011, the non-conflicted members of the Board of Directors agreed to the following bonus for the performance of Dr. Jan Groen in 2011:

- EUR 82,000 cash bonus
- 45,000 new warrants (employee stock options) formally issued on March 15, 2012 to vest straight-line over 4 years. The exercise price is based on the 30-day average market price prior to their issuance. The warrants are not exercisable until after the third anniversary the date of their grant.
- The IFRS share-based compensation of the above 45,000 warrants granted in 2012 amounts to EUR 51,000.

At the board meeting of December 5, 2012, the non-conflicted members of the Board of Directors agreed to the following bonus for the performance of Dr. Jan Groen in 2012:

- EUR 85,000 cash bonus
- 45,000 new warrants (employee stock options) formally granted on January 1, 2013 to vest straight-line over 4 years. The exercise price is based on the 30-day average market price prior to their grant. The warrants are not exercisable until after the third anniversary the date of their grant.

The IFRS share-based compensation of the above 45,000 warrants granted in 2012 amounts to EUR 52,000.

During the course of 2012, the Company has not deviated from its remuneration policy for the executive director.

#### **Remuneration earned by other Executive Managers**

The 2012 combined remuneration package of the 3 other executive management team members (excluding the CEO) - i.e. Christopher Thibodeau, Joseph Sollee and Francis Ota - including employer taxes, together with the remuneration of Decofi sprl (represented by Philip Devine), the former CFO of the Company, was EUR 928,000.

	EUR
Fixed gross remuneration <sup>1</sup> :	762,000
Bonuses paid and awarded <sup>2</sup> (gross)	117,000
Pension benefits:	19,000
Other benefits <sup>3</sup> :	30,000
Total	928,000

#### Notes:

- 1: Includes employer taxes and vacation pay accrual. Excludes VAT.
- 2: Excludes value of warrants the Board of Directors has agreed to issue to certain other executive managers.
- 3: Includes for some individuals a Company car, meal vouchers, and other similar benefits. Excludes reimbursement of normal professional expenses such as telephone and Company travel expenses.

The total remuneration and benefits paid to the executive management team members (including the CEO) in 2012, 2011 and 2010 was EUR 1.4 million, EUR 1.3 million and EUR 0.9 million, respectively (gross amount, excluding VAT and stock based compensation). In the aforementioned figures, the service fees and board fees of the managers hired on the basis of a service agreement are included with the salaries of the other management team members. The number of managers included in the definition of the Executive Management Team has been reduced over the recent years to fit the new company strategy.

Cash bonuses were awarded to certain management team members in 2012 (in addition to stock option bonuses mentioned in this report) as follows (amounts exclude employer taxes):

•	CEO	EUR 85,000
•	EVP Corp. Dev. & Legal Affairs	EUR 39,000
•	EVP Commercial Operations	EUR 66,000
•	EVP Finance	EUR 12,000

The primary performance objectives for the bonuses of the above management team members in 2012 were the following:

- · respect of the board-approved annual budget, with a focus on cash-flow management
- share value measured against a relevant industry index
- meeting measurable operational targets, such as the commercialization of its ConfirmMDx™ for Prostate test and attainment of revenue targets

In the course of 2012, no warrants or other rights were exercised by or lapsed for the executive managers.

During the course of 2012, the Company has not deviated from its remuneration policy for the executive managers.

#### Warrants to be granted in 2013

In addition, based on a decision of the Board of Directors on December 5, 2012, the Company has contractually agreed to grant new warrants to certain executive managers in 2013, as part of the 2012 bonuses.

Grantee	Warrants
CEO	45,000
EVP Corp. Dev. & Legal Affairs	35,000
EVP Commercial Operations	30,000
EVP Finance	10,000

These warrants have the following characteristics:

- Exercise price based on the 30-day market average price in the period preceding the date of grant (one warrants shall entitle its owner to acquire one share);
- Vesting: straight-line on a quarterly basis over 4 years (no vesting if less than one year of service or employment is provided) although the vesting period may start on a date earlier than the date of the grant of the warrants;
- · Exercise Period: the warrants are not exercisable until after the third anniversary the date of their grant;
- Duration of warrants: 10 years.

#### Special provisions of the contractual relationship of the Executive Managers

The executive managers have contractual agreements which date from before the entry into force of the law of April 6 2010 on corporate governance in public and listed companies and are in conformity with common employment law.

More specifically:

- the employment contract with Dr Jan Groen provides that if the employment contract is terminated for a reason other than serious misconduct, he will be entitled to a severance pay of three (3) months gross remuneration per initiated period of five (5) years of service with the company, however, such severance pay will be at a minimum equivalent to nine (9 months) of gross remuneration. This agreement was entered into on April 3, 2010, i.e. before the entry into force of the law of April 6, 2010 on corporate governance in public and listed companies;
- the employment contract with Mr Joseph Sollee provides that if the employment contract is terminated for a reason other than serious misconduct, he will be entitled to a severance pay of four (4) months gross remuneration and benefits; this period is extended to six (6) months in case of a change of control; and
- the employment contract with Mr Christopher Thibodeau provides that if the employment contract is terminated for a reason other than serious misconduct, he will be entitled to a severance pay of three (3) months gross remuneration and benefits.
- the employment contract with Mr Christopher Thibodeau provides that if the employment contract is terminated for a reason other than serious misconduct, he will be entitled to a severance pay of three (3) months gross remuneration and benefits;

The service contract with Decofi sprl (represented by Philip Devine (former CFO)) was terminated in 2012. In accordance with the termination provisions of the, Decofi sprl received an indemnity payment equal to ten (10) months of the service fees at the then applicable monthly rate.

The contracts with the Executive managers and the executive director do not include a provision as referred to in Article 96, §3, al 2, 11° of the Belgian Company Code. There is no contractual clause in the employment contracts or service agreements with the executive directors/management stating that the variable part of the remuneration based upon faulty financial information will be recovered by the Company.

#### 2012 Share-based compensation of Directors and Executive Managers

During the course of 2012, the following share-based compensation was given to Directors and Executive managers of MDxHealth:

- Each non-executive director received 6,000 new warrants
- Dr. Jan Groen, CEO and executive director, received 45,000 new warrants
- The 3 other current members of the Executive management team received a total of 75,000 new warrants
- No warrants were granted in 2012 to the former member of Executive management, Decofi sprl (represented by Philip Devine (former CFO))

The warrants granted to non-executive directors at the annual general shareholders meeting of May 25, 2012 have the following characteristics:

- Exercise price of EUR 1.52 (one stock option (warrant) gives right to buy one share)
- Cliff vesting over 1 year for all beneficiaries
- Duration of options: 10 years

The warrants granted to executive management were awarded at the Board of Directors' meeting of March 15, 2012 and have the following characteristics:

- Exercise price of EUR 1.72 (one stock option (warrant) gives right to buy one share)
- Straight-line vesting over 4 years for all beneficiaries
- Exercise Period: the warrants are not exercisable until after the third anniversary the date of their grant;
- Duration of warrants: 10 years

The company has not materially deviated from its remuneration policy during the financial reported year.

## 6.4.13. Performance by the statutory auditor of exceptional activities or execution of special instructions (Article 134 C.C.)

During the past fiscal year, in addition to their usual activity, the statutory auditor performed additional activities on behalf of the Company mainly for the issuance of special reports related to warrant plans, grant report certification, for participation to the audit committees and for participation to special projects. The total amount paid for these additional activities is EUR 19.000.

#### 6.4.14. Independence and competence of an audit committee member

The rules for publicly-listed companies require that the audit committee be composed of at least one independent director with the necessary competence in auditing and accounting, which is and has always been the case for MDxHealth's audit committee.

- Mrs. Ruth Devenyns, who assumed the position of Audit Committee Chairperson since August 2011, meets the criteria of independence:
  - She is in her first mandate on the Board of MDxHealth and has never held any Executive management position with the Company.
  - She owns no shares in the Company. She has been granted 6,000 warrants in 2012 entitling her to subscribe

to the Company's shares. However, this does not prejudice her independence in the sense of article 526ter of the Company code because (i) the number of warrants granted to non-executive directors is limited, (ii) the shareholders' general meeting approved such grant by approving the May 2012 Stock Option Plan on June 15, 2012 and (iii) the granting of a limited number of warrants to non-executive directors was recommended by the nomination and remuneration committee in order to attract and retain talents in the Company.

- She fulfills the other criteria of independence as listed in section 3.1.3.
- Mrs. Ruth Devenyns meets the criteria of necessary competence in auditing and accounting:
  - She has worked in the venture capital sector

#### 6.4.15. Conflicts of interest (Article 523 C.C.)

In accordance with Article 523 of the Belgian Company Code, the Board of Directors clearly stated each time they experienced an interest of a patrimonial nature potentially departing from the interests of the Company. The following conflict of interest has been reported in 2012:

#### Minutes of the Meeting of the Board of Directors held on June 28, 2012

Prior to the deliberations, Gengest BVBA represented by Rudi Mariën, informed the other members of the board of directors, that it potentially has an interest of a financial nature that conflicts with the interests of the Company in connection with the proposed issuance of the new shares. Gengest BVBA explained such as follows:

Mr. Rudi Mariën owns directly or indirectly shares in Biovest Comm. VA and is the permanent representative of Gengest BVBA, a director of the Company.

The decision to issue the second tranche of shares with cancellation of the preferential subscription rights for the benefit of Biovest Comm. VA could lead to a situation where the interests of Rudi Mariën, the permanent representative of Gengest BVBA and of the Company are not aligned, inter alia with respect to the decision on the price and of the number of shares to be issued to Biovest Comm. VA.

Mr. Mariën informed the board of directors of the above potential conflict and of its potential consequences and did not participate in the deliberation with respect to the decisions concerned. The board of directors took note of Mr. Mariën's position and decided to inform the statutory auditor of the Company thereof, in accordance with article 523 of the Company Code.

The financial consequences of the transaction relate to the capital increase referred to in section 5.1.5.15 of this report

#### 6.4.16. Disclosures within the framework of the takeover directive

#### **Capital structure**

At the end of 2012, the issued capital of MDxHealth SA amounted to EUR 20,351,568.70 represented by 25,513,440 shares without nominal value. All shares have the same rights and obligations and participate equally in the profits of MDxHealth SA.

MDxHealth SA does not own any of the issued and outstanding shares of MDxHealth SA.

Shareholders holding more than 3% of the outstanding shares of the Company who make themselves known to the

Company and to the FSMA are disclosed in section 4.8 of the 2012 Registration Document and on the Company's website at www.mdxhealth.com/investors/shareholder-information.

#### Restrictions concerning the transfer of securities

The Company's articles of association do not impose any restrictions on the transfer of securities in addition to the restrictions provided for in the Belgian Company Code.

#### Holders of securities with special control rights

The Company has not granted any special control rights to the holders of its securities.

#### Mechanism for control of share plans for employees

There are no shares or similar plans for employees other than the stock option plans disclosed elsewhere in this document.

#### Restrictions concerning the exercise of the voting right

Each shareholder of MDxHealth SA is entitled to one vote per share. There is only one category of shares (common shares). Voting rights can be suspended, amongst others, in relation to shares:

- which were not fully paid up, notwithstanding the request thereto of the Board of Directors of the Company;
- to which more than one person is entitled, except in the event a single representative is appointed for the exercise of the voting right;
- which entitle their holder to voting rights above the threshold of 3%, 5%, or any multiple of 5% of the total number
  of voting rights attached to the outstanding financial instruments of the Company on the date of the relevant
  general shareholders' meeting, except in the event where the relevant shareholder has notified the Company and
  the FSMA at least 20 days prior to the date of the general shareholders' meeting on which he or she wishes to vote
  of its shareholding exceeding the thresholds above; and
- of which the voting right was suspended by a competent court or the FSMA.

### Agreements between shareholders which are known to the issuer and may result in restrictions on the transfer of securities and/or exercise of voting rights

There are no declared or known agreements between shareholders.

#### Rules for the appointment and the replacement of directors and the amendment of the articles of association

Pursuant to the Company's articles of association, the Board of Directors of the Company is to be composed of at least 3 directors. The Company's corporate governance charter requires that the Board of Directors is, to the extent possible, composed of at least five directors, of which at least three directors are independent directors, and to the extent possible, at least half of the directors are Non-Executive Directors. The directors of the Company are appointed by the general shareholders' meeting. However, in accordance with the Belgian Company Code, if the mandate of a director becomes vacant due to his death or resignation, the remaining directors have the right to appoint temporarily a new director to fill the vacancy until the first general shareholders' meeting after the mandate became vacant. The new director completes the term of the director whose mandate became vacant. The corporate governance charter provides that directors can be appointed for a maximum (renewable) term of four years. At the date of this document,

the Board of Directors is composed of 7 members, 3 of whom are independent directors.

No shareholder is known to have a significant influence on the nomination of the directors or to have a significant influence on any decision that may cause a direct or indirect advantage to this shareholder.

Amendments to the articles of association (other than an amendment of the corporate purpose) require the presence or representation of at least 50% of the share capital of the Company and the approval of at least 75% of the votes cast. An amendment of the Company's corporate purpose, requires the approval of at least 80% of the votes cast at a general shareholders' meeting, which in principle can only validly pass such resolution if at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, are present or represented. In the event where the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second general shareholders' meeting can validly deliberate and decide regardless of the number of shares present or represented.

#### Powers of directors, in particular the power to issue or buy back shares

The Board of Directors of MDxHealth SA has the broadest powers to manage and represent the Company, except to the extent provided otherwise by applicable law or the Company's articles of association.

By virtue of the resolution of the extraordinary general shareholders' meeting held on June 15, 2012, the Board of Directors has been expressly authorized to increase the share capital in one or more transactions with an amount of up to EUR 14,854,527.86 (the "Authorized Capital"), subject to certain limitations and conditions described below. The Board of Directors can exercise this power for a period starting on the date of the publication of the relevant resolution of the extraordinary general shareholders' meeting in the Annexes to the Belgian Official Gazette and ending on the date of the annual general shareholders' meeting to be held in 2015 which shall resolve on the annual accounts relating to the accounting year ending on December 31, 2014. This authorization may be renewed in accordance with the relevant legal provisions.

The capital increases to which can be decided according to this authorization, can take place in accordance with the modalities as are to be decided by the board of directors, such as:

- · by means of contribution in cash or in kind, within the limits as permitted by the Belgian Company Code,
- through conversion of reserves and issuance premiums,
- · with or without issuance of new shares, with or without voting rights,
- through issuance of convertible bonds, subordinated or not,
- · through issuance of warrants or bonds to which warrants or other tangible values are attached, and/or
- through issuance of other securities, such as shares in the framework of a stock option plan.

In the framework of the use of its powers within the framework of the authorized capital, the board of directors can limit or cancel the preferential subscription right of the shareholders in the interest of the company, subject to the limitations and in accordance with the conditions provided for by the Belgian Company Code.

This limitation or cancellation can also occur to the benefit of the employees of the company and its subsidiaries, and, to the extent permitted by law, to the benefit of one or more specific persons that are not employees of the company or its subsidiaries.

If, following a capital increase that has been decided within the framework of the authorized capital, an issuance premium is paid, the board of directors is authorized and obliged to book the amount of such issuance premium onto the account "Issuance Premiums", that shall serve as guarantee for third parties in the same manner as the company's share capital and which, apart from the possibility to convert this reserve into share capital, can only be disposed of in accordance with the rules provided by the Belgian Company Code for amendments to the articles of association.

By virtue of the resolution of the extraordinary general shareholders' meeting held on June 15, 2012, the board of directors has also been expressly authorized to increase the share capital in one or more transactions following a notification by the Belgian Financial Services and Markets Authority that it has been informed of a public takeover bid on the company's financial instruments, through contributions in cash with cancellation or limitation of the preferential subscription rights of the shareholders (including for the benefit of one or more well defined persons who are not employees of the company) or through contributions in kind, with issuance of shares, warrants or convertible bonds, subject to the terms and conditions provided for in the Belgian Company Code. The board of directors can exercise this power for a period of maximum three years starting as of the date of the publication of the relevant resolution of the extraordinary general shareholders' meeting in the Annexes to the Belgian Official Gazette.

The board of directors is authorized, with power of substitution, to amend the articles of association upon each capital increase realized within the framework of the authorized capital, in order to bring them in accordance with the new situation of the share capital and the shares.

At the date of this document, the Board of Directors has used the above described powers under the Authorized Capital as follows:

• On July 4, the Board of Directors used the Authorized Capital for a private placement of 6,891,113 new shares with institutional investors at a price of EUR 1.45. This transaction reduced the available Authorized Capital by EUR 5,497,040.84.

### Significant agreements which take effect alter or terminate upon a change of control of the issuer following a takeover bid

According to the terms and conditions of the warrants issued by MDxHealth, non-vested warrants become exercisable in case of a change of control of the Company. In addition, material agreements with EXACT Sciences include change of control clauses.

### Agreements with Directors or employees providing for compensation if they resign or are made redundant without valid reason or if their employment ceases because of a public takeover bid

There are individual agreements between the Company and certain Members of the Management Committee that provide a severance payment of up to 12 months, should this agreement be terminated due to the Company's change of control.

After deliberation and decision upon the annual accounts, the shareholders' meeting shall be requested to release the directors and the statutory auditor from liability for the execution of their mandate during the past fiscal year.

Done on February 27, 2013

On behalf of the Board of Directors

# 7. Business Glossary

Alkylating agents	A class of oncology therapeutic drugs. Alkylating agents stop tumor growth by making DNA strands unable to uncoil and separate, a necessary step in DNA replication and tumor growth.
Assay	A term for a single experiment or a diagnostic test incorporating the required markers to analyze a clinical specimen.
Bioinformatics	The use of techniques from applied mathematics, informatics, statistics, and computer science to solve biological problems and identify significant correlations.
Biopsy	A procedure where a tumor tissue sample is removed from the body for laboratory examination to determine whether or not cancer or some other disease is present. A biopsy can be performed using a needle to extract a small amount of cells or as a surgical procedure to remove a larger piece of tissue.
Biotechnology	Biotechnology is a technology based on or influencing biological processes, especially when used in agriculture, food science, and medicine.
Cancer	Cancer is a type of disease caused by genetic instability and characterized by uncontrolled division of cells and the ability of these cells to invade other organs.
CAP	The College of American Pathologists (CAP) is a U.S. accrediting agency for the U.S. Centers for Medicare and Medicaid Services (CMS).
Cell	The basic unit of a living organism. Each cell is surrounded by a membrane and has a nucleus containing a set of genes that provide it with the information necessary to operate and divide.
cGMP certification	Current Good Manufacturing Practices- quality systems requirements for manufacture, testing and development of medical products to ensure manufacturing practices, designs and controls provide safe, accurate, reliable and repeatable results. cGMP's are enforced by the FDA Food and Drug Administration. GMP compliance is recognized worldwide as an international standard of manufacture.
Chemotherapy	Drug treatment that destroys cancer cells. Chemotherapy may be used in addition to surgery and is sometimes used in combination with other therapies such as radiation.
CLIA	The U.S. Clinical Laboratory Improvement Amendments (CLIA) establishes quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results.
Clinical sample	A sample taken from the body (ex. blood, urine, tissue) and analyzed in order to gain information about a person's medical state.
Clinical trial	A research study, usually in diseased patients, to test drugs, procedures, or testing technologies to determine how well they work compared to other practices or the natural course of the disease.
Clinical verification	A product development stage that consists of testing a product prototype on a set of clinical samples.
Commercial Implementation Trial (product pipeline step)	A phase within the product development process that supports the acceptance of the newly developed assay in the market.
Commercial Pivotal Trial (product pipeline step)	A phase within the product development process to evaluate the clinical validation of the assay in collaboration with a clinical facility.
CPT codes	Current Procedural Terminology Codes- numbers assigned to every medical task used by physicians and or laboratories to determine amount of reimbursement that practitioner will receive from insurer. CPT codes are assigned by AMA American Medical Association to provide uniform definition for services and reimbursement.
Cytosine	Cytosine is one of the 5 main nucleotides of DNA and RNA used in storing and transporting genetic information.
Development Validation (product pipeline step)	A phase within the product development process to evaluate the performance of the newly developed assay using a defined sample set.
Development Verification (product pipeline step)	A phase within the product development process to define the performance characteristics of the assay.

Diagnosis	Identification of a condition or disease (ex. breast cancer), by its signs, symptoms, and the results of laboratory or histopathological tests.	
DNA (Deoxyribonucleic Acid)	DNA is a nucleic acid polymer, usually in the form of a double helix, of which the genes are made and code for life processes.	
Freedom to operate (FTO)	FTO, within an intellectual property setting, refers to the ability of a company to commercially produce, market and use a new product, process or service without infringing the intellectual property rights of others.	
Gene	A unit of genetic information. Genes are encoded in a cell's DNA and the proteins they express control the physical development and behavior of the cell or the whole organism.	
Gene expression	Gene expression is a multi-step process by which a gene's DNA sequence is converted into proteins.	
In-Vitro Diagnostics (IVD)	IVDs are tests performed outside the human body on clinical samples such as blood, urine, or biopsy tissue.	
Kit (diagnostic kit)	In-vitro diagnostic test that is packaged in a box which that can be shipped to end-user laboratories.	
LDT	Laboratory Developed Test-refer to assays developed in a laboratory for use within that laboratory. While these tests are not currently regulated by FDA Food and Drug Administration, the lab must validate all aspects of the test to ensure patient safety, reliability, repeatability, accuracy as well as validating all instruments, reagents and or supplies used in the test.	
Marker	A substance native to the organism, whose presence is indicative of a particular medical condition.	
Marker ID	A product development stage that consists of identifying and prioritizing promising markers.	
Marker & Assay Development	A product development stage that consists of testing promising markers on clinical samples (to establish initial sensitivity and specificity for a defined clinical indication), and consequently developing a robust and reproducible assay for the marker in question.	
Methylation	Control mechanism that regulates gene expression in DNA without causing a permanent genetic alteration.	
Methylation-Specific PCR (MSP)	A technology for detecting gene methylation.	
MGMT	The O <sup>6</sup> -methylguanine DNA-methyltransferase (MGMT) gene has been widely studied and shown to be able to predict glioblastoma cancer patient response to alkylating agents.	
PCR	The polymerase chain reaction is a technique for the in vitro amplification of specific DNA sequences by the simultaneous primer extension of complementary strands of DNA.	
Pharmacogenomics	The study and application of DNA and RNA based biomarkers to predict how an individual's genes affect the body's response to a therapeutic drug.	
PSA	Prostate-Specific-Antigen, a widely used but widely criticized blood-based screening test for Prostate cancer.	
Recurrence	A return of cancer after treatment.	
Research Discovery (product pipeline step)	Research phase of the product development process that consists primarily of discovering new biomarkers in clinical samples from patients with and without cancer or between samples from patients responding or not responding to a certain drug.	
Research Feasibility (product pipeline step)	A phase within the product development process to optimize the biomarker performance for the development of the diagnostic assay.	
Screening	The testing of a population for disease.	
Sensitivity	A measure of a diagnostic test's accuracy. Sensitivity measures the percentage of people with a certain medical condition that produces a positive test result. Tests with good sensitivity produce few false negative results.	
Service laboratory	Laboratory that provides medical testing services.	
Service lab and kit development	The final stages of product development that are specific to the underlying product's intended distribution channel (service laboratories or diagnostic kit companies).	
Specificity	A measure of a diagnostic test's accuracy. Specificity measures what percentage of people without a medical condition the test result is negative. Tests with good specificity produce few false positive results.	
Tumor	Tissue growth where the cells that make up the tissue have multiplied uncontrollably. A tumor can be benign (non-cancerous) or malignant (cancerous).	

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