MDxHealth®

Annual Report 2015

Molecular Diagnostics for Urological Cancer

LETTER TO SHAREHOLDERS

Dear Shareholders,

2015 was another exciting year with substantial progress and achievements for your Company. During the year, we continued our efforts to establish MDxHealth as the leader in molecular diagnostics within the urology community. Our lead product, ConfirmMDx® for Prostate Cancer, experienced continuing growth and adoption in the US. In September 2015, we acquired NovioGendix, a private Dutch molecular diagnostic company specializing in uro-oncology and providing a path for us to enter the rapidly growing liquid biopsy market. Financial metrics, including total revenue and gross margin, advanced significantly.

As healthcare systems move increasingly toward outcome-based, accountable care, our molecular diagnostic tests are well positioned to make clinically meaningful impacts on better patient outcomes and simultaneously improved healthcare economics. For example, ConfirmMDx for Prostate Cancer directly contributes to these goals by giving urologists important additional information about their patients' biopsy results, reducing unnecessary invasive procedures and thereby reducing healthcare costs. Although still early in its growth phase, commercial adoption of ConfirmMDx in 2015 demonstrates that our commercialization strategy and marketing programs are effective in convincing urologists to use this important new test. Additionally, we made significant progress in further establishing the ConfirmMDx brand, achieving test volume growth, and gaining further reimbursement for the product.

Meeting Our Objectives

In 2015 we achieved our key business objectives and showed that ConfirmMDx is becoming a diagnostic standard of care among urologists for patients with inconclusive biopsy results who are being considered for repeat procedures. We delivered more than 15,000 ConfirmMDx test results in 2015, a 76% increase over 2014. Since the launch of our test in mid 2012, we have delivered more than 35,000 ConfirmMDx test results to over 2,500 urologists. This rapid adoption, supported by strong scientific and clinical evidence published in peer-reviewed journals, has resulted in the execution of 19 US commercial 3rd party payor contracts following a positive local coverage determination (LCD) by Medicare.

For 2015, the continued adoption of our ConfirmMDx for Prostate Cancer test by the urology community, increasing reimbursement coverage for this test, and milestone and royalty payments from licensing arrangements resulted in total revenue of $17.6 million, a growth of 51% compared to $11.7 million in 2014. We also reported a 9% improvement in our EBITDA and year-end cash, and ended the year with cash and cash equivalents of $31.7 million, which include proceeds of approximately $31 million from a private placement of equity during the year.

Entering the Liquid Biopsy Market through the NovioGendix Acquisition

On September 18, 2015, we acquired NovioGendix, a privately held company based in Nijmegen (The Netherlands). NovioGendix is a molecular diagnostic research and services company providing an expert-based, integrated approach in developing advanced and clinically useful assays for uro-oncology practices. MDxHealth's strategy is to become a one-stop shop for the urologist with the capacity to handle any type of specimen (i.e., blood, urine, and tissue). An increasing focus today within the urology community is on 'liquid' biopsies, which offers a non-invasive or minimially invasive

approach to deliver real-time diagnostic information. As a result of the NovioGendix acquisition, MDxHealth has launched SelectMDx, a urine-based mRNA Prostate cancer test that complements our existing prostate cancer product offering, ConfirmMDx, which is a tissue based assay. SelectMDx provides actionable information to assist urologists in identifying patients best served by a traditional prostate biopsy. SelectMDx was introduced in the Netherlands as a CE marked test in late 2015, based on quality and validation requirements of the International Standards Organization (ISO). In addition, we recently announced the launch of SelectMDx in the US as a laboratory developed test (LDT). Broader European Union (EU) and rest-of-works (ROW) market introduction is proceeding this year.

Broadening Reimbursement Coverage and Increased Market Share

Local Coverage Determination (LCD) for Medicare reimbursement of ConfirmMDx for Prostate Cancer became effective November 2014, and is a key element driving our managed care strategy. We continue to expand our contracts with many of the largest preferred provider organizations (PPOs) in the US, bringing the current total to over 30 commercial managed care agreements. Additionally, MDxHealth continues to pursue insurance coverage by private payors and other PPOs and integrated healthcare networks. We believe the clinical utility of our ConfirmMDx test, combined with our experience and knowledge of the factors needed to gain reimbursement, will continue to enable us to expand coverage of ConfirmMDx in the US market throughout 2016.

We will continue to focus our sales efforts for ConfirmMDx principally in the US, but we will continue to explore the potential for our technology and diagnostic tests in other markets, including Asian markets. The US marketing effort will continue to be directed towards increasing adoption and utilization of the ConfirmMDx for Prostate Cancer test in urology practices. We plan to continue to expand our direct, uro-oncology-focused sales force in the coming years, while expanding co-marketing agreements to accelerate our commercialization efforts.

Our Pipeline

We continue to expand our pipeline of novel, molecular-diagnostic solutions with the addition of a cancer aggressiveness risk score to our ConfirmMDx for Prostate Cancer test, implemented in December 2015. Outside of prostate cancer, our most advanced development program is for bladder cancer. In 2010 we published the first data on a development-stage bladder cancer test in the *European Journal of Urology*. In 2016 we published a verification study for bladder cancer. The design of the study was to validate our newly developed multiplex AssureMDx for Bladder Cancer test to rule-out bladder cancer in patients diagnosed with blood in the urine (hematuria), who are traditionally followed with cytology and cystoscopy. The AssureMDx for Bladder Cancer test represents a 1 million patient opportunity within the US urology marketplace alone and could represent another $500 million potential market opportunity. Thus, we believe that the bladder cancer test could be an important new product in our urology portfolio.

Our People

Over the years we have invested significantly in people to build MDxHealth as the leader in molecular diagnostics for uro-oncology. Receiving the prestigious 2016 Frost & Sullivan Global Prostate Cancer Diagnostic Award is the result of hard work and dedication of our talented, highly-educated workforce which today comprises approximately 135 employees. Due to their strong commitment to the

business we now have two products on the market to provide urologist with actionable information to manage their patients. On behalf of the Board of Directors, we sincerely thank all of our employees, consultants and advisors, who contribute daily to our progress.

The Future

We are very pleased with our progress and expect 2016 to be another very exciting year of growth and accomplishment as we advance our strategic plan to become the leading urological oncology diagnostics company bringing innovative molecular diagnostic tests to the market. The investment we have made and will continue to make in our epigenetic platform and molecular products, the focus on quality, design control and clinical validation, as well as the early success of our ConfirmMDx Prostate Cancer test and progress with our reimbursement strategy is clearly recognized by both the clinical and financial markets. We believe that we are in the early stages of a sustained growth cycle, with the ultimate goal of offering clinicians a range of complementary molecular tests for the diagnosis, staging and treatment of urological cancers.

The Board of Directors of MDxHealth sincerely appreciates the support and contributions of our shareholders and other investors, scientific collaborators, the medical community, and other stakeholders who have entrusted us to deliver on our mission of providing advanced molecular products to aid physicians in the personalized treatment of those in their care.

Dr. Jan Groen
Chief Executive Officer

Mr. Edward L. Erickson
Chairman of the Board

KEY FINANCIALS

CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

IN '000 USD	*2015*	*2014*	*2013*
Revenues	17,640	11,671	7,554
Gross profit	10,735	5,218	1,761
Research and development expenses	3,257	2,376	4,567
Selling, general and administrative expenses	22,358	18,321	13,219
Other operating (income)/expenses	-498	-137	46
Operating Profit/(Loss) (EBIT)	-14,382	-15,342	-16,071
Financial income	13	109	114
Financial expenses	104	23	218
Income taxes	-	-	-
Net profit / (Loss)	-14,473	-15,256	-16,175

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

IN '000 USD	*2015*	*2014*	*2013*
ASSETS			
Total non-current assets	13,096	2,840	1,762
Total current assets	44,646	28,113	27,622
Of which cash and cash equivalents	31,680	18,897	24,683
Total assets	57,742	30,953	29,384
LIABILITIES AND SHAREHOLDERS' EQUITY			
Total equity	44,262	23,776	24,537
Non-current liabilities	2,705	83	-
Current liabilities	10,775	7,094	4,847
Total liabilities and shareholders' equity	57,742	30,953	29,384

CONSOLIDATED CASH FLOW STATEMENT

IN '000 USD	*2015*	*2014*	*2013*
Operating cash flow	-14,394	-18,513	-14,105
Investing cash flow	-7,576	-1,256	-1,251
Financing cash flow	35,042	14,666	24,280
Net change in cash and cash equivalents	13,072	-5,786	8,924
Cash and cash equivalents at end of period	31,680	18,897	24,683

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INTRODUCTION

RISK FACTORS[ϕ]

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. This discussion highlights some of the risks, which may affect our business, financial condition and results of operation. These are the risks and uncertainties we believe are most important for you to consider. We cannot be certain that we will successfully address these risks. If we are unable to address these risks, our business may not grow, our stock price may suffer and we may threaten the viability of our business. Additional risks and uncertainties not presently known to us, which we currently deem immaterial or which are similar to those faced by other companies in our industry or business in general, may also impair our business operations.

Risks Related to Our Business

WE HAVE A HISTORY OF LOSSES, AND WE EXPECT TO INCUR NET LOSSES FOR THE NEXT SEVERAL YEARS.

We have incurred substantial net losses since our inception, and we expect to continue to incur additional losses for the next several years. For the years ended December 31, 2013, 2014, and 2015, we had a net loss of $16.2 million, $15.3 million, and $14.4 million respectively. From our inception through December 31, 2015, we had an accumulated deficit of $156 million. We expect to continue to incur significant operating expenses and anticipate that our expenses will increase due to costs relating to, among other things:

- developing, presenting and publishing additional clinical and economic utility data intended to increase payor coverage and clinician adoption of our current and future solutions;
- expansion of our operating capabilities;
- expansion of the size and geographic reach of our sales force and our marketing capabilities to commercialize potential future solutions;
- employment of additional clinical, quality control, scientific, customer service, laboratory, billing and reimbursement and management personnel; and
- employment of operational, financial, accounting and information systems personnel, consistent with expanding our operations and our status as a newly public company following this offering;
- researching, developing, validating and commercializing potential future diagnostic solutions in other urological cancer areas including our bladder cancer solution currently in development;
- acquiring complementary technologies and/or acretive companies ; and
- maintenance, expansion and protection of our intellectual property portfolio and trade secrets.

ϕ This Annual Report includes market, economic and industry data, which were obtained by MDxHealth from industry publications and surveys, industry reports prepared by consultants, internal surveys and customer feedback. Where appropriate, specific sources are identified in the Annex to this document, as indicated by endnote references.

Even if we achieve significant revenues, we may not become profitable, and even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain consistently profitable could adversely affect the market price of our common stock and could significantly impair our ability to raise capital, expand our business or continue to pursue our growth strategy. For a detailed discussion of our financial condition and results of operations, see "Management's Discussion and Analysis".

OUR FINANCIAL RESULTS ARE LARGELY DEPENDENT ON SALES OF ONE TEST, CONFIRMMDX FOR PROSTATE CANCER, AND WE WILL NEED TO GENERATE SUFFICIENT REVENUES FROM THIS AND OTHER FUTURE SOLUTIONS TO GROW OUR BUSINESS.

Our ability to generate revenue is currently largley dependent on sales of our ConfirmMDx for Prostate Cancer test. In 2015, sales of our ConfirmMDx test accounted for 88% of the Company's total revenues, increasing from 81% of total revenues in 2014. In November 2015, we launched a new test, SelectMDx for Prostate Cancer, in the Netherlands, and have recently launched SelectMDx in the US as a service test from our Irvine, California facility. While we intend to expand the commercialization of SelectMDx into other regions of Europe and internationally, and anticipate that sales of SelectMDx will increase gradually and complement sales of ConfirmMDx, we expect that sales of ConfirmMDx will continue to account for a substantial portion of our total revenues for at least the next several years. The commercial success of our ConfirmMDx and SelectMDx tests and our ability to generate product sales will depend on several factors, including the following:

- acceptance by the medical community;
- the number of patients undergoing a prostate biopsy procedure in the US;
- acceptance, endorsement and formal policy approval of favorable reimbursement for our test by Medicare and other third-party payors;
- our ability to successfully market ConfirmMDx;
- the amount and nature of competition from other prostate cancer products and procedures; and
- our ability to establish and maintain commercial manufacturing, distribution, sales force and laboratory testing capabilities.

Sales of our ConfirmMDx test as a proportion of the Company's total revenues is expected to deccrease over the next several years, based on anticipated sales of our SelectMDx test and other tests in development. We are in the process of developing a test for bladder cancer monitoring, which we target for initial launch in the US in late 2016. However, there can be no assurance that we will be able to successfully develop and launch this bladder test, or that the bladder test or our SelectMDx for Prostate Cancer test will be successfully commercialized. If we are unable to increase sales of ConfirmMDx or successfully develop and commercialize other solutions or enhancements, our revenues and our ability to achieve profitability would be impaired, and the market price of our shares could decline.

IF WE ARE UNABLE TO RAISE ADDITIONAL CAPITAL ON ACCEPTABLE TERMS IN THE FUTURE, IT MAY LIMIT OUR ABILITY TO EXECUTE OUR BUSINESS PLAN, AND WE MAY HAVE TO CURTAIL OR CEASE OPERATIONS.

At the end of 2015, our cash and cash equivalents totaled $31.7 million. Based on its assessment of operational and industry factors, our Board of Directors believes that there is enough cash to sustain

the Company's current projects at least until the date of the annual general shareholders' meeting scheduled for May 2017. Although we believe that we have sufficient capital to fund our operations for at least the next twelve months, we expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, commercial operations and research and development activities. Excluding the net proceeds of $29.5 million generated by our private placement in June 2015, MDxHealth had a net cash burn of $13.9 million in 2015 compared to a net cash burn of $20.5 million in 2014. This 32% decrease in net cash burn by the Company is a result of expanding cash collections from payors, including Medicare, partially offset by cash used in operating activities supporting the commercialization of the ConfirmMDx test and the development of new products and product enhancements in the uro-oncological market. Additional capital, if needed, may not be available on satisfactory terms, or at all. If we are unable to obtain needed financing on acceptable terms, we may not be able to implement our business plan, which could have a material adverse effect on our business, financial condition and results of operations. If we raise additional funds through the sale of equity, convertible debt or other equity-linked securities, our stockholders' ownership will be diluted. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies, ConfirmMDx or our solutions under development, or grant licenses on terms that are not favorable to us, which could lower the economic value of those programs to our company. If adequate funds are not available, we may have to scale back our operations or limit our research and development activities, which may cause us to grow at a slower pace, or not at all, and our business could be adversely affected.

INCREASED COMPETITION, INCLUDING FROM COMPETITORS DEVELOPING AND MARKETING NOVEL OR IMPROVED METHODS FOR DETECTING PROSTATE CANCER, AND THE FAILURE TO PROVIDE A HIGHER QUALITY OF SERVICE THAN THAT OF OUR COMPETITORS, COULD ADVERSELY AFFECT OUR REVENUE AND PROFITABILITY OR MAY MAKE OUR TECHNOLOGIES LESS COMPETITIVE OR OBSOLETE.

The molecular diagnostics field is characterized by rapid technological changes, frequent new product introductions, changing customer preferences, emerging competition, evolving industry standards, reimbursement uncertainty and price competition. Moreover, the molecular diagnostics field is intensely competitive both in terms of service and price, and continues to undergo significant consolidation, permitting larger clinical laboratory service providers to increase cost efficiencies and service levels, resulting in more intense competition. Some of our existing competitors and many potential competitors have substantially greater financial, selling, logistical and laboratory resources, more experience in dealing with third-party payors, and greater market penetration, purchasing power and marketing budgets, as well as more experience in providing diagnostic services.

The market for assessing men at risk for prostate cancer is large, with an estimated 5 million American men presenting with an elevated Prostate-Specific Antigen (PSA) score and/or abnormal DRE finding, leading to more than 1.3 million American men undergoing a prostate biopsy.[1] As a result, this market has attracted competitors, some of which possess significantly greater financial and other resources and development capabilities than we do. Some companies and institutions are developing serum-based tests and diagnostic tests based on the detection of proteins, nucleic acids

or the presence of fragments of mutated genes in the blood that are associated with prostate cancer. For our *ConfirmMDx for Prostate Cancer* tissue-based test, MDxHealth is aware of the presence of three 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 Hologic, a urine-based test, is on the US 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. In 2013, OPKO, a NYSE listed company, launched the 4Kscore test, a blood based 4-plex test which combines the results of the blood test with clinical information in an algorithm that calculates a patient's percent risk for aggressive prostate cancer prior to a biopsy. We expect additional competition as other established and emerging companies enter the prostate cancer diagnostic market and new tests and technologies are introduced. These competitors could have technological, financial, reputational and market access advantages over us.

IF OUR LABORATORY FACILITY BECOMES INOPERABLE OR IF WE FAIL TO MAINTAIN LEGAL AND REGULATORY REQUIREMENTS, WE WILL BE UNABLE TO PERFORM OUR CONFIRMMDX TEST AND OUR BUSINESS WILL BE HARMED.

We perform all of our ConfirmMDx testing in our laboratory facility located in Irvine, California. We do not have redundant laboratory facilities in the US. Our laboratory facilities could become inoperable due to circumstances beyond our control, which could adversely affect our business and operations. Our facilities, the equipment we use to perform our tests and services and our other business process systems would be costly to replace and could require substantial time to repair or replace.

The facilities may be damaged or destroyed by natural or man-made disasters, including earthquakes, wildfires, floods, acts of terrorism or other criminal activities, infectious disease outbreaks and power outages, which may render it difficult or impossible for us to perform our tests for some period of time. In particular, the Irvine area is situated on or near earthquake fault lines and, in recent years, has experienced several wildfires. Any of these disasters may temporarily interrupt our ability to receive specimens or materials from our suppliers and to have access to our various systems necessary to operate our business. The inability to perform our tests and services would result in the loss of customers and harm our reputation, and we may be unable to regain those customers in the future. We carry insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

The facilities may also be rendered inoperable as a result of regulatory sanction. We are subject to US and state laws and regulations regarding the operation of clinical laboratories. The US Federal Clinical Laboratory Improvement Amendments, or CLIA, and laws of California and certain other states, impose certification requirements for clinical laboratories, and establish standards for quality assurance and quality control, among other things. Clinical laboratories are subject to inspection by regulators, and to sanctions for failing to comply with applicable requirements. Sanctions available under CLIA include prohibiting a laboratory from running tests, requiring a laboratory to implement a corrective plan, and imposing civil monetary penalties. If we fail to meet any applicable requirements

of CLIA or state law, that failure could adversely affect any future consideration by the US Centers for Medicare & Medicaid Services, or CMS, of our technologies, prevent their approval entirely, and/or interrupt the commercial sale of any products and otherwise cause us to incur significant expense.

In the event our facility is rendered inoperable, we would need to engage a third party to perform laboratory testing services on our behalf. In order to rely on a third party to perform these testing services, we could only use another facility with established state licensure and CLIA accreditation. We cannot assure you that we would be able to find another CLIA-certified facility, or that another laboratory would be willing to perform the necessary tests for us on commercially reasonable terms, or at all. Finding a new laboratory that meets the required state licensure and CLIA accreditation standards or developing new systems necessary to operate our business would be time-consuming and costly and could result in delays in our ability to provide ConfirmMDx testing services or to provide the same level of quality in ConfirmMDx testing services as we currently provide, which would harm our reputation and adversely affect our business, results of operations and financial condition. In addition, requirements of third-party payors and regulatory limitations on marking-up of laboratory testing could substantially limit our ability to profit from testing that we do not ourselves perform.

WE RELY ON A LIMITED NUMBER OF THIRD PARTIES FOR MANUFACTURE AND SUPPLY OF ALL OF OUR LABORATORY INSTRUMENTS AND MATERIALS, INCLUDING CONSUMABLES, AND WE MAY NOT BE ABLE TO FIND REPLACEMENT SUPPLIERS OR MANUFACTURERS IN A TIMELY MANNER IN THE EVENT OF ANY DISRUPTION, WHICH COULD ADVERSELY AFFECT OUR BUSINESS.

Many of the consumable supplies and reagents used as raw materials in our ConfirmMDx testing process are procured from a limited number of suppliers, some of which are sole-source. In addition, we rely on a limited number of suppliers, or in some cases a single supplier, for certain equipment with which we perform ConfirmMDx testing services. To date we have acquired substantially all of our equipment and materials on a purchase order basis; as such, our suppliers and manufacturers are not contractually committed to supply equipment and materials to us. Because we cannot ensure the actual production or manufacture of such critical equipment and materials, or the ability of our suppliers to comply with applicable legal and regulatory requirements, we may be subject to significant delays caused by interruption in production or manufacturing. If any of our third-party suppliers or manufacturers were to become unwilling or unable to provide this equipment or these materials in required quantities or on our required timelines, we would need to identify and acquire acceptable replacement sources on a timely basis. Even if we were to identify other suppliers and manufacturers for such equipment and materials, there can be no assurance that we would be able to enter into agreements with such suppliers and manufacturers or otherwise obtain such items on a timely basis or on acceptable terms, if at all. If we encounter delays or difficulties in securing necessary laboratory equipment or materials, including consumables, we could face an interruption in our ability to perform ConfirmMDx testing services and experience other disruptions that would adversely affect our business, results of operations and financial condition.

PERFORMANCE ISSUES, SERVICE INTERRUPTIONS OR PRICE INCREASES BY OUR SHIPPING CARRIER COULD ADVERSELY AFFECT OUR BUSINESS, RESULTS OF OPERATIONS AND FINANCIAL CONDITION AND HARM OUR REPUTATION AND ABILITY TO PROVIDE CONFIRMMDX TESTING SERVICES ON A TIMELY BASIS.

Expedited, reliable shipping is essential to our operations. One of our marketing strategies entails highlighting our ability to perform testing services and deliver an actionable report to healthcare

providers in a timely manner. We rely almost exclusively on a single carrier, Federal Express, for reliable and secure point-to-point transport of patient samples. Should Federal Express encounter delivery performance issues such as loss, damage or destruction of a sample, it would be difficult to replace our patient samples in a timely manner and such occurrences may damage our reputation and lead to decreased referrals from healthcare providers for our services and increased cost and expense to our business. In addition, any significant increase in shipping rates or fuel surcharges could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions by delivery services we use would adversely affect our ability to receive and process patient samples on a timely basis.

If Federal Express or we were to terminate our relationship, we would be required to find another party to provide expedited, reliable point-to-point transport of our patient samples. There are only a few other providers of such nationwide transport services and there can be no assurance that we will be able to enter into arrangements with such other providers on acceptable terms, if at all. Even if we were to enter into an arrangement with such provider, there can be no assurance that they will provide the same level of quality in transport services. If the new provider does not provide the required quality and reliable transport services, it could adversely affect our business, reputation, results of operations and financial condition.

WE MAY BE SUBJECT TO SUBSTANTIAL COSTS AND LIABILITY, OR BE PREVENTED FROM USING TECHNOLOGIES INCORPORATED IN OUR CONFIRMMDX AND SELECTMDX TESTS, AS A RESULT OF LITIGATION OR OTHER PROCEEDINGS RELATING TO PATENT RIGHTS.

Third parties may assert infringement or other intellectual property claims against our licensors, our licensees, our suppliers, our strategic partners or us. We pursue a patent strategy that we believe provides us with a competitive advantage in the assessment of prostate cancer and is designed to maximize our patent protection against third parties in the US and, potentially, in certain foreign countries. We have filed and licensed patents and patent applications that we believe cover the methods we have designed to help detect prostate cancer and other cancers. In order to protect or enforce our patent rights, we may have to initiate actions against third parties. Any actions regarding patents could be costly and time-consuming and divert the attention of our management and key personnel from our business. Additionally, such actions could result in challenges to the validity or applicability of our patents. Because the US Patent & Trademark Office maintains patent applications in secrecy until a patent application is published or the patent is issued, we have no way of knowing if others may have filed patent applications covering technologies used by us or our partners. Additionally, there may be third-party patents, patent applications and other intellectual property relevant to our technologies that may block or compete with our technologies. Even if third-party claims are without merit, defending a lawsuit may result in substantial expense to us and may divert the attention of management and key personnel. In addition, we cannot provide assurance that we would prevail in any such suits or that the damages or other remedies, if any, awarded against us would not be substantial. Claims of intellectual property infringement may require that we, or our strategic partners, enter into royalty or license agreements with third parties that may not be available on acceptable terms, if at all. These claims may also result in injunctions against the further development and commercial sale of services or products containing our technologies, which would have a material adverse effect on our business, financial condition and results of operations.

Also, patents and patent applications owned by us may become the subject of interference proceedings in the US Patent and Trademark Office to determine priority of invention, which could

result in substantial cost to us as well as a possible adverse decision as to the priority of invention of the patent or patent application involved. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application subject to such a proceeding.

IF WE ARE UNABLE TO PROTECT OUR INTELLECTUAL PROPERTY EFFECTIVELY, WE MAY BE UNABLE TO PREVENT THIRD PARTIES FROM USING OUR INTELLECTUAL PROPERTY, WHICH WOULD IMPAIR OUR COMPETITIVE ADVANTAGE.

We rely on patent protection as well as a combination of trademark, copyright and trade secret protection and other contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. It is not certain that any of our currently pending or future patent applications will result in issued patents, or that any patents issued or licensed to us will not be challenged, invalidated or held unenforceable. Issued patents may not be broad enough to provide any meaningful protection. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

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 our patents and our in-licensed rights. In order to protect or enforce our 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 our business, and could put our patents at risk of being invalidated or narrowly interpreted.

MDxHealth also relies on trade secret protection and contractual restrictions to protect our proprietary technology. This only provides limited protection and may not adequately protect MDxHealth's rights. Typically, MDxHealth requires our 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 our 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.

Furthermore, in the life sciences field, courts frequently render opinions that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of isolated DNA and/or methods for analyzing or comparing DNA. Such decisions may adversely impact our ability to obtain new patents and facilitate third-party challenges to our existing patents.

MOLECULAR DIAGNOSTICS PATENTS AND PATENT APPLICATIONS INVOLVE HIGHLY COMPLEX LEGAL AND FACTUAL QUESTIONS, WHICH, IF DETERMINED ADVERSELY TO US, COULD NEGATIVELY IMPACT OUR PATENT POSITION.

The patent positions of molecular diagnostics companies can be highly uncertain and involve complex legal and factual questions. The interpretation and breadth of claims allowed in some patents covering genetic methods and biomarkers may be uncertain and difficult to determine, and

are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the United States Patent and Trademark Office, or USPTO, are sometimes uncertain and could change in the future. In addition, from time to time, the United States Supreme Court, other federal courts, the United States Congress, the USPTO or similar foreign authorities may change the standards of patentability. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. US patents and patent applications may also be subject to interference proceedings, and US patents may be subject to reexamination proceedings, post-grant review and/or inter partes review in the USPTO. Foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, reexamination, post-grant review, inter partes review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us, or may limit the number of patents or claims we can obtain. The laws of some countries do not protect intellectual property rights to the same extent as US laws and those countries may lack adequate rules and procedures for defending our intellectual property rights.

If we fail to obtain and maintain patent protection and trade secret protection of our current or future solutions, we could lose our competitive advantage and competition we face would increase, reducing any potential revenues and adversely affecting our ability to attain or maintain profitability.

IF WE ARE UNABLE TO EFFECTIVELY MAINTAIN OUR LICENSES AND COLLABORATIONS WITH THIRD PARTIES, IT COULD HARM OUR BUSINESS.

We license from third parties technology necessary to develop and commercialize our products. Our most significant license covers our platform technology, methylation specific PCR, or MSP, used in ConfirmMDx and which may be required for future solutions we develop. We license this technology from Johns Hopkins University. Our rights to use this and other licensed technologies, data and materials and to employ the inventions claimed in licensed patents are subject to the continuation of and our compliance with the terms of the applicable licenses. We are obligated under these licenses to, among other things, pay certain royalties upon commercial sales of our products. These licenses generally last until the expiration of the last to expire of the patents included within the licenses that cover our use within our products, but the licenses may be terminated earlier in certain circumstances. Termination of any of these licenses could prevent us from producing or selling some or all of our products, and a failure of the licensors to abide by the terms of the licenses or to prevent infringement by third parties could harm our business and negatively impact our market position. Failure of a licensor to abide by the terms of a license or to prevent infringement by third parties could also harm our business and negatively impact our market position.

We are also engaged in a number of collaborations and licenses with commercial partners that are material to our future revenue and profitability. We partner with leading pathology laboratories with large urology client bases, such as Miraca Life Sciences, Bostwick Labs and LI Path, to assist us in

promoting the ConfirmMDx test, helping to improve brand awareness, facilitate account access and accelerate test adoption. In addition, we have licensed certain of our non-core epigenetic technologies to commercial partners, several of whom have launched products that generate royalties and other fees to us, including Exact Sciences, which has successfully launched its Cologuard® test for colon cancer in 2014, Laboratory Corporation of America (Labcorp), which commercializes the MGMT test for Glioblastoma. If we are unable to maintain these partnerships, it could adversely affect our revenues and profitability. For example, in 2013 our partnership with Merck Serono was terminated following their unsuccessful clinical trial for their drug indicated for Glioblastoma. Although our current business model has significantly de-emphasized fee-for-service collaborations with pharmaceutical companies, in 2013 the termination of our Merck Serono collaboration resulted in a material reduction in potential revenues from this collaboration.

OUR SUCCESS DEPENDS ON OUR ABILITY TO RETAIN OUR MANAGERIAL PERSONNEL AND TO ATTRACT ADDITIONAL PERSONNEL.

Our success depends largely on the skills, experience and performance of key members of our senior management team including Dr. Jan Groen, our President and Chief Executive Officer, Chris Thibodeau, our Chief Commercial Officer, Joe Sollee, our Executive Vice President Corporate Development and General Counsel, Francis Ota, our Executive Vice President Finance, Philip Ginsburg, our Executive Vice President and Chief Medical Officer and Miriam Reyes, our Senior Vice President of Laboratory Operations. These executives are critical to directing and managing our growth and development in the future. Our success is substantially dependent upon our senior management's ability to lead our Company, implement successful corporate strategies and initiatives, develop key relationships, including relationships with collaborators and business partners, and successfully commercialize ConfirmMDx test. Competition for desirable personnel is intense, and there can be no assurance that we will be able to attract and retain the necessary staff. The failure to maintain management or to attract sales personnel as we move towards the commercialization of our ConfirmMDx test could materially adversely affect our business, financial condition and results of operations.

IF WE LOSE THE SUPPORT OF OUR KEY SCIENTIFIC COLLABORATORS, IT MAY BE DIFFICULT TO ESTABLISH TESTS USING OUR TECHNOLOGIES AS A STANDARD OF CARE FOR COLORECTAL CANCER SCREENING, WHICH MAY LIMIT OUR REVENUE GROWTH AND PROFITABILITY.

We have established relationships with leading key opinion leaders and scientists at important research and academic institutions, such as Johns Hopkins University, Tufts Medical Center, University of Colorado, and University of Gent, that we believe are key to establishing tests using our technologies as a standard of care for cancer assessment and diagnosis. If our collaborators determine that cancer testing using our technologies are not appropriate options for prostate cancer diagnosis, or superior to available prostate cancer methods, or that alternative technologies would be more effective in the early diagnosis of prostate cancer, we would encounter significant difficulty establishing tests using our technologies as a standard of care for prostate cancer diagnosis, which would limit our revenue growth and profitability.

PRODUCT AND PROFESSIONAL LIABILITY SUITS AGAINST US COULD RESULT IN EXPENSIVE AND TIME-CONSUMING LITIGATION, PAYMENT OF SUBSTANTIAL DAMAGES AND INCREASES IN OUR INSURANCE RATES.

The marketing, sale and use of our ConfirmMDx test could lead to product liability claims against us if someone were to allege that our test failed to perform as it was designed, or if someone were to

misinterpret test results or improperly rely on them for clinical decisions. For example, ConfirmMDx testing could provide incorrect results which a patient or physician may rely upon. In addition, we may be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide as part of the results generated by ConfirmMDx. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain product and professional liability insurance, our insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could harm our reputation, result in a stoppage of ConfirmMDx testing services or cause current customers or partners to terminate existing agreements and potential customers or partners to seek other molecular diagnostic testing solutions, any of which could impact our results of operations.

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

WE WILL NEED TO GROW THE SIZE OF OUR ORGANIZATION, AND WE MAY EXPERIENCE DIFFICULTIES IN MANAGING THIS GROWTH.

Our current organization and our systems and facilities will not be adequate to support our future growth. In order to effectively manage our operations and any significant growth, we may need to:

- scale our internal infrastructure, including establishing laboratory facilities and purchasing capital equipment, while continuing to provide quality services on a timely basis;
- maintain and strengthen our relationships with our customers as we increase the number of our sales and marketing personnel and increase our presence in the various geographic markets we serve;
- attract and retain sufficient numbers of talented employees, including marketing personnel and contracted sales representatives, clinical laboratory scientists, laboratory technicians and administrative employees, to handle the increasing number of tests we are requested to conduct;
- manage our relationships with shipping partners to ensure their ability to handle increasing sample transport and deliveries;
- expand our compliance and quality assurance systems; and
- advance our operational, financial and management controls and reporting systems and procedures.

As our ConfirmMDx test volume grows, we will need to continue to expand our testing capacity, implement increases in scale and related processing, customer service, billing and systems process improvements, and expand our internal quality assurance program and technology platform. We will

also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our tests. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available. As additional products and services are developed, we may need to bring new equipment on-line, implement new systems, technology, controls and procedures and hire personnel with different qualifications.

The value of ConfirmMDx depends, in large part, on our ability to perform the tests on a timely basis and at a high quality standard, and on our reputation for such timeliness and quality. Any failure to implement necessary procedures, transition to new equipment or processes or hire the necessary personnel could result in higher costs of processing or an inability to meet market demand. We may not be able to perform tests on a timely basis at a level consistent with demand, our efforts to scale our commercial operations could negatively affect the quality of test results and we may not be successful in responding to the growing complexity of our testing operations. If we encounter difficulty meeting market demand or quality standards for our tests, our reputation could be harmed, and our prospects and business could suffer.

In addition, our growth may place a significant strain on our management, operating and financial systems and our sales, marketing and administrative resources. As a result of our growth, our operating costs may escalate even faster than planned, and some of our internal systems may need to be enhanced or replaced. If we cannot effectively manage our expanding operations and our costs, we may not be able to grow effectively or we may grow at a slower pace, and our business could be adversely affected.

If we are not able to successfully implement the tasks necessary to further expand our operations, our business, results of operations and financial results could be adversely affected. If we are not able to effectively expand our organization by hiring new employees and engaging additional consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our tests and, accordingly, may not achieve our research, development and commercialization goals.

WE MAY ENGAGE IN ACQUISITIONS THAT COULD DISRUPT OUR BUSINESS, CAUSE DILUTION TO OUR STOCKHOLDERS AND REDUCE OUR FINANCIAL RESOURCES.

In addition to our acquisition of NovioGendix, a privately held company based in Nijmegen (The Netherlands), in September 2015, we may enter into other transactions in the future to acquire other businesses, products or technologies. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

OUR INTERNATIONAL OPERATIONS SUBJECT US TO VARIOUS RISKS, AND OUR FAILURE TO MANAGE THESE RISKS COULD ADVERSELY AFFECT OUR RESULTS OF OPERATIONS.

We face significant operational risks as a result of doing business internationally, such as:

- fluctuations in foreign currency exchange rates;
- potentially adverse tax consequences, including liabilities imposed from inconsistent enforcement;
- challenges in staffing, managing and providing solutions across a significant distance, in different languages and among different cultures;
- managing the different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a variety of foreign laws, treaties and regulations;
- reduced protection of, or difficulties in enforcing, intellectual property rights in multiple countries;
- costs and difficulties of customizing products for foreign countries; and
- tariffs, trade barriers and other regulatory or contractual limitations on our ability to sell or develop our products in certain foreign markets.

Following our acquisition of NovioGendix, in 2015 we launched a urine-based SelectMDx for Prosate Cancer testing solution in the Benelux Union region of Europe through our molecular diagnostic laboratory located in Nijmegen, the Netherlands. We also plan to commercialize the SelectMDx Prosate Cancer test as a CE-marked kit in Europe and internationally. In addition, we expect to sell our ConfirmMDx for Prostate Cancer test through distribution partners in Europe and internationally. We have limited experience commercializing our testing solutions outside the US, whether directly or through a partnership. Moreover, there is no guarantee that we will be successful in commercializing our testing solutions or in attracting or retaining desirable distribution partners for markets outside the United States. Distributors may not commit the necessary resources to market and sell our product candidates effectively or may choose to favor marketing the products of our competitors. If we are not successful in commercializing our testing solutions outside the US, or if international distributors do not perform adequately, or if we are unable to enter into effective arrangements with distributors in particular geographic areas, we may not realize international sales and growth.

Our results of operations may be particularly affected by volatility in currency exchange rates and our ability to effectively manage our currency transaction risks. In general, we conduct our business, earn revenue and incur costs in the local currency of the countries in which we operate. During the year ended December 31, 2015, approximately 95% of our revenue was generated, and approximately 87% of our total costs were incurred in, US Dollars. As we continue to expand internationally, our exposure to currency risks will increase. Historically, we have not managed our foreign currency exposure in a manner that would eliminate the effects of changes in foreign exchange rates. Changes in exchange rates between the foreign currencies in which we do business and the euro will affect our revenue, cost of sales, and operating margins, and could result in exchange losses in any given reporting period.

Changes in tax laws, treaties or regulations could adversely affect our financial results. Our future effective tax rates could be adversely affected by changes in tax laws, treaties and regulations, both internationally and domestically, including possible changes to the patent income deduction regime in Belgium or the way it proportionately impacts our effective tax rate. An increase of our future

effective tax rates could have a material adverse effect on our business, financial position, results of operations and cash flows.

Our failure to manage the market and operational risks associated with our international operations effectively could limit the future growth of our business and adversely affect our results of operations.

FAILURE IN OUR INFORMATION TECHNOLOGY, TELEPHONE OR OTHER SYSTEMS COULD SIGNIFICANTLY DISRUPT OUR OPERATIONS AND ADVERSELY AFFECT OUR BUSINESS AND FINANCIAL CONDITION.

Information technology and telephone systems are used extensively in virtually all aspects of our business, including laboratory testing, sales, billing, customer service, logistics and management of medical data. The success of our business depends on the ability to obtain, process, analyze, maintain and manage this data. Our management relies on our information systems because:

- patient samples must be received, tracked and processed on a timely basis;
- test results must be monitored and reported on a timely basis;
- billing and collections for all customers must be managed efficiently and accurately;
- third-party ancillary billing services require proper tracking and reporting;
- pricing and other information related to ConfirmMDx is needed by our sales force and other personnel in a timely manner to conduct business;
- centralized procurement and test inventory management systems are required for effective test inventory management;
- regulatory compliance requires proper tracking and reporting; and
- proper recordkeeping is required for operating our business, regulatory compliance, managing employee compensation and other personnel matters.

Our business, results of operations and financial condition may be adversely affected if, among other things:

- our information technology, telephone or other systems are hacked, subject to cyber-attacks, interrupted or fail for any extended length of time;
- services relating to our information technology, telephone or other systems are not kept current;
- our information technology, telephone or other systems become unable to support expanded operations and increased levels of business;
- information is lost or unable to be restored or processed; or
- information security is breached.

Our success depends, in part, on the continued and uninterrupted performance of our information technology, telephone and other systems, which are vulnerable to damage from a variety of sources, including telecommunications or network failures, computer viruses, natural disasters and physical or electronic break-ins. We are especially vulnerable to losses of patient information which could result in violations of privacy and security laws in and outside of Belgium, the Netherlands, and the US. Despite the precautionary measures we have taken to prevent breakdowns in our information technology and telephone systems, sustained or repeated system failures that interrupt our ability to

process test orders, deliver test results or perform tests in a timely manner or that cause us to lose patient information could adversely affect our business, results of operations and financial condition.

SECURITY BREACHES, LOSS OF DATA AND OTHER DISRUPTIONS COULD COMPROMISE SENSITIVE INFORMATION RELATED TO OUR BUSINESS OR PREVENT US FROM ACCESSING CRITICAL INFORMATION AND EXPOSE US TO LIABILITY, WHICH COULD ADVERSELY AFFECT OUR BUSINESS AND REPUTATION.

In the ordinary course of our business, we collect and store sensitive data, including legally-protected health information, credit card information and personally identifiable information about our customers, payors, recipients and collaboration partners, including test results. We also store sensitive intellectual property and other proprietary business information, including that of our customers, payors and collaboration partners. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. These applications and data encompass a wide variety of business critical information, including research and development information, commercial information and business and financial information. We face four primary risks relative to protecting this critical information: loss of access risk, inappropriate disclosure or access risk, inappropriate modification risk, and the risk of our being unable to identify and audit our controls over the first three risks.

We are highly dependent on information technology networks and systems, including the internet, to securely process, transmit and store this critical information. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure or modification of confidential information. The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party billing and collections provider, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions.

A security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information (PHI), could harm our reputation, compel us to comply with federal and/or state breach notification laws, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Any such breach or interruption could compromise our networks or those of our third-party billing and collections provider, and the information stored there could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure, modification of, or other loss of information could result in legal claims or proceedings, and civil, criminal and other liability under laws and regulations that protect the privacy

and security of personal information, such as the US Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the US Health Information Technology for Economic and Clinical Health Act, or HITECH, and the regulations promulgated thereunder. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform tests, provide test results, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, develop and commercialize tests, collect, process and prepare company financial information, provide information about our tests, educate patients and clinicians about our service and manage the administrative aspects of our business, any of which could damage our reputation and adversely affect our business. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position.

In addition, the interpretation and application of consumer, health-related, privacy, security and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. For example, In October 2015, the Court of Justice of the European Union declared that the US-EU Safe Harbor is invalid. In February 2016, the European Commission announced an agreement with the Department of Commerce to replace the invalidated Safe Harbor agreement on transatlantic data flows with a new EU-US "Privacy Shield." Nevertheless, legal uncertainty remains concerning EU-to-US data transfers. The Privacy Shield will not be effective until it is approved by the EU's 28 member states. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business and our reputation. Complying with these various laws could cause us to incur substantial costs or require us to restructure our business practices and compliance procedures in a manner adverse to our business.

WE USE HAZARDOUS MATERIALS THAT REQUIRE EXPERTISE AND EXPENSE FOR HANDLING, STORAGE OR DISPOSAL AND MAY RESULT IN CLAIMS AGAINST US.

We work with hazardous materials, including chemicals, biological agents and compounds, and human tissue, that could be dangerous to human health and safety or the environment. Our operations also produce hazardous and biohazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair business efforts. If we do not comply with applicable regulations, we may be subject to fines and penalties. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot assure you that this is the case or eliminate the risk of accidental contamination or injury from these materials. Our general liability insurance and/or workers' compensation insurance policy may not cover damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our operations could be suspended or otherwise adversely affected.

Risks Related to Billing and Reimbursement

HEALTH INSURERS AND OTHER THIRD-PARTY PAYORS MAY DECIDE NOT TO COVER OR TO REVOKE COVERAGE OF, OR MAY PROVIDE INADEQUATE REIMBURSEMENT FOR, OUR EXISTING OR FUTURE SOLUTIONS, WHICH COULD JEOPARDIZE OUR COMMERCIAL PROSPECTS.

Successful commercialization of our ConfirmMDx test and our new SelectMDx test depends, in large part, on the availability of coverage and adequate reimbursement from government and private payors. Favorable third-party payor coverage and reimbursement are essential to meeting our immediate objectives and long-term commercial goals. We do not recognize revenue for test results delivered without a contract for reimbursement or a history of consistent payment. In 2015, the estimated value of all ConfirmMDx tests performed was $36 million, of which amount $15.2 million was recognized as revenue, leaving uncollected outstanding unrecognized revenues of $20.8 million. This compares to 2014 when the estimated value of total tests performed was $19.1 million, from which the Company recognized $9.4 million, leaving uncollected outstanding unrecognized revenues of $9.3. The unrecognized and uncollected amount has been excluded from the Company's revenues in each year. While collection efforts continue on these outstanding amounts, there can be no assurance regarding the timing and amount of actual collections.

In the US, for new diagnostic solutions, each private and government payor decides whether to cover the test, the amount it will reimburse for a covered test and the specific conditions for reimbursement. Clinicians and recipients may be likely not to order a diagnostic test unless third-party payors pay a substantial portion of the test price. Therefore, coverage determinations and reimbursement levels and conditions are critical to the commercial success of a diagnostic product, and if we are not able to secure positive coverage determinations and reimbursement levels, our business will be materially adversely affected.

Coverage and reimbursement by a payor may depend on a number of factors, including a payor's determination that our current and future solutions are:

- not experimental or investigational;
- medically necessary;
- appropriate for the specific recipient;
- cost-saving or cost-effective; and
- supported by peer-reviewed publications.

If third-party payors decide not to cover our diagnostic solutions or if they offer inadequate payment amounts, our ability to generate revenue from ConfirmMDx and future solutions could be limited. Any third-party payor may stop or lower payment at any time, which could substantially reduce our revenue.

Payment for diagnostic tests furnished to Medicare beneficiaries (patients aged 65 or older) is typically made based on a fee schedule set by the US Centers for Medicare & Medicaid Services, or CMS. In recent years, payments under these fee schedules have decreased and may decrease further. As a Medicare-participating laboratory based in California, we bill Noridian Healthcare Solutions, or Noridian, the Medicare Administrative Contractor, or MAC, for California, and are subject to Noridian's local coverage and reimbursement policies. Palmetto GBA, the current MAC for North Carolina, South Carolina, Virginia and West Virginia and the former MAC for California,

developed the Molecular Diagnostic Services Program, or MolDX, in 2011. Laboratories that perform molecular diagnostic testing and submit claims to Palmetto GBA or Noridian are subject to the MolDX program, since Noridian is responsible for administering the MolDX program and implementing the MolDX guidelines developed by Palmetto in California.

In late 2012, we submitted our ConfirmMDx for Prostate Cancer scientific and medical dossier to the MolDX Program for the technical assessment of the peer reviewed published data that support the analytical and clinical validation of the assay. By virtue of the local coverage determination (LCD) issued by Palmetto GBA in November 2014, ConfirmMDx passed the technical assessment, however it was determined that additional clinical utility data would be required for unrestricted coverage (reference: *MolDX: ConfirmMDx Epigenetic Molecular Assay (L35368)*; available at http://www.cms.gov/medicare-coverage-database/).

Although we received a positive Medicare LCD coverage determination and what we believe is a favorable reimbursement rate for our ConfirmMDx test, limited coverage is currently being provided under a new program entitled Coverage with Data Development. As part of an ongoing commitment to ensure that Medicare covers the appropriate use of the ConfirmMDx test, Palmetto GBA expects MDxHealth to continue accruing patients in our prospective, randomized PASCUAL clinical utility trial currently in process, and to enroll providers into our ConfirmMDx Certification and Training Registry. The LCD provides for coverage initially limited to patients of physicians enrolled in the ConfirmMDx Registry. Prior to the issuance of the LCD in November 2014, we had not billed Medicare for any testing of Medicare patients, resulting in $7.9 million of uncollected outstanding unrecognized revenues attributable to Medicare patients in 2014. In 2015, we commenced billing for and have begun to receive payments for ConfirmMDx testing of Medicare patients of physicians enrolled in the ConfirmMDx Registry, in accordance wth the tems of the LCD. We continue to enroll and accept physicians into the ConfirmMDx Registry. Medicare billings now represent approximately 28% of total billings. For additional information please refer to our revenue recognition policy in “Financials; Audited Consolidated Financial Statements; Note 2: Accounting Policies”.

In accordance with the terms of the ConfirmMDx LCD, we are conducting a clinical utility study to determine the repeat biopsy rate, and expect to complete the study in 2017. Pending completion of the study, the LCD provides for reimbursement of cases that are ordered by urologists trained and registered in a ConfirmMDx Registry. Unrestricted Medicare coverage, with the ConfirmMDx Registry requirement removed, is expected with favorable clinical utility trial findings. However, there are no assurances that the additional clinical data will be favorable or that unrestricted coverage will be granted for Medicare beneficiaries.

Obtaining coverage and reimbursement by commercial payors is a time-consuming and costly process, without a guaranteed outcome, since each commercial payor makes its own decision as to whether to establish a policy to reimburse for a test, which is usually a time-consuming and costly process. In addition, several payors and other entities conduct technology assessments of new medical tests and devices and provide the results of their assessments for informational purposes to other parties. These assessments may be used by third-party payors and healthcare providers as grounds to deny coverage for or refuse to use a test or procedure. We believe we have received a negative technology assessment from at least one of these entities and could receive more.

Reimbursement for ConfirmMDx comes primarily from Medicare, private third-party payors such as insurance companies and managed care organizations, Medicaid and hospitals. The reimbursement process can take six months or more to complete depending on the payor. We continue to work with third-party payors to seek such coverage and to appeal denial decisions based on existing and ongoing studies, peer reviewed publications, support from physician and patient groups and the growing number of ConfirmMDx tests that have been reimbursed by public and private payors. There are no assurances that the current policies will not be modified in the future. If our test is considered on a policy-wide level by major third-party payors, whether at our request or on their own initiative, and our test is determined to be ineligible for coverage and reimbursement by such payors, our collection efforts and potential for revenue growth could be adversely impacted.

Following its recent commercial launch in the US, our new urine-based SelectMDx for Prostate Cancer test will face reimbursement challenges and risks similar to those encounted with our ConfirmMDx test. We cannot assure you that adequate coverage and reimbursement for ConfirmMDx or future solutions will be provided in the future by any third-party payor.

Outside of the US, various coverage, pricing and reimbursement approvals are required. We expect that it will take several years to establish broad coverage and reimbursement for our tests with payors in countries outside of the US where we elect to commercialize our solutions, and our efforts may not be successful. Even if public or private reimbursement is obtained, it may cover competing tests, the reimbursement may be conditioned upon local performance of the tests or other requirements we may have difficulty satisfying. Reimbursement levels outside of the US may vary considerably from the reimbursement amounts we receive in the US. In addition, because we plan in many circumstances to rely on distributors to obtain reimbursement for our tests, to the extent we do not have direct reimbursement arrangements with payors, we may not be able to retain reimbursement coverage in certain countries with a particular payor if our agreement with a distributor is terminated or expires or a distributor fails to pay us for other reasons. We may also be negatively affected by the financial instability of, and austerity measures implemented by, several countries in the European Union and elsewhere.

BILLING COMPLEXITIES ASSOCIATED WITH OBTAINING PAYMENT OR REIMBURSEMENT FOR OUR TESTS MAY NEGATIVELY AFFECT OUR REVENUE, CASH FLOW AND PROFITABILITY.

Substantially all of our current revenue is derived from ConfirmMDx for which we bill on a fee-for-service basis, including reimbursements by third-party payors, such as Medicare, Medicaid and other governmental payor programs, hospitals, private insurance plans and managed care organizations and direct payments from individual patients. Billing for molecular diagnostics testing services is generally highly complex. Our billing department works closely with a third-party provider that specializes in billing solutions for clinical laboratories and other healthcare organizations to ensure accuracy of billing, timely collections, and resolution of appeals and billing discrepancies.

Depending on our billing arrangement with each third-party payor and applicable law, we are often obligated to bill in the specific manner prescribed by the various payors, each of which may have different requirements. Among the potential factors complicating our billing of third-party payors are:

- disputes among payors regarding which party is responsible for payment;
- disparity in coverage among various payors;

- different process, information and billing requirements among payors; and
- incorrect or missing billing information.

We also face risks in our collection efforts, including potential write-offs of doubtful accounts and long collection cycles for accounts receivable.

Additionally, from time to time, payors change processes that may affect timely payment. These changes may result in uneven cash flow or impact the timing of revenue recognized with these payors. With respect to payments received from governmental programs, factors such as a prolonged government shutdown could cause significant regulatory delays or could result in attempts to reduce payments made to us by government healthcare programs. These billing complexities, and the related uncertainty in obtaining payment for ConfirmMDx testing services, could negatively affect our revenue, cash flow and profitability. In addition, increases in write-offs of doubtful accounts, delays in receiving payments or potential retroactive adjustments and penalties resulting from audits by payors could adversely affect our business, results of operations and financial condition.

CHANGES IN LAWS, REGULATIONS, PAYOR POLICIES OR CONTRACTING ARRANGEMENTS WITH PAYORS MAY ADVERSELY AFFECT COVERAGE OR REIMBURSEMENT FOR CONFIRMMDX TESTING SERVICES, WHICH MAY DECREASE OUR REVENUE AND ADVERSELY AFFECT OUR RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

Governmental payors, as well as private insurers, and other private payors have implemented and will continue to implement measures to control the cost, utilization and delivery of healthcare services, including laboratory services. US Congress has from time to time considered and implemented changes to laws and regulations governing healthcare service providers, including specialized diagnostic service providers. These changes have adversely affected and may in the future adversely affect coverage for laboratory services, including the molecular diagnostics testing services we provide. We also believe that healthcare professionals will not use ConfirmMDx if third-party payors do not provide adequate coverage and reimbursement for them.

Reimbursement to healthcare providers, such as specialized diagnostic service providers like us, is subject to continuing change in policies by governmental payors, such as Medicare and Medicaid, private insurers, including managed care organizations, and other private payors, such as hospitals and private medical groups. In addition, reimbursement from governmental payors is subject to statutory and regulatory changes, retroactive rate adjustments and administrative rulings, and other policy changes, all of which could materially decrease the range of services for which we are reimbursed or the reimbursement rates paid for ConfirmMDx testing services. For example, ACA provides that payments under the Medicare Clinical Laboratory Fee Schedule, or CLFS, are to receive a negative 1.75% annual adjustment through 2015 and a productivity adjustment pursuant to the CLFS, further reducing payment rates. Some commercial payors are guided by the CLFS in establishing their reimbursement rates. In February 2012, the US Middle Class Tax Relief and Job Creation Act of 2012 was signed into law, which, in part, rebases the CLFS by negative 2%, reducing payment rates in 2013 and thereafter. Because the majority of our revenue is currently derived from the Medicare program and we expect this to continue in the foreseeable future, we are particularly impacted by changes in Medicare reimbursement. We cannot predict whether Medicare and other third-party payor reimbursement rates that mirror Medicare's will be sufficient to make our tests commercially attractive.

Further, with respect to the CLFS, the US Protecting Access to Medicare Act of 2014, or PAMA, will make significant changes to the way that Medicare will pay for clinical laboratory services by moving the clinical laboratory fee schedule away from a system of payments based on historical charges to a market-based payment system. Beginning January 1, 2016, and every three years thereafter (and annually for "advanced diagnostic laboratory tests"), laboratories that receive the majority of their Medicare revenues from payments made under the CLFS or the physician fee schedule will be required to report the payment rates that were paid to the laboratory by commercial health plans, Medicare Advantage plans and Medicaid managed care organizations and the volume of tests for each such payor during the reporting period. Included are any multiple rates during the period, but excluded are capitation or similar payments. Payments rates must be reported net of all discounts and other price concessions. Potentially, low-volume labs and labs on which Medicare makes low expenditures will be excluded from the reporting obligation. CMS will use the reported information to develop uniform national Medicare payment rates, without geographical or other adjustments. These rates will be equal to the volume-weighted median of the reported rates for the tests. These rates will be paid to independent clinical laboratories and to hospitals for their outpatients for tests that are performed after January 1, 2017. However, the new rates are subject to a six-year phase in period that will run from 2017 to 2022. Pursuant to the phase in, rates may not be reduced through the new methodology by more than 10% per test per year in 2017, 2018 and 2019. The maximum reduction is increased to 15% per test per year in 2020, 2021 and 2022. Cumulative payment reductions through the phase-in period could therefore be as much as 75%.

These reductions, however, will not initially apply to a "new test" (new or substantially revised Healthcare Common Procedure Coding System, or HCPCS, code after the date of the Act's enactment that is not an advanced diagnostic laboratory test). Until rates based on reported payor data can be established, rates for new tests will be set by the defined process of "cross-walking" or by a defined process of "gap-filling" where cross-walking is not possible. Another special rule applies to "advanced diagnostic laboratory tests." These are tests that are offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and which is either an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result, a test that "is cleared or approved by the Food and Drug Administration" or a test that meets other criteria established by CMS. Where payment for an advanced diagnostic laboratory test was not made prior to the enactment of the Act under the clinical laboratory fee schedule, payment will be made for three quarters based upon the laboratory's actual list charge. Then, beginning in January 2017, payment will be made based on the volume-weighted median private payor rates these laboratories are required to report. If the actual list charge substantially exceeds private payor rates, then, when reported, CMS will have the ability to recoup payments in excess of 130% of the weighted median of reported private payor rates that were made during the initial period. We cannot determine at this time the full impact of the new law on our business, financial condition and results of operations.

Although CMS has not yet issued regulations to implement PAMA, we believe our ConfirmMDx test would be considered an advanced diagnostic laboratory test. We may or may not seek designation as an advanced diagnostic laboratory test for any of our tests. While we do not believe the new payment rate system under PAMA will have a negative effect on the current payment rates of our ConfirmMDx test beginning in 2017, regulations implementing PAMA have not yet been

promulgated. As a result, there can be no assurance that adequate Medicare payment rates will continue to be assigned to our tests.

Other Medicare policy changes may include competitive bidding by clinical laboratories for the provision of services, which was the subject of a CMS demonstration project pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003, or MMA. In July 2008, the Medicare Improvements for Patients and Providers Act of 2008 was enacted, which, among other things, repealed the competitive bidding demonstration project for clinical laboratory services. If competitive bidding is implemented in the future, competitive bidding could decrease our reimbursement rates for clinical laboratory tests. Medicare's coverage and reimbursement policies are often the product of its contractors, such as the Medicare Administrative Contractors, or MACs, who carry out LCDs and pricing. This can result in variable treatment around the country.

Finally, some private insurers and other third-party payors link their rates to Medicare's reimbursement rates, and a reduction in Medicare reimbursement rates for clinical laboratory services could result in a corresponding reduction in the reimbursements we receive from such third-party payors. Any reductions in reimbursement levels for ConfirmMDx would decrease our revenue and adversely affect our results of operations and financial condition.

OPERATING AS A NON-CONTRACTING PROVIDER WITH CERTAIN PAYORS MAY ADVERSELY AFFECT OUR RESULTS OF OPERATIONS AND FINANCIAL CONDITION, AND CONTRACTING WITH THOSE PAYORS MAY BE DISADVANTAGEOUS TO US.

We are currently considered to be an out-of-network or "non-contracting provider" by a number of third-party payors because we have not entered into a specific contract to provide testing services to their insured patients at specified rates of reimbursement. ConfirmMDx is currently covered by policies serving approximately 50 % of the at-risk male population between the ages of 50 and 74 in the US. As a non-contracting provider, many payors pay us a smaller percentage of our charges that they recognize to be reasonable, and expect us to collect greater coinsurance or copayments from our patients. Rather than collecting these higher coinsurance and copayment amounts from these patients, when permitted by law to do so, we may instead choose to charge them only the lower coinsurance and copayments amounts that would have applied to them if we had been contracted with their payor, which results in decreased revenues. In instances where we are prohibited by law from treating these patients as if we were in-network, thus requiring these patients to pay higher coinsurance or copayments to us, our customers may decide to reduce or avoid prescribing ConfirmMDx testing services for such patients, which would adversely affect our results of operations and financial condition.

Should any of the third-party payors with whom we are not contracted insist that we enter into a contract for the ConfirmMDx testing services we provide, the resulting contract may contain pricing and other terms that are materially less favorable to us than the terms under which we currently operate. If revenue from a particular payor grows, there is heightened risk that such a third-party payor will insist that we enter into contractual arrangements that contain such terms. If we refuse to enter into a contract with such a third-party payor, they may refuse to cover and reimburse for ConfirmMDx testing services, which may lead to a decrease in case volume and a corresponding decrease in our revenues. If we contract with such a third-party payor, although our case volume may increase as a result of the contract, our revenue per case under the contractual agreement and

gross margin may decrease. The overall net result of contracting with third-party payors may adversely affect our business, results of operations and financial condition.

IF THE UTILITY OF CONFIRMMDX AND SELECTMDX ARE NOT SUPPORTED BY PEER-REVIEWED MEDICAL PUBLICATIONS, THE RATE OF ADOPTION OF OUR TEST BY CLINICIANS AND THE COVERAGE AND REIMBURSEMENT DETERMINATIONS BY THIRD-PARTY PAYORS FOR OUR TESTING SERVICES MAY BE NEGATIVELY AFFECTED.

Healthcare providers typically take a long time to adopt new products, testing practices and clinical treatments, partly because of perceived liability risks and the uncertainty of third-party coverage and reimbursement. It is critical to the success of our sales efforts that we educate a sufficient number of patients, clinicians and administrators about molecular diagnostics testing, in general, as well as about our ConfirmMDx tests and our future tests, if any, and demonstrate the clinical benefits of these tests. It is likely that clinicians may not adopt, and third-party payors may not cover or adequately reimburse for, our tests unless they determine, based on published peer-reviewed journal articles and the experience of other clinicians, that our tests provide accurate, reliable and cost-effective information.

As the healthcare reimbursement system in the United States evolves to place greater emphasis on comparative effectiveness and outcomes data, we cannot predict whether we will have sufficient data, or whether the data we have will be presented to the satisfaction of any payors seeking such data in the process of determining coverage for diagnostic tests.

The administration of clinical and economic utility studies is expensive and demands significant attention from our management team. Data collected from these studies may not be positive or consistent with our existing data, or may not be statistically significant or compelling to the medical community. If the results obtained from our ongoing or future studies are inconsistent with certain results obtained from our previous studies, adoption of diagnostic services would suffer and our business would be harmed.

Peer-reviewed publications regarding our tests may be limited by many factors, including delays in the completion of, poor design of, or lack of compelling data from clinical studies that would be the subject of the article. If our tests or the technology underlying our current test or future tests do not receive sufficient favorable exposure in peer-reviewed publications, the rate of clinician adoption of our test and positive reimbursement coverage decisions for our tests could be negatively affected. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for tests such as ours, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenue from any product that is the subject of a study.

Risks Relating to Regulatory and Compliance Matters

OUR FAILURE TO COMPLY WITH GOVERNMENTAL PAYOR REGULATIONS COULD RESULT IN OUR BEING EXCLUDED FROM PARTICIPATION IN MEDICARE, MEDICAID OR OTHER GOVERNMENTAL PAYOR PROGRAMS, WHICH WOULD SUBSTANTIALLY DECREASE OUR REVENUE AND ADVERSELY AFFECT OUR RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

Approximately 50% of our target patient population for ConfirmMDx diagnostic testing includes US men over the age of 65, substantially all of whom are covered by Medicare or Medicare Advantage

programs. The Medicare program is administered by the Centers for Medicare and Medicaid Services, or CMS, which, like the states that administer their respective state Medicaid programs, imposes extensive and detailed requirements on diagnostic services providers, including, but not limited to, rules that govern how we structure our relationships with physicians, how and when we submit reimbursement claims and how we provide ConfirmMDx testing services. Our failure to comply with applicable Medicare, Medicaid and other governmental payor rules could result in exclusion from participation in one or more governmental payor programs, our returning funds already paid to us, civil monetary penalties, criminal penalties and/or limitations on the operational function of our laboratory. If we were unable to receive reimbursement under a governmental payor program, a material portion of our revenue would decline, which could adversely affect our results of operations and financial condition.

HEALTHCARE REFORM MEASURES COULD HINDER OR PREVENT THE COMMERCIAL SUCCESS OF OUR DIAGNOSTIC TESTS.

The pricing and reimbursement environment may change in the future and become more challenging as a result of any of several possible regulatory developments, including policies advanced by the US government, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, there have been a number of legislative and regulatory proposals and initiatives to change the healthcare system in ways that could affect our ability to profitably sell any diagnostic products we may develop and commercialize. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our diagnostic products from governmental agencies or other third-party payors, which would adversely affect our business strategy, operations and financial results.

The US Patient Protection and Affordable Care Act of 2010 (as amended by the Health Care and Education Reconciliation Act of 2010), or ACA, made substantial changes to the current system for paying for healthcare in the United States. For example, beginning in 2013 through December 31, 2015, each medical device manufacturer was required to pay sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices that are listed with the FDA. The medical device tax has been suspended for 2016 and 2017, but is scheduled to return beginning in 2018. Although the FDA has issued draft guidance that, if finalized, would regulate certain LDTs as medical devices, none of our LDTs, such as our ConfirmMDx and SelectMDx tests, are currently listed with the FDA. We cannot assure you that the tax will not apply to services such as ours in the future.

Other significant measures contained in the ACA include, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. In addition, the ACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to control healthcare expenditures for consideration by Congress. If Congress fails to act on such proposal(s) and does not pass alternative legislation achieving similar savings, the Secretary of the US Department of Health and Human Services is required to implement the IPAB's proposal(s). IPAB proposals may have a negative impact on payment rates for services, including ConfirmMDx tests.

In addition to the ACA, other recent legislative changes have been proposed and adopted in the United States since the ACA was enacted. Recent legislative changes specific to coverage and reimbursement of laboratory tests are addressed above. Healthcare legislative reforms affecting providers generally include the US Budget Control Act of 2011, which, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. On April 1, 2013, the cuts to the federal budget resulting from sequestration were implemented, requiring a 2% cut in Medicare payment for all services, including our diagnostic tests. These cuts will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayor Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to providers such as hospitals, imaging centers and cancer treatment centers, and increased the government's statutory recovery period for overpayments to providers from three to five years. Congress is also considering major changes to the way in which Medicare pays for services under the Physician Fee Schedule.

State legislation on reimbursement applies to Medicaid reimbursement and Managed Medicaid reimbursement rates within that state. Some states have passed or proposed legislation that would revise reimbursement methodology for clinical laboratory payment rates under those Medicaid programs. In October 2011, CMS approved California's plan to reduce certain Medi-Cal payments by 10% retroactive to June 1, 2011. In February 2012, Medi-Cal began the recoupment process by sporadically adjusting payments on new claims. According to the California Department of Health Care Services, or DHCS, the cut applies to various healthcare providers and outpatient services including laboratory services with certain exceptions. Moreover, state legislation required DHCS to develop a new rate-setting methodology for clinical laboratories and laboratory services that is based on the average of the lowest prices other third-party payors are paying for similar services, and to implement an additional 10% reduction, effective July 1, 2012 through June 30, 2015, to payments for clinical laboratory and laboratory services. DHCS has developed and CMS has approved the new rate methodology, which involves the use of the range of rates that fell between zero and 80% of the calculated California Medicare rate and the calculation of a weighted average (based on units billed) of such rates. Effective July 1, 2015, this new methodology was implemented by DHCS. Although recent changes to reimbursement methodology in states outside of California have not materially changed the payment rate for our tests, we cannot be certain that these or future changes will not affect payment rates in the future.

Federal and state budgetary limitations and changes in healthcare policy, such as the creation of broad limits for diagnostic products could substantially diminish the sale, or inhibit the utilization, of future diagnostic tests, increase costs, divert management's attention and adversely affect our ability to generate revenue and achieve profitability. Additionally, on several occasions, the US Congress has considered imposing a 20% co-insurance amount for clinical laboratory services, which would require beneficiaries to pay a significant portion of the cost of their clinical laboratory testing. Although that requirement has not been enacted at this time, Congress could decide to impose such an obligation at some point in the future, which would make it more difficult for us to collect adequate reimbursement for, and increase use of, our diagnostic test.

These laboratory-specific changes and other non-laboratory specific changes in laws, regulations, payor policies or contracting arrangements with payors may adversely affect coverage or

reimbursement for our testing solutions, which may decrease our revenue and adversely affect our results of operations and financial condition. We also cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the US in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by new legislation, cost reduction measures and the expansion in government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursements by payors for our products or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations. In addition, sales of our tests outside the US make us subject to international regulatory requirements and cost-reduction measures, which may also change over time.

WE CONDUCT BUSINESS IN A HEAVILY REGULATED INDUSTRY, AND CHANGES IN REGULATIONS OR VIOLATIONS OF REGULATIONS MAY, DIRECTLY OR INDIRECTLY, REDUCE OUR REVENUE, ADVERSELY AFFECT OUR RESULTS OF OPERATIONS AND FINANCIAL CONDITION AND HARM OUR BUSINESS.

The clinical laboratory testing industry is highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely to us in the future. Areas of the regulatory environment that may affect our ability to conduct business include, without limitation:

- federal and state laws in and outside of Belgium and the United States applicable to test ordering, documentation of tests ordered, billing practices and claims payment and/or regulatory agencies enforcing those laws and regulations;
- federal and state laboratory anti-mark-up laws;
- coverage and reimbursement levels by Medicare, Medicaid, other governmental payors and private insurers;
- restrictions on coverage of and reimbursement for ConfirmMDx tests;
- laws governing laboratory testing, including the US Clinical Laboratory Improvement Amendments of 1988, or CLIA, and state licensing laws;
- laws governing the development, use and distribution of diagnostic medical devices and laboratory developed tests;
- laws governing the handling and disposal of medical and hazardous waste; and
- Occupational Safety and Health Administration, or OSHA, rules and regulations in the US.

These laws and regulations are extremely complex and in many instances there are no significant regulatory or judicial interpretations of these laws and regulations. While we believe that we are currently in material compliance with applicable laws and regulations, a determination that we have violated these laws, or the public announcement that we are being investigated for possible violations of these laws, would adversely affect our business, prospects, results of operations and financial condition. In addition, a significant change in any of these laws may require us to change our business model in order to maintain compliance with these laws, which could reduce our revenue or increase our costs and adversely affect our business, prospects, results of operations and financial condition.

IF WE FAIL TO COMPLY WITH HEALTHCARE REGULATIONS, WE COULD FACE SUBSTANTIAL PENALTIES AND OUR BUSINESS, OPERATIONS AND FINANCIAL CONDITION COULD BE ADVERSELY AFFECTED.

Our business operations and activities are directly, or indirectly, subject to certain healthcare laws and regulations promulgated by the government (local, national and federal) in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the US Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or for recommending or arranging for the purchase, lease or order of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

- the US Stark Law, which prohibits, among other things, physicians who have a financial relationship, including an investment, ownership or compensation relationship with an entity, from referring Medicare patients to that entity for designated health services, which include clinical laboratory services, unless an exception applies. Similarly, entities may not bill Medicare or any other party for services furnished pursuant to a prohibited referral. Recent case law has extended the Stark law's prohibition to referrals of Medicaid patients as well. Unlike the federal Anti-Kickback Statute, the Stark Law is a strict liability statute, meaning that all of the requirements of a Stark Law exception must be met in order for referrals to an entity by a physician with a financial relationship with the entity to be compliant with the law;

- US civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from "knowingly" presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other governmental third-party payors that are false or fraudulent, "knowingly" making a false statement material to an obligation to pay or transmit money to the federal government or "knowingly" concealing or "knowingly" and improperly avoiding or decreasing an obligation to pay money to the federal government, apply to clinical laboratories that submit claims to Medicare and other federal healthcare programs ("knowingly" is defined under the false Claims Act as acting with actual knowledge, reckless disregard or deliberate ignorance);

- laws, including HIPAA and HITECH, addressing health information practices, patient privacy and electronic data security. As a health care provider in the US, we are a covered entity under HIPAA, and our failure to comply with HIPAA requirements can result in substantial civil and criminal penalties, as well as costs of investigating breaches, providing required notification, and undertaking other mitigation. HIPAA has a tiered system of money penalties, based on the degree of negligence or willfulness of the breach, and whether or not it was timely corrected. Possible penalties range up to $50,000 for each violation, subject to a $1.5 million maximum for identical violations during a calendar year. Criminal penalties may be imposed on any person who knowingly obtains or discloses individually identifiable health information, also called "protected health information" or "PHI," in violation of HIPAA. The penalties depend on intent; violations committed with intent to sell, transfer, or use the information for commercial advantage, personal gain, or malicious harm, carry the largest penalties—fines up to $250,000, imprisonment up to 10 years, or both;

- laws governing the certification and licensing of clinical laboratories, including operational, personnel and quality requirements designed to ensure that testing services are accurate and timely, and federal and state laws governing the health and safety of clinical laboratory employees;

- consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- state and local law equivalents of each of the above laws, such as anti-kickback, self-referral, false claims, consumer protection and unfair competition laws which may apply to our business practices. In particular, state anti-kickback laws and self-referral laws may be more restrictive than their federal counterparts. For example, the anti-kickback laws in the states of Florida and New York may be more restrictive than the federal Anti-Kickback Statute with respect to compensation paid to independent contractor marketers;

- the provisions of the US Civil Monetary Penalties Law, which prohibit the offering or giving of remuneration to a Medicare or Medicaid beneficiary, including the provision of free items and services, that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a governmental program; and

- the US Physician Payment Sunshine Act, subject to specific exceptions, requires drug and medical device manufacturers to disclose to HHS any direct or indirect payments that they make to physicians or any direct ownership interests that physicians or their immediate family members hold in them. While we do not believe we are currently subject to the requirements of the Sunshine Act, if we are subject to the Act in the future and we fail to meet its reporting requirements, civil monetary penalties may be imposed on us.

In addition, the approval and commercialization of any of our tests outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws and the US's Foreign Corrupt Practices Act.

Our efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. Although we have in place a code of business conduct and ethics, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including our relationships with physicians and other healthcare providers, our sales and marketing efforts and our billing and claims processing practices could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from

participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

OUR BUSINESS COULD BE HARMED FROM THE LOSS OR SUSPENSION OF A LICENSE OR IMPOSITION OF A FINE OR PENALTIES UNDER, OR FUTURE CHANGES IN, THE LAW OR REGULATIONS OF THE US CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988, OR CLIA, OR THOSE OF OTHER STATE OR LOCAL AGENCIES.

We are subject to CLIA, which is administered by CMS and extends federal oversight to virtually all clinical laboratories by requiring that they be certified by the federal government or by a federally-approved accreditation agency. CLIA is designed to ensure the quality and reliability of clinical laboratories by, among other things, mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. Laboratories must undergo on-site surveys by the US Federal CLIA program at least every two years or accreditation by a private CMS approved accrediting agency such as the College of American Pathologists, among others. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as significant fines criminal penalties, expanded regulatory monitoring, and/or cancelled or suspended Medicare payments.

We are also subject to regulation of laboratory operations under state clinical laboratory laws of California, where our facility is located, and of certain other US states, from where we accept specimens. State clinical laboratory laws may require that laboratories and/or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. For example, California requires that we maintain a license to conduct testing in California, and California law establishes standards for our day-to-day laboratory operations, including the training and skill required of laboratory personnel and quality control. In some respects, notably with respect to qualifications of testing personnel, California's clinical laboratory laws impose more rigorous standards than does CLIA. Certain other states, including Florida, Maryland, New York and Pennsylvania, require that we hold licenses to test specimens from patients residing in those states, and additional states may require similar licenses in the future. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations, which could adversely affect our business and results of operations.

OUR PRODUCTS ARE CURRENTLY SUBJECT TO THE FDA'S AND EU EXERCISE OF ENFORCEMENT DISCRETION, AND WE COULD INCUR SUBSTANTIAL COSTS AND DELAYS ASSOCIATED WITH MEETING REQUIREMENTS FOR PREMARKET CLEARANCE OR APPROVAL OR EXPERIENCE DECREASED DEMAND OR REIMBURSEMENT FOR OUR PRODUCTS IF THE FDA OR EU ENFORCEMENT POLICIES CHANGE.

The US Food and Drug Administration, or FDA, regulates the sale and distribution in interstate commerce of products classified as medical devices under the Federal Food, Drug, and Cosmetic Act, or FDCA, including in vitro diagnostic, or IVD, devices such as ConfirmMDx tests. Generally, medical devices must undergo premarket review by the FDA, either through clearance of a 510(k) premarket notification or approval of a premarket approval application, or PMA, which can be a lengthy, expensive and uncertain process. However, the FDA has historically exercised enforcement discretion with respect to IVD tests that are developed by a single laboratory for its own use, called laboratory developed tests, or LDTs, which are therefore not subject to FDA regulation or premarket review. See

"Business—Government Regulation." We believe that our products all qualify as LDTs, which are currently subject to the FDA's exercise of enforcement discretion. As a result, we believe our products are exempt from regulation under current FDA enforcement policies.

CLIA presently requires us to establish that our LDTs accurately identify the specific genes, proteins and other substances that they purport to identify. Regulation by the FDA would be expected to require us to also establish that our LDTs have the clinical significance in terms of patient care that we hold them out as having through our marketing activities. On July 31, 2014, the FDA notified Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs, and on October 3, 2014, the FDA published two draft guidances setting out that proposed framework. Our ConfirmMDx tests may, therefore, become subject to the FDA's enforcement of its medical device regulatory requirements, including the requirement for premarket clearance or approval. While the FDA has proposed that devices that are already in use at the time the FDA initiates enforcement of the premarket review requirements will be permitted to remain in use – pending the FDA's review and consideration of the premarket submission – so long as a premarket submission is timely made, we may nevertheless be required to cease commercial sales of our products and conduct additional clinical testing prior to making submissions to the FDA to obtain premarket clearance or approval. While it may take many months for the FDA to review comments on these future draft guidances and finalize the guidances for enforcement, we cannot predict the ultimate timing or form of any such regulation of LDTs and the potential impact on our existing products, our products in development or the materials used in our products.

The FDA has issued other draft guidance documents that may impact our products or our future products if they were to become subject to FDA regulation, including draft guidance on mobile medical applications and final guidance on in vitro companion diagnostic devices. We cannot predict the potential impact of these guidance documents on our existing products, our products in development or the materials used in our products. We expect that new legislative proposals regarding the FDA's oversight of LDTs will continue to be introduced from time to time. The uncertainty regarding the status of LDTs under FDA regulation may negatively impact the willingness of third parties to supply us with necessary reagents and testing devices or promote our tests and may ultimately require us to seek 510(k) clearance or PMA approval for our existing products and products under development. It is also possible that the FDA might require our suppliers of reagents and testing devices to obtain approvals or additional approvals for their products, thereby making those products unavailable to us, or interfering with their availability, and potentially interfering with our ability to perform testing.

While we qualify all materials used in our products in accordance with CLIA regulations and guidelines, the FDA could promulgate regulations or guidance documents impacting our ability to purchase materials necessary for the performance of our products. Should any of the reagents we obtain from suppliers and use in our products be affected by future regulatory actions, our business could be adversely affected, including by increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents necessary to perform testing with our products.

We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for our products, whether through finalization of the draft guidances issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. Such guidance, enforcement policies or legislation may result in increased regulatory burdens, including a

requirement to obtain clearance or approval to market our products. Depending on their intended use, some or all of our products may be categorized as “high risk” by the FDA, which could require us to seek premarket review for some or all of our products in order to distribute them commercially. This could affect our ability to continue marketing our products and to develop and introduce new products.

If premarket review is required for some or all of our products, our business could be negatively impacted until clearance or approval to market our products is obtained, and the FDA could require that we stop selling our products pending clearance or approval. Even if our products are allowed to remain on the market prior to completion of premarket review, orders or reimbursement may decline if there is uncertainty about our products, if we are required to label our products as investigational by the FDA and to offer them only for investigational purposes, or if the labeling claims the FDA allows us to make are very limited. The premarket review process may involve, among other things, successfully completing additional clinical trials and submitting a 510(k) or PMA to the FDA. If we are required to conduct premarket clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our product development costs, delay commercialization of any future products and interrupt sales of our current products. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. If premarket review is required by the FDA, there can be no assurance that our products will be cleared or approved on a timely basis, if at all, nor can there be any assurance that any cleared or approved labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our products. As a result, we could experience significantly increased development costs and a delay in generating additional revenue from our products, or from other products now in development, which could adversely affect our business, financial condition and results of operations.

The FDA requires medical device manufacturers to comply with, among other things, current good manufacturing practices for medical devices, known as the Quality System Regulation, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process; the medical device reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; labeling regulations, including the FDA’s general prohibition against promoting products for unapproved or “off-label” uses; and the reports of corrections and removals regulation, which requires manufacturers to report to the FDA if a device correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device which may present a risk to health.

Even if we were able to obtain FDA clearance or approval for one or more of our products, if required, a product may be subject to limitations on the indications for which it may be marketed or to other regulatory conditions. In addition, such clearance or approval may contain requirements for costly post-market testing and surveillance to monitor the safety or effectiveness of the product. The FDA has broad post-market enforcement powers, and if unanticipated problems with our products

arise, or if we or our suppliers fail to comply with regulatory requirements following FDA clearance or approval, we may become subject to enforcement actions such as:

- disputes among payors regarding which party is responsible for payment;
- restrictions on manufacturing processes;
- restrictions on product marketing;
- untitled or warning letters;
- withdrawal or recall of products from the market;
- refusal to approve pending PMAs or PMA supplements to approved PMAs or to clear pending 510(k)s that we submit;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory clearances or approvals;
- limitation on, or refusal to permit, import or export of our products;
- product seizures;
- injunctions; or
- imposition of civil or criminal penalties.

Until the FDA finalizes a new oversight framework, we will continue to market our products under the FDA's exercise of enforcement discretion for LDTs. We do not currently have an FDA submission in process for any of our products, and we may be unable to compile and submit any required validation and other data to the FDA in the necessary timeframe to successfully obtain FDA clearance for these products if and when a final FDA oversight framework is put into effect.

Outside of the US, sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. In order to market our tests in other countries, we may be required to obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. The European Union/European Economic Area, or EU/EEA, requires a CE conformity mark in order to market medical devices. Many other countries, such as Australia, India, New Zealand, Pakistan and Sri Lanka, accept CE or FDA clearance or approval, although others, such as China, Brazil, Canada and Japan require separate regulatory filings.

Further, the advertising and promotion of our products in the EEA is subject to the laws of individual EEA Member States implementing the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State laws governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our tests to the general public and may impose limitations on our promotional activities with healthcare professionals.

Further, in the EEA, before we may commercialize a test in kit form, we would be required to comply with the essential requirements of the EU Medical Devices Directive (93/42/EEC). Compliance with these requirements would entitle us to affix the CE marking of conformity to our kits as medical devices, without which they could not be commercialized in the EEA. In order to demonstrate compliance with the essential requirements and obtain the right to affix the CE marking of

conformity, we would be required to undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the Medical Devices Directive, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization accredited by a Member State of the EEA to conduct conformity assessments. The Notified Body would typically audit and examine the quality system for the manufacture, design and final inspection of our devices before issuing a certification demonstrating compliance with the essential requirements. There can be no assurance that we will be able to qualify our test kits for an EC Declaration of Conformity which would allow us to affix the CE mark to our tests, or that we will be able to maintain this conformity.

OUR EMPLOYEES, INDEPENDENT CONTRACTORS (INCLUDING SALES REPRESENTATIVES), CONSULTANTS, STRATEGIC PARTNERS AND VENDORS MAY ENGAGE IN MISCONDUCT OR OTHER IMPROPER ACTIVITIES, INCLUDING NONCOMPLIANCE WITH REGULATORY STANDARDS AND REQUIREMENTS AND MISUSE OF PROPRIETARY INFORMATION.

We are exposed to the risk that employees, independent contractors, consultants, commercial partners and vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent failures to: (1) comply with government regulations that are applicable to us; (2) comply with clinical laboratory standards we have established; (3) comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (4) report financial information or data accurately, or disclose unauthorized activities to us. These laws and regulations may impact, among other things, our current as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent misconduct, including fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. It is not always possible to identify and deter employee and other third-party misconduct. The precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any actions are instituted against us under these laws or regulations, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

In addition, many of our employees, consultants and independent contractors were previously employed at or may have previously been or are currently providing consulting services to, other clinical laboratories or diagnostics companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or these consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Further, we may be

subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our tests. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

MDXHEALTH'S OPERATING RESULTS COULD BE MATERIALLY ADVERSELY AFFECTED BY UNANTICIPATED CHANGES IN TAX LAWS AND REGULATIONS, ADJUSTMENTS TO ITS TAX PROVISIONS, EXPOSURE TO ADDITIONAL TAX LIABILITIES, OR FORFEITURE OF ITS TAX ASSETS.

The determination of MDxHealth's provision for income taxes and other tax liabilities requires significant judgment, including the adoption of certain accounting policies and MDxHealth's determination of whether its deferred tax assets are, and will remain, tax effective. Although we believe our estimates and judgments are reasonable, they remain subject to review by the relevant tax authorities. We cannot guarantee that our interpretation will not be questioned by the relevant tax authorities, or that the relevant tax laws and regulations, or the interpretation thereof by the relevant tax authorities, will not be subject to change. Any adverse outcome of such a review may lead to adjustments in the amounts recorded in our financial statements, and could have a materially adverse effect on our operating results and financial condition.

We are subject to laws and regulations on tax levies and other charges or contributions in different countries, including transfer pricing and tax regulations for the compensation of personnel and third parties. MDxHealth's tax structure involves a number of transfers and transfer price determinations between its parent company and its subsidiaries or other affiliates.

Our effective tax rates could be adversely affected by changes in tax laws, treaties and regulations, both internationally and domestically, including possible changes to the patent income deduction regime and wage withholding tax incentive for qualified research and development personnel in Belgium and other tax incentives, or the way they proportionally impact our effective tax rate. An increase of the effective tax rates could have an adverse effect on our business, financial position, results of operations and cash flows.

In addition, we may not be able to use, or changes in tax regulations may affect the use of, certain tax assets or credits that we have built over the years. Some of these tax loss carry forwards may be forfeited in whole, or in part in, as a result of transactions, or their utilisation may be restricted by statutory law in the relevant jurisdiction. Any corporate reorganisation within the MDxHealth group or relating to our shareholding structure may result in partial or complete forfeiture of tax loss carry forwards. The tax burden would increase if profits could not be set off against tax loss carry forwards. Our increasing international business may make us subject to income tax and other taxes in countries where it was previously not the case.

IF WE FAIL TO COMPLY WITH THE TERMS AND CONDITIONS OF CONDITIONAL GRANTS AND SUBSIDIES, THIS MAY AFFECT MDXHEALTH'S ABILITY TO FINANCE ITS RESEARCH & DEVELOPMENT ACTIVITIES.

Since inception, we have received multiple conditional advances totaling $12.7 million for innovation granted by the Wallonia regional government and Flanders IWT. All Wallonia grants have been completed. The Flanders IWT grant is a 36 month project and is scheduled to be completed by October 1, 2016. If we fail to comply with our contractual obligations under the applicable innovation grant agreements, including if we lose our exclusive right to commercially develop our product

candidates, we could be forced to repay the sums advanced ahead of schedule. Such premature repayment could adversely affect our ability to finance our research and development projects. In addition, we cannot ensure that we will then have the additional financial means needed, the time or the ability to replace these financial resources with others.

EXPLANATORY NOTES

This document serves as an Annual Report for the fiscal year ended December 31, 2015 and does not require the Belgian Financial Services and Markets Authority (FSMA) to review and approve.

The financial information in the Annual Report is 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 section 5 Consolidated Financial Statements and Statutory Financial Statements of the Annual Report have been audited by BDO Réviseurs d'Entreprises Soc. Civ. SCRL and approved and authorized for issue by the Board of Directors at its meeting of April 18, 2016. 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 27, 2016.

This Annual Report is for MDxHealth SA. The information in this document covers the consolidated situation of MDxHealth SA and its subsidiaries. Throughout this document, references to "MDxHealth", the "Company" "we", "us" or "our" are to MDxHealth SA together with its consolidated subsidiary. Effective January 1, 2013, the Company changed the presentation currency of the consolidated financial statements from the Euro (EUR or €) to the US Dollar (USD or $). The Company's functional currency changed also from the Euro to the US Dollar as of July 1, 2014.

This Annual Report is structured similarly to the 2014 Annual Report. However, we draw the attention of the reader to the fact that the structure and presentation of this Annual Report is signifcantly different compared to the annual report of 2013 and to previous registration documents of 2012 and 2011, the purpose being to clarify the way in which the information is presented to the shareholders and to appropriately reflect the Company's current business model.

Language of this Annual Report

This Annual Report has been prepared in English and translated into French. The Company is responsible for the consistency between the French and English versions of the Annual Report. In the case of discrepancies between the different versions of this Annual Report, the English version will prevail.

Responsibility for this Annual Report

In accordance with Article 61, §1 and §2 of the Belgian Prospectus Act, the Company, represented by its Board of Directors, assumes responsibility for the information contained in this Annual Report. Having taken all reasonable care to ensure that such is the case, the Company, represented by its

Board of Directors, declares that, to the best of its knowledge, the information contained in this Annual Report is in accordance with the facts and contains no omission likely to affect its import.

Statutory auditor

BDO Réviseurs d'Entreprises Soc. Civ. SCRL (BDO), 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, was re-appointed on May 29, 2015 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 2018. BDO has been the statutory auditor since January 10, 2003. On May 29, 2015, Mr. Gert Claes of BDO replaced Mr. Bert Kegels, who had represented BDO since May 29, 2009, in accordance with legal requirements for Public Interest Entities.

Forward-looking statements

All statements in this Annual Report that do not relate to historical facts and events are "forward-looking statements". Forward-looking statement can be found under the captions "Risk factors", "Management discussion and analysis", "Business" and in other sections of this Annual Report. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes," "estimates," "anticipates," "expects," "intends," "may," "will," "plans," "continue," "ongoing," "potential," "predict," "project," "target," "seek" or "should" or, in each case, their negative or other variations or comparable terminology or by discussions of strategies, plans, objectives, targets, goals, future events or intentions. These forward-looking statements appear in a number of places throughout this Annual Report. Forward-looking statements include statements regarding MDxHealth's intentions, beliefs or current expectations concerning, among other things, its results of operations, prospects, growth, strategies and dividend policy and the industry in which MDxHealth operates. In particular, certain statements are made in this Annual Report regarding management's estimates of future growth.

By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. Forward-looking statements are not guarantees of future performance. You should not place undue reliance on these forward-looking statements. Any forward-looking statements are made only as of the date of this Annual Report and, without prejudice to the Company's obligations under applicable law in relation to disclosure and ongoing information, MDxHealth does not intend, and does not assume any obligation, to update forward-looking statements set forth in this Annual Report.

Many factors may cause MDxHealth's results of operations, financial condition, liquidity and the development of the industries in which MDxHealth competes to differ materially from those expressed or implied by the forward-looking statements contained in this Annual Report. The risks described under "Risk factors" are not exhaustive. Other sections of this Annual Report describe additional factors that could adversely affect MDxHealth's results of operations, financial condition, liquidity and the development of the sectors in which MDxHealth operates. New risks can emerge from time to time, and it is not possible for MDxHealth to predict all such risks, nor can MDxHealth

assess the impact of all such risks on its business or the extent to which any risks, or combination of risks and other factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, you should not rely on forward-looking statements as a prediction of actual results.

Jurisdiction and service of process in the United States and enforcement of foreign judgments in Belgium

The Company is a Belgian public limited liability company. Some of the Company's directors and members of its executive management team are non-residents of the United States. Some of the Company's assets and of the assets of such non-resident persons are located outside the US. As a result, it may not be possible for investors to effect service of process within upon such persons or the Company or to enforce against them in the US courts a judgment obtained in such courts whether or not based on the civil liability provisions of the US securities laws or other laws of the United States or any state thereof.

Original actions or actions for the enforcement of judgments of US courts relating to the civil liability provisions of the federal or state securities laws of the United States are not directly enforceable in Belgium. The United States and Belgium currently do not have a multilateral or bilateral treaty providing for reciprocal recognition and enforcement of judgments, other than arbitral awards, in civil and commercial matters. In order for a final judgment for the payment of money rendered by US courts based on civil liability to produce any effect on Belgian soil, it is accordingly required that this judgment be recognised and be declared enforceable by a Belgian court pursuant to the relevant provisions of the 2004 Belgian Code of Private International Law (the "PIL Code"). Recognition or enforcement does not imply a review of the merits of the case and is irrespective of any reciprocity requirement. A US judgment will, however, not be recognised or declared enforceable in Belgium if it infringes upon one or more of the grounds for refusal which are exhaustively listed in article 25 of the PIL Code. In addition to recognition or enforcement, a judgment by a federal or state court in the United States against the Company may also serve as evidence in a similar action in a Belgian court if it meets the conditions required for the authenticity of judgments according to the law of the state where it was rendered.

In addition, with regard to enforcements by legal proceedings in Belgium (including the recognition of foreign court decisions in Belgium), a registration tax at the rate of 3% of the amount of the judgment is payable by the debtor, if the sum of money which the debtor is ordered to pay by a Belgian court, or by a foreign court judgment that is either (i) automatically enforceable and registered in Belgium, or (ii) rendered enforceable by a Belgian court, exceeds €12,500. The registration tax is payable by the debtor. A stamp duty is payable for each original copy of an enforcement judgment rendered by a Belgian court, with a maximum of €1,450.

Availability of the Annual Report

This Annual Report has been prepared in English and has been translated into French. The Company is responsible for the consistency between the English and French version of the Annual Report. In any event, in case of inconsistencies between the different versions of this Annual Report, the English version shall prevail.

Copies of this Annual Report are available to the public without charge. The Annual Report will be made available to the public at no cost at the Company's registered office and upon request to:

MDxHealth SA
Attention: Investor Relations
CAP Business Center
Rue d'Abhooz, 31
4040 Herstal, Belgium
Email: ir@mdxhealth.com

An electronic version of the Annual Report is also available on MDxHealth's website (www.mdxhealth.com). The posting of this Annual Report 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 Annual Report.

Other Available Information

MDxHealth has filed its deed of incorporation and must file its restated articles of association and all other deeds and resolutions that are to be published in the Annexes to the Belgian Official Gazette (Belgisch Staatsblad/Moniteur Belge) with the clerk's office of the commercial court of Liège (Belgium), where they are available to the public. The Company is registered with the register of legal entities (Liège) under enterprise number 0479.292.440. A copy of the Company's most recently restated articles of association and corporate governance charter is also available on its website free of charge (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 Company's board of directors and statutory auditor relating thereto are be filed with the Belgian National Bank, where they are available to the public. Furthermore, as a company with shares listed on the regulated market of Euronext Brussels, the Company also publishes an annual financial report (which includes its audited statutory and consolidated financial statements, the report of its board of directors and the report of the statutory auditor) and an annual announcement preceding the publication of the annual financial report, as well as a half-yearly financial report on the first six months of its financial year (which includes a condensed set of financial statements and an interim management report). Copies of these documents are available on the Company's website and on STORI, the Belgian central storage mechanism, which is operated by the FSMA and can be accessed via www.fsma.be.

The Company must also disclose price sensitive information (inside information) and certain other information to the public. In accordance with the Belgian Royal Decree of November 14, 2007 on the obligations of issuers of financial instruments that are admitted to trading on a regulated market, such information and documentation is made available through the Company's website, press releases and the communication channels of Euronext Brussels and on STORI.

General industry, market and other information

This Annual Report includes market, economic and industry data, which were obtained by MDxHealth from industry publications and surveys, industry reports prepared by consultants, internal surveys and customer feedback. These market data are primarily presented in "Business" and "Management Discussion and Analysis". Where appropriate, specific sources are identified in the Annex to this document, as indicated by endnote references. Third party sources the Company has used generally state that the information they contain has been obtained from sources believed to be reliable. Some of these third party sources also state, however, that the accuracy and completeness of such information is not guaranteed and that the projections they contain are based on significant assumptions. As MDxHealth does not have access to the facts and assumptions underlying such market data, or statistical information and economic indicators contained in these third party sources, MDxHealth is unable to verify such information and, while MDxHealth believes it to be reliable, MDxHealth cannot guarantee its accuracy or completeness.

In addition, certain information in this Annual Report is not based on published data obtained from independent third parties or extrapolations therefrom, but rather is based upon MDxHealth's best estimates, which are in turn based upon information obtained from trade and business organisations and associations, consultants and other contacts within the industries in which MDxHealth competes, information published by MDxHealth's competitors and MDxHealth's own experience and knowledge of conditions and trends in the markets in which MDxHealth operates.

MDxHealth cannot assure you that any of the assumptions that MDxHealth has made while compiling this data from third party sources are accurate or correctly reflect MDxHealth's position in the industry and none of MDxHealth's internal estimates have been verified by any independent sources. MDxHealth does not make any representation or warranty as to the accuracy or completeness of this information. MDxHealth has not independently verified this information and, while MDxHealth believes it to be reliable, it cannot guarantee its accuracy.

The summaries and descriptions of legal provisions, accounting principles or comparisons of such principles, legal company forms or contractual relationships reported in this Annual Report may under no circumstances be interpreted as a basis for credit or other evaluation, or as investment, legal or tax advice for prospective investors. Prospective investors are urged to consult their own financial adviser, accountant or other advisers concerning the legal, tax, economic, financial and other aspects associated with the trading or investment in the shares.

Certain monetary amounts and other figures included in this Annual Report have been subject to rounding adjustments. Accordingly, any discrepancies in any tables between the totals and the sums of amounts listed are due to rounding.

EXPLANATORY NOTES

In this Annual Report, references to "euro", "EUR" or "€" are references to the euro, the single currency of the participating member states in the Third Stage of European Economic and Monetary Union of the Treaty Establishing the European Community, as amended from time to time; references to "US Dollar", "USD" or "$" are references to the United States dollar, the lawful currency of the United States of America.

FACTS & FIGURES

BUSINESS

OVERVIEW

MDxHealth is a multinational healthcare company that provides actionable molecular diagnostic information to personalize the diagnosis and treatment of cancer.

Over the past three years, the wide-spread adoption of our ConfirmMDx® for Prostate Cancer testing solution within the US urology community has established the Company as a market leader in the important and growing field of cancer diagnostics. More than 2,600 urologists, representing 25% of practicing urologists in the US, have ordered our proprietary ConfirmMDx test on over 40,000 patients since its launch in mid-2012.

Our goal is to build on the success of our lead product, leveraging our expertise in molecular diagnostics, to establish MDxHealth as the molecular diagnostics market leader in urological oncology. Our strategic roadmap to achieve this goal includes:

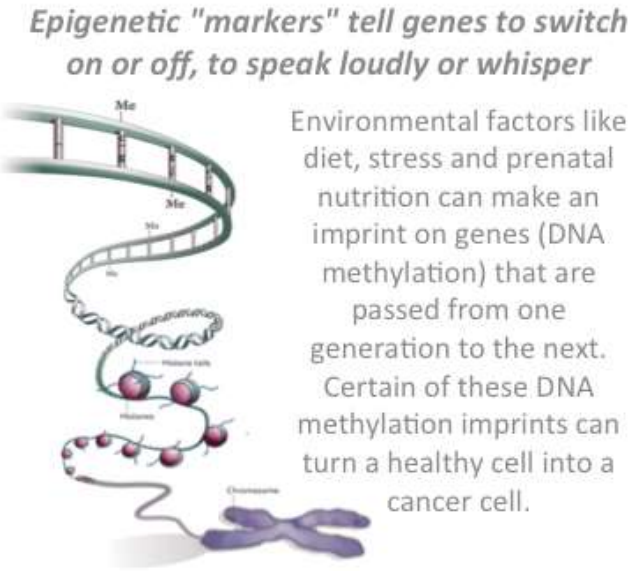
- increasing utilization of our lead product, ConfirmMDx for Prostate Cancer
- expanding our product and service offerings in urologic oncology
- securing favorable reimbursement for our solutions in the US and internationally
- expanding the clinical utility and actionability of our current and future solutions

The launch of our new SelectMDx™ for Prostate Cancer test in both the US and Europe represents the first of several significant planned steps to expand the solutions we offer in urological oncology. Importantly, SelectMDx also represents our entry into the new and expanding “liquid biopsy" testing market, which is expected to top $28 billion annually at its peak. SelectMDx is indicated for men who have not yet had a biopsy, and is therefore designed to test urine specimens that can be gathered non-invasively. In 2016, we plan to expand the availability of SelectMDx from its initial launch in the Benelux Union region to include additional countries in Europe. In addition, we plan to launch our second liquid biopsy solution, the urine-based AssureMDx™ for Bladder Cancer test, in late 2016.

Following our launch of SelectMDx, we now have two complementary tests available in the Prostate Cancer field, each representing a potential global market opportunity of greater than $2 billion, with SelectMDx addressing the pre-biopsy (or biopsy ‘naïve’) market, and ConfirmMDx addressing the post-biopsy market.

Bringing Innovation to Life

The Company's lead product, ConfirmMDx, is based on a groundbreaking epigenetic technology able to identify key changes in gene activity that do not involve changes to the underlying genetic code. We believe that ConfirmMDx is the first diagnostic test based on epigenetic markers to gain broad market acceptance as a standard of care, having been included in the US National Comprehensive Cancer Network (NCCN) Guidelines for prostate cancer. Building on more than a decade of research at MDxHealth, our epigenetic technologies have also been incorporated into molecular tests for brain cancer and colon cancer that are currently available in the clinic. We continue to leverage our many years of expertise in the epigenetics arena to develop new tests in urologic oncology, including our AssureMDx for Bladder Cancer test, which we plan to launch before the end of 2016.



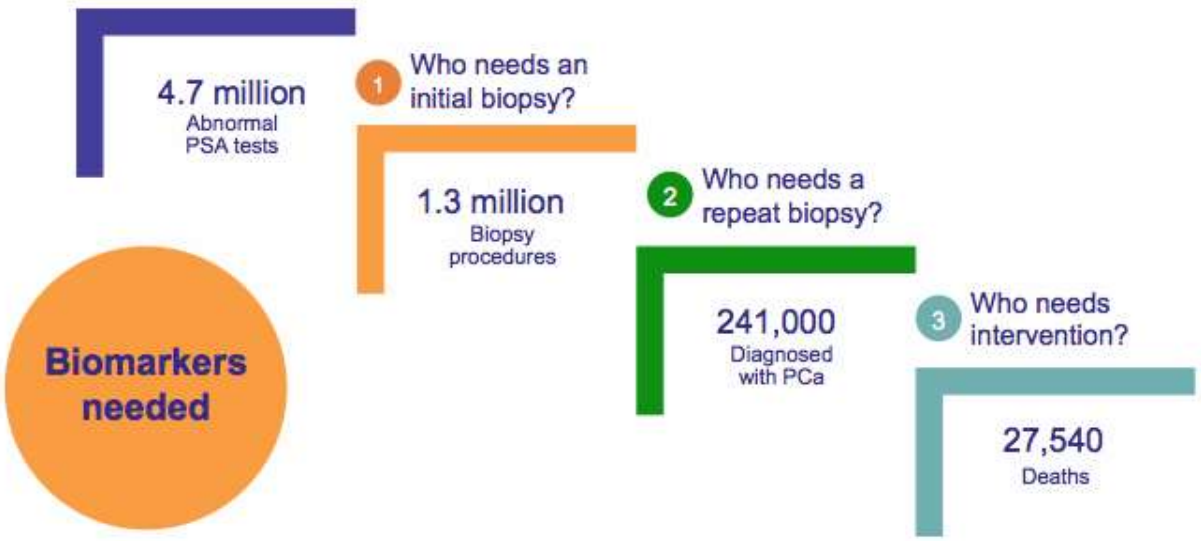
With the recent acquisition of NovioGendix, the Company continues its commitment to bring cutting edge technologies to empower clinicians and their patients to personalize the diagnosis and treatment of cancer. Founded be the inventor of the PCA3 test, NovioGendix worked closely with colleagues at Radboud University in Nijmegen, the Netherlands, to identify and clinically validate mRNA markers that improve the detection of aggressive and potentially lethal prostate cancers. We plan to maintain the molecular research facilities located on the Radboud University Medical Center campus, which will complement our existing research joint venture with the University of Gent in Belgium.

We believe that the combination of our proprietary, accurate and scalable epigenetic and mRNA testing technologies provide MDxHealth with a key competitive advantage in the diagnosis, prognosis and management of cancer. In addition to our ongoing and planned studies to expand the clinical utility of prostate cancer solutions, our product pipeline includes tests for bladder, kidney, and other urologic cancers. For other (non-urologic) cancer types, we have engaged partners to commercialize our epigenetic technologies, as shown by the successful launches of Cologuard® for colon cancer by licensee Exact Sciences and PredictMDx® for Glioblastoma by licensee Laboratory Corporation of America (Labcorp).

We currently offer our laboratory solutions from our 13,444 sqft, College of American Pathology (CAP)-accredited and Clinical Laboratory Improvement Amendments of 1988 (CLIA) and ISO 9001:2008 certified, molecular laboratory facility located at our US headquarters in Irvine, California and through our state-of-the-art 1,735 sqft diagnostic facilities in Nijmegen, The Netherlands. Our European corporate headquarters is located in Herstal, Belgium and our NXTGNT (Epi)genomics research joint-venture with the University of Gent is located in Ghent, Belgium.

BACKGROUND

Prostate cancer is the most frequent cancer in men, with one out of six men being diagnosed during their lifetime. Annually in the US, on the approximately 20 million men screened by the Prostate-Specific Antigen (PSA) test, there are:



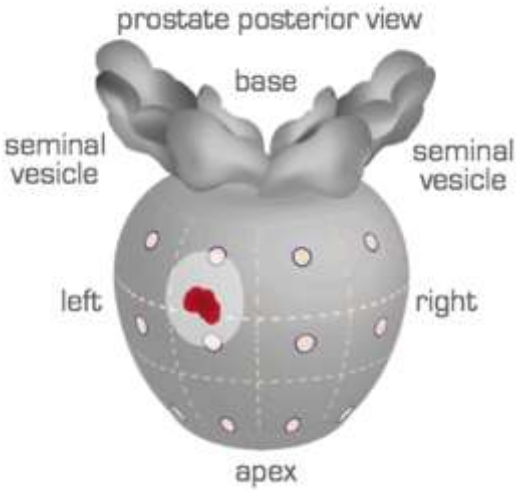
Although prostate cancer remains one of the deadliest cancers in men,[1] its accurate diagnosis and follow-up remain a challenge and come at a considerable cost to the healthcare system. Approximately $4.4 billion is spent annually on screening, diagnosing and staging, and an additional $9.9 billion is spent annually on treatment of these patients, totaling nearly $15 billion per year on prostate cancer in the US alone. Annually, over $4 billion is spent on pharmaceutical treatment for prostate cancer, which is expected to increase to $8.7 billion by 2019.[2] Since the introduction of serum prostate-specific antigen (PSA) testing in the 90s, the incidence of prostate cancer increased and mortality dropped. However, PSA-testing also led to an increased number of unnecessary biopsies and detection of low grade, indolent disease that would not have been life threatening. This is particularly the case in a PSA 'grey-zone' below 10.0 ng/ml, where approximately 70% of men have a negative biopsy result. Men with indolent disease who undergo treatment may suffer complications, with no survival benefit. Conversely, men with Gleason score (GS) 8-10 prostate cancer have a relatively high probability of dying from the disease within 10 years, whereas this risk is minimal for men with low-grade disease.

In the last 5 years, the urology community has seen a significant shift in not only prostate cancer screening, but also in the management of men with prostate cancer. This evolution has lead to dramatic changes in testing needs and treatment solutions, but not without some consequences. The USPSTF guidance on PSA screening lead to a reduction in prostate cancer detection rates initially, but recent reports suggest that delayed detection has resulted in in an increase of higher grade prostate cancer upon biopsy.

The major challenge, or clinical need, facing the urologic community in this arena is to improve the detection of clinically significant or high-grade PCa at an early stage. Both overdiagnosis and overtreatment

could be reduced if PCa-specific biomarkers are available to accurately distinguish indolent from aggressive tumors.

Under the current standard of care, men with an elevated (i.e., ≥ 4.0 ng/ml) or rising PSA score and/or abnormal digital rectal exam (DRE) are considered at high risk for cancer and will often be referred for a prostate biopsy to determine if prostate cancer is present.

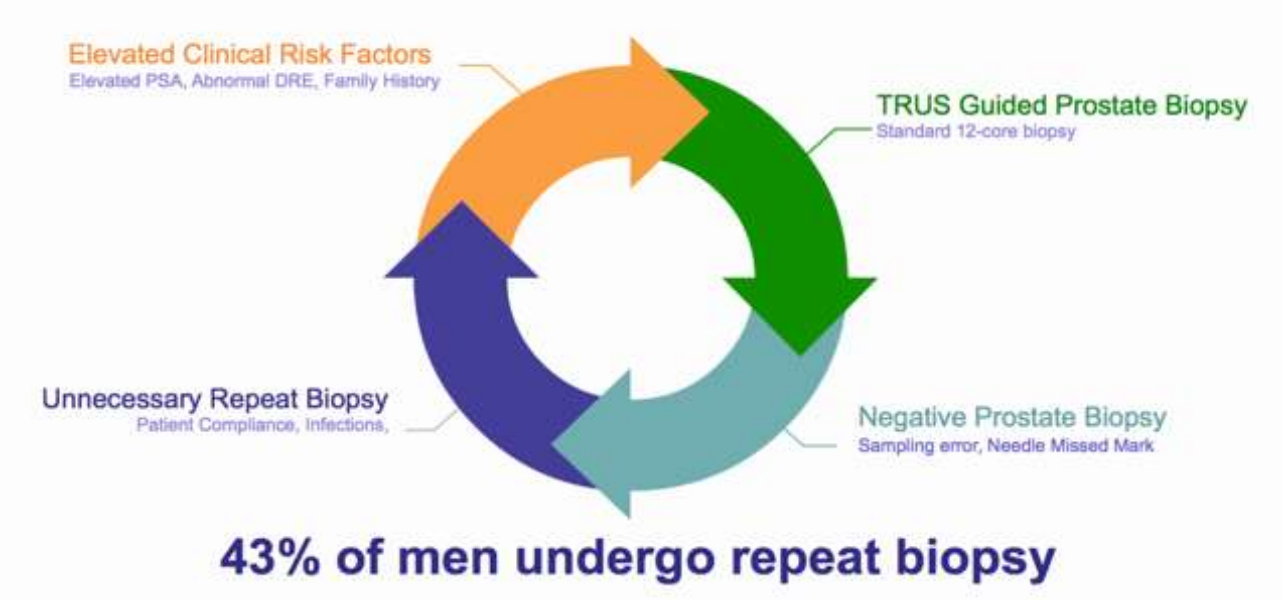


The standard prostate biopsy procedure takes 10-12 core needle samples, which are submitted to a pathologist for visual inspection under a microscope to determine the presence or abscence of prostate cancer. However, this schema actually samples less than 1% of the entire prostate gland and results in limited histopathological analysis. Sampling error is an inherent and well-documented issue with false-negative rates (FNR) of prostate biopsy procedures reported as high as 25-35%.[2]

Of the nearly 2 million prostate biopsies performed each year worldwide, less than a third find cancer. Most of these men could have avoided a painful and invasive prostate biopsy procedure, with its associated side effects and costs. Moreover, following this standard of care biopsy procedure, we create a substantial pool of men, numbering well in excess of 1 million, with a negative biopsy reading but still facing elevated clinical risk factors. Concerns over missed cancer (i.e. false-negative biopsy results), coupled with the high rate of clinically significant cancer detected upon repeat biopsy, pose a diagnostic dilemma:

- 43% of patients with a negative initial biopsy will undergo a repeat biopsy, with many undergoing 3rd and 4th biopsies
- repeat biopsies are invasive procedures resulting in increased risk of infection and hospitalization
- significant costs are attributed to unnecessary procedures and their associated complications

For patients with an initial negative biopsy but with persistently elevated or rising PSA, abnormal DRE or other risk factors, few options are currently available to guide a urologist in determining whether or when an additional biopsy procedure is warranted. Fear of occult (hidden) prostate cancer leads to additional procedures, leading many men to receive 2nd, 3rd and 4th repeat biopsy procedures to rule-out the presence of cancer.[3]



OUR SOLUTION TO RULE-OUT CANCER FREE MEN FROM REPEAT BIOPSY

Our ConfirmMDx for Prostate Cancer testing solution addresses false-negative biopsy concerns, helping urologists:

> ***"Rule-out"*** otherwise cancer-free men from undergoing unnecessary repeat biopsies and screening procedures, helping to reduce complications, patient anxiety and excessive healthcare expenses associated with these procedures.
>
> ***"Rule-in"*** high-risk men with a previous negative biopsy result who may be harboring undetected cancer (false-negative biopsy result) and therefore may benefit from a repeat biopsy and potentially treatment.

For men with an initial negative biopsy, independently published clinical studies have shown that the ConfirmMDx test is the most significant, independent predictor of patient outcome relative to other available clinical factors such as age, PSA and DRE results.

Patients with DNA methylation-negative ConfirmMDx test result have a low likelihood for prostate cancer.

Previous diagnostic studies have established the utility of ConfirmMDx as a significant, independent predictor of prostate cancer, with a negative predictive value (NPV) of 90% for all cancers and a NPV of 96% for significant cancers. [1-4]

In 2015, we enhanced the test results for ConfirmMDx positive patients. In addition to the existing prostate map of the DNA methylation results, we now also provide the physician with an indication of the patient's likelihood of harboring high grade, or aggressive and potentially lethal, prostate cancer versus low grade prostate cancer. The enhanced prognostic information provided in the ConfirmMDx results report for DNA methylation-positive patients is based on multiple studies indicating the tests abilty to stratify those patients with aggressive prostate cancer from those with non-aggressive prostate cancer. This additional actionable information from ConfirmMDx provides urologists with enhanced diagnostic, prognostic and clinical guidance to help manage their patients.

With approximately 1 million US men receiving a negative biopsy result each year with potentially inconculsive results, we believe that our ConfirmMDx solution addresses a significant unmet medical need for timely, actionable information that can aid in the reduction of unnecessary repeat biopsies. Assuming a 30% test adoption rate, we estimate the potential US market for ConfirmMDx in excess of $1 billion and we estimate the potential global market opportunity to be greater than $2 billion.[4]

We believe that incorporating ConfirmMDx for Prostate Cancer into clinical practice can substantially reduce the number of unnecessary repeat biopsies, yielding clinical and economic value for healthcare providers, patients and payors.

Epigenetics in Cancer

The use of epigenetic testing for prostate cancer detection using methylation specific PCR (MSP) and cancer-associated epigenetic biomarkers to improve upon histopathology has been well validated in both scientific and clinical studies. DNA methylation, the most common and useful measure of epigenetic abnormality testing, is responsible for the silencing of key tumor suppressor genes. DNA methylation biomarkers associated with prostate cancer have been extensively evaluated and more than 45 studies on the ConfirmMDx genes and technology have been published in peer reviewed, scientific and medical journals.

GSTP1 is the most intensely studied and widely reported epigenetic biomarker associated with prostate cancer diagnosis, encoding the glutathione S-transferase Pi 1 protein involved in detoxification, due to its high sensitivity and specificity. Complementing GSTP1, methylation of the APC and RASSF1 genes is frequently found in prostate cancer, and these markers have demonstrated a "field effect" aiding in the identification of biopsies with false-negative histopathological results.[4]

The concept of a field cancerization effect, when first reported in medical literature by Slaughter in 1953, described the changes in tissues surrounding cancer lesions and their association with development of tumors. Later, the term "field effect" evolved to include molecular changes in adjacent, benign-looking tissues. The epigenetic field effect is a molecular mechanism whereby cells adjacent to cancer foci can contain DNA methylation changes, which may be indistinguishable by histopathology, but detectable by MSP testing. The presence of epigenetic field effects associated with prostate cancer has been widely published and is the basis of activity for the ConfirmMDx assay to aid in the detection of occult prostate cancer on previously biopsied, histopathologically negative tissue.[4]

Clinical Studies[1]

ANALYTICAL VALIDATION

A tissue biopsy-based epigenetic multiplex PCR assay for prostate cancer detection, BMC Urology (2012, 12:16) MDxHealth validation study describes the successful development of the ConfirmMDx multiplex DNA methylation test. In the same study the effect of prostate needle core biopsy sample volume and age of formalin-fixed paraffin-embedded (FFPE) samples was evaluated. ConfirmMDx can be applied to small biopsy specimens widening clinical applicability, and the age of the FFPE-samples does not have a negative impact on the performance of the test.[5]

CLINICAL VALIDATION

MATLOC Study. As reported in the *Journal of Urology (Volume 189, Issue 3, 1110-1116, 2013)*, MDxHealth's MATLOC (Methylation Analysis to Locate Occult Cancer) study demonstrated that ConfirmMDx for Prostate Cancer improved on histopathology alone, by accurately identifying two-thirds of the prostate cancer patients missed in the previous biopsy and correctly identifying approximately two-thirds of the men who could forego a repeat biopsy. In this study, ConfirmMDx yielded sensitivity of 68%, specificity of 64%, and a NPV of 90% to confirm the absence of cancer in histopathologically negative biopsy cores. This represents a significant improvement over histopathology alone, which yields a NPV of 65% to 75%.[4-5]

DOCUMENT Study. As reported in the *Journal of Urology (Volume 191, Issue 4, E713 - E714, 2014)*, MDxHealth's DOCUMENT (Detection of Cancer Using Methylated Events in Negative Tissue) study demonstrated that the ConfirmMDx for Prostate Cancer test is the most significant, independent predictor for prostate cancer detection in a repeat biopsy in a cohort of US men. These findings are consistent with and confirm the results from the earlier European MATLOC study. This blinded, multicenter, confirmatory clinical validation study on 350 PSA-screened men, used the same assay cut-offs applied in the MATLOC study and verified test's high negative predictive value. Led by principle investigator Alan Partin, MD, PhD, Professor and Chief of Urology at the James Buchanan Brady Urological Institute at Johns Hopkins School of Medicine.[6]

RISK SCORE VALIDATION STUDIES

Previous diagnostic studies have established the utility of ConfirmMDx as a significant, independent predictor of prostate cancer, with a negative predictive value (NPV) of 90% for all cancers and a NPV of 96% for significant cancers. Recent studies have shown that, in methylation-positive men, DNA-methylation intensities of the three epigenetic markers in ConfirmMDx can help to identify those men harboring clinically significant PCa, resulting in an improved positive predictive value. [7]

Although the ConfirmMDx test was developed to help reduce unnecessary repeat biopsies, by virtue of its high NPV, the test was also shown to be the most significant independent predictor for prostate cancer detection on repeat biopsy as reported in recent clinical validation studies. To further enhance the clinical utility of a positive test result, a risk score for ConfirmMDx methylation-positive men was developed to

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increase the positive predictive value (PPV), especially for those potentially harboring aggressive prostate cancer.

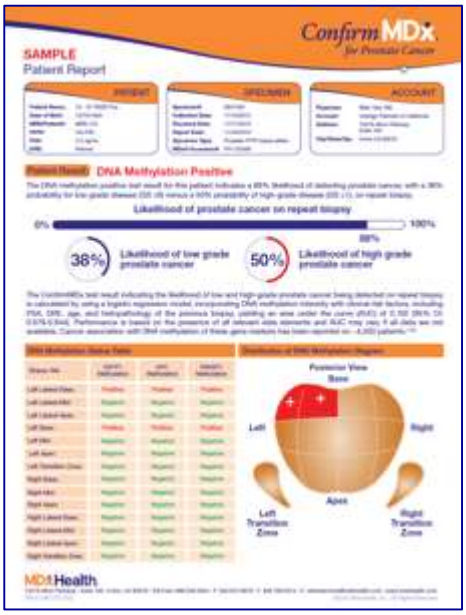
At the 2014 ASCO Genitourinary Cancers Symposium in San Francisco, USA (January 30 - February 1, 2014), MDxHealth presented data demonstrating that epigenetic profiling of selected genes provided prognostic information, corresponding to Gleason score that could help to identify patients with aggressive prostate cancer. The results were reported on a selected panel of genes that MDxHealth had previously identified as exhibiting prognostic value, including the GSTP1, APC and RASSF1 genes from the ConfirmMDx for Prostate Cancer test.

At the 2015 ASCO Genitourinary Cancers Symposium in Orlando, USA (February 26-28, 2015), MDxHealth and our collaborators presented data demonstrating that the intensity of field effect hypermethylation of GSTP1, APC and RASSF1 in benign biopsy cores correlates with the level of hypermethylation present in the cancer cores from the same patient. In Gleason score 6 (GS6) cancer cores, the intensity of hypermethylation is higher in subjects who also have cores of GS7 than in subjects with GS6 cores only. These findings support the feasibility of an algorithm that is sensitive to the aggressiveness of undetected prostate cancer.

In two previously published cohorts, consisting of men with histopathologically negative index biopsies, followed by either a positive (cases) or negative (controls) repeat biopsy, data on DNA-methylation testing results were combined. A methylation intensity (EpiScore) based algorithm was developed in methylation-positive men, using the area under the curve of the receiver operating characteristic as a metric to correlate clinically significant cancer with this EpiScore.

Next, a risk score was developed as a combination of EpiScore with traditional clinical risk factors to further improve the identification of clinically significant cancer. Compared to other risk factors the detection of DNA-methylation in histopathologically negative biopsies was the most significant and important predictor of high-grade (Gleason Score ≥ 7) cancer, resulting in a NPV of 96%. In methylation-positive men, EpiScore was significantly higher for those men with significant cancer detected upon repeat biopsy, compared to those with either no or likely indolent cancer. The risk score resulted in a further improvement of patient risk stratification and was a significantly better predictor compared to currently used metrics such as PSA and the Prostate Cancer Prevention Trial (PCPT) risk calculator (RC). A decision curve analysis indicated strong clinical utility for the risk score when implemented as a decision-making tool for repeat biopsy. These studies demonstrate that ConfirmMDx has significant prognostic value and is able to identify men at increased risk for high-grade, aggressive prostate cancer in both histopathology negative and positive biopsies.

The risk score, based on DNA-methylation intensity and traditional clinical risk factors, improves the identification of men with clinically significant cancer detected upon repeat biopsy, with a maximum avoidance of unnecessary repeat biopsies. This risk score resulted in a better patient risk stratification and significantly outperformed current risk prediction models such as the PCPTRC and PSA. The risk score may help to identify patients with histopathologically negative biopsies harboring significant prostate cancer. (paper submitted to The Prostate 2016)



CLINICAL UTILITY

In a report entitled "Reduced Rate of Repeated Prostate Biopsies Observed in ConfirmMDx Clinical Utility Field Study", AM HEALTH DRUG BENEFITS (Volume 7, Issue 3, 129-34, 2014), Wonjo et al reported on the real-world use of the ConfirmMDx assay, demonstrating that the test impacts physician behavior. A total of 5 clinical urology practices that had ordered a minimum of 40 ConfirmMDx tests for patients with previous, cancer-negative biopsies over the course of 18 months participated in the study. A total of 138 patients who were considered at risk for malignancy based on traditional risk factors, but had ConfirmMDx negative test results, were identified and all were included in the analysis. A very low rate of repeat biopsies (4.4%) was observed in the ConfirmMDx negative men, as compared to the 43% rate of repeat biopsy reported in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, a large population-based randomized trial designed and sponsored by the National Cancer Institute. Repeat biopsies had been performed in 6 of the 138 (4.3%) men with a negative assay result, in whom no evidence of cancer was found on histopathology. These positive clinical utility results, which demonstrated a 10-fold reduction in the rate of repeat biopsy as compared to the reported standard of care, served as the basis for ConfirmMDx's Medicare coverage.[8-9]

In connection with the effectiveness of a positive Local Coverage Decision (LCD) for ConfirmMDx on November 3, 2014 under the MolDX program, we implemented a comprehensive Certification and Training Registry (ConfirmMDx Registry or CTR) as mandated by the LCD. As one of the first companies to obtain a coverage determination (an 'LCD') with MolDX under its Coverage with Data Development (CDD) program, MDxHealth continues to work closely with MolDX, administered by Palmetto GBA, in generating clinical utility evidence for ConfirmMDx. In addition to the ConfirmMDx Registry, which is expected to collect a large pool of valuable clinical utility data potentially covering thousands of Medicare tested patients, MDxHealth has several retrospective and prospective, randomized and non-randomized clinical utility studies underway, including the ongoing PASCUAL study. PASCUAL is a randomized, controlled prospective 600-patient study designed to track the clinical utility of the ConfirmMDx assay in US urologic practices for the management of patients with a previous histopathologically cancer-negative biopsy, but clinical risk factors suggesting the need for a repeat biopsy. The study, initiated in H2 2014, is fully enrolled and is expected to conclude in 2017. With the recent inclusion of ConfirmMDx in the NCCN guidelines, we believe

that the heavily weighted ConfirmMDx Regitstry, in combination with PASCUAL and other clinical utility studies, will add to the entire body of evidence in support of continued Medicare coverage.

HEALTH ECONOMICS

Budget Impact Model: Epigenetic Assay Can Help Avoid Unnecessary Repeated Prostate Biopsies and Reduce Healthcare Spending. American Health Drug and Benefits (Volume 6, Issue 1, 15-24, 2013). In a budget impact model ("BIM") developed to evaluate the effect of the ConfirmMDx assay on healthcare spending, the model demonstrates the potential healthcare savings associated with the reduction of repeat biopsies and complications avoided. The BIM compares a standard of care scenario, based upon up-to-date prostate cancer biopsy statistics, procedures and Medicare fee schedules, to a new scenario wherein the ConfirmMDx assay is employed for decisions on repeat biopsy. With a significant reduction in procedures and healthcare costs in the first year of adoption, the model supports the coverage of the ConfirmMDx assay given the clinical and economic benefits.[9]

In summary, ConfirmMDx for Prostate Cancer is an important diagnostic aid for patient management decisions regarding repeat prostate biopsy on men with histopathologically negative previous biopsy results but considered at risk for occult prostate cancer. The MSP technology and epigenetic biomarkers have been extensively tested and validated in both retrospective and prospectively designed studies. The assay provides ease-of-use as it is designed to test residual prostate core biopsy tissues from the previous negative biopsy, eliminating the need and expense associated with return patient visits for specimen acquisition. The improved clinical performance over histopathology alone provides urologists with actionable information and can aid in the earlier detection of clinically significant cancer while greatly contributing to a reduction of unnecessary, invasive, sometimes harmful and costly repeat biopsies.

OUR SOLUTION TO IMPROVE PATIENT SELECTION FOR INITIAL PROSTATE BIOPSY

Our SelectMDx for Prostate Cancer testing solution addresses the need to improve patient selection for the 2 million men being considered for biopsy each year, helping urologists:

> ***"Rule-out"*** otherwise cancer-free men from undergoing unnecessary initial biopsies and screening procedures, helping to reduce complications, patient anxiety and excessive healthcare expenses associated with these procedures.
>
> ***"Rule-in"*** high-risk men with increased likelihood of high grade prostate cancer, therefore providing actionable results to determine who will benefit most from biopsy.

Our non-invasive urine based SelectMDx for Prostate Cancer test, launched in November 2015 in the Benelux Union region of Europe, identifies men at low risk for prostate cancer, helping to both reduce unnecessary prostate biopsy procedures with their concomitant complications and expense, while also

helping to identify those men at increased risk of harbouring high-grade disease who may benefit most from early detection and treatment.

Of the nearly 2 million prostate biopsies performed each year worldwide, less than a third find cancer. Most of these men could have avoided a painful and invasive prostate biopsy procedure, with its associated side effects and costs. Assuming a 30% test adoption rate, we estimate the potential EU and US market for SelectMDx opportunity to be greater than $1 billion.

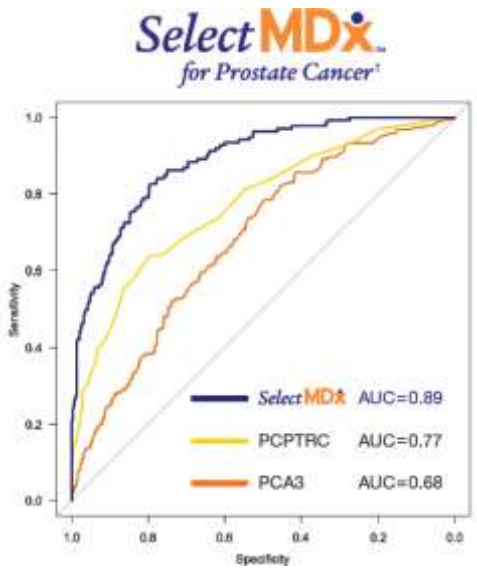
SelectMDx for Prostate Cancer is a urine-based RT qPCR assay, based on 3 mRNA genes (HOXC3, DLX1, KLK3) and was first commercialized in November 2015 as a laboratory testing service in our Nijmegen, Netherlands laboratory. We recently launched SelectMDx in the US as a laboratory developed test through our CLIA certified Irvine, California laboratory. We also plan to offer SelectMDx as a CE marked IVD kit in Europe and other countries outside of the US.

Clinical Validation

A multicenter validation study, published in the European Journal of Urology 2016, demonstrates that SelectMDx for Prostate Cancer is a powerful predictor for the detection of high-grade prostate cancer. The multimodal approach reached an overall AUC of 0.89 (95% confidence interval 0.86-0.92), with the mRNA signature, PSA density, DRE and previous cancer-negative prostate biopsies serving as the most significant components, while PSA, age, and family history also contributed to a lesser degree. The risk score based on the mRNA liquid biopsy assay combined with traditional clinical risk factors identified men at risk of harboring high-grade prostate cancer and resulted in a significantly better patient risk stratification compared to current methods in clinical practice. Therefore, the risk score could reduce the amount of unnecessary prostate biopsies. [10]

SelectMDx results in the multicenter validation study exhibited superior performance compared to existing urine-based tests, in particular, the PSA and PCA3 assays.

ROC Curve for Clinically Significant Cancer



BUSINESS STRATEGY

We are dedicated to providing novel, clinically actionable and timely information to improve the assessment and care of cancer patients. Key elements of our strategy include:

- **Increasing utilization of our lead product, ConfirmMDx for Prostate Cancer, in the US.** We are pursuing broad-based adoption of ConfirmMDx for Prostate Cancer, encouraging its clinically appropriate use in prostate biopsy recipients with inconclusive results with the objective of improving management and outcomes. Since the launch of ConfirmMDx in June 2012, over 2,600 urologists have ordered the test and more than 40,000 patents have been tested. To increase utilization of ConfirmMDx, we plan to build upon our marketing and medical education programs and leverage our sales and marketing team that interacts directly with clinicians, nurses, laboratory partners and pathology personnel.

- **Expanding our product and service offerings in urologic oncology.** We have launched our non-invasive urine based SelectMDx for Prostate Cancer test as a laboratory service in the US and in the Benelux Union region of Europe. SelectMDx identifies men at low risk for prostate cancer, helping to both reduce unnecessary prostate biopsy procedures with their concomitant complications and expense, while also helping to identify those men at increased risk of harbouring high-grade disease who may benefit most from early detection and treatment. Later this year, we expect to expand the commercialization of the SelectMDx test by offering it as a CE marked in vitro diagnostic kit in Europe and in other countries internationally. In addition, we believe there is a meaningful market opportunity internationally for our ConfirmMDx test and have recently begun our international expansion. We have signed a distribution arrangement for our ConfirmMDx test with Teva Pharmaceuticals in Israel and South Genetics in South America. We intend to continue investigating partnerships for our offerings in other regions. We also intend to expand our service

offerings with the planned launch of our non-invasive, urine-based AssureMDx for Bladder Cancer test in the US in H2 of 2016.

- **Securing favorable reimbursement for ConfirmMDx and our other solutions.** Securing a favorable Local Coverage Decision (LCD) and a favorable reimbursement rate from Palmetto GBA, administrator of the MolDX technology assessment program for the Centers for Medicare & Medicaid Services (CMS), for our ConfirmMDx for Prostate Cancer test was a major milestone towards achieving material commercial success. The LCD, when combined with existing Preferred Provider Organization (PPO) and network contracts, expands access for ConfirmMDx to approximately 214 million covered lives in the US. Importantly, with approximately half of our patient population over the age of 65, the LCD establishes a significant foundation for broad reimbursement. The LCD not only sets the reimbursement price for Medicare patients, but also establishes reimbursement for Medicare Advantage patients covered by private commercial payors. Medicare Advantage is a program whereby patients aged 65 years or older may elect enhanced coverage through a private payor contracted with Medicare to provide expanded benefits. By virtue of the CMS policies, payors contracted to offer Medicare Advantage programs are legally obligated to honor the LCD. MDxHealth will also pursue direct contracts with these payors to cover ConfirmMDx testing for their patient population under the age of 65 years old. Furthermore, we believe the clinical utility and actionability of our ConfirmMDx test, combined with our experience and knowledge of the factors needed to gain reimbursement, will enable us to expand coverage of ConfirmMDx among the private payor market. We will continue to build on our successful strategy, using our Medicare LCD and existing Preferred Provider PPO contracts as a foundation to secure additional contracts from major national and regional managed care organizations, insurance carriers, and self-insured employer groups.

- **Expanding the clinical utility and actionability of our current and future solutions.** A key driver for the adoption of our current and future testing solutions is our ability to substantiate clinical utility and actionability through clinical trials and peer-reviewed publications. Completed and ongoing trials have been designed to evaluate the further clinical utility and actionability of ConfirmMDx, SelectMDx, and other solutions in development, and are an integral part of our business strategy and marketing programs.

We will continue to invest in clinical trials to expand the utility and rate of adoption of our current and future solutions. Many of the investigators in our sponsored trials are well-recognized key opinion leaders in the field and contribute to the education of their peers by way of publications, presentations of their clinical knowledge and experience with developing molecular diagnostic testing solutions.

RESEARCH AND DEVELOPMENT

MDxHealth is a front-runner in epigenetic research with a proven track record to identify, develop, validate and deliver molecular diagnostic assays. Leveraging our patented methylation specific PCR technology (MSP) and proprietary portfolio of genes, we have built a robust portfolio of biomarkers for diagnostic, prognostic and predictive molecular assays for prostate, colorectal, lung, bladder and brain cancers, among many others. In addition, MDxHealth has numerous proprietary (RNA and DNA) biomarkers for other urological cancer types ready for development.

We endeavor to stay at the cutting edge of epigenetic solutions in the molecular diagnostics arena by continuously exploring and developing new and improved clinically relevant products, approaches and techniques. Since 2010, when we first announced the transition in our business model from a research and licensing company to a commercial clinical diagnostic company, we have been selective with our R&D efforts with the goal to narrow our focus on select number of core development projects to bring to the urology market. With our current focus on urologic cancers, we have either delayed, partnered or frozen many of our developemt programs previously identified in our product pipeline. Our ongoing core research and development efforts include:

- further enhancement of our ConfirmMDx and SelectMDx for Prostate Cancer tests
- new product development in other urologic cancers, such as AssureMDx for Bladder Cancer and kidney
- discovery and development of new (epi)genetic biomarkers
- technology platform development to increase throughput and economic efficiencies in our testing and laboratory operations
- our research and development efforts are not limited to specific technology platforms, biomarkers or methodologies. We seek to leverage current and future innovations in biomarker identification and measurement in developing future solutions. Over the past decade, MDxHealth has assembled a world-class scientific team and acquired unique experience in the application of *Next-Generation* and *Deep Sequencing* technologies for the identification and validation of powerful RNA and DNA biomarkers.

Development of AssureMDx for Bladder Cancer Test

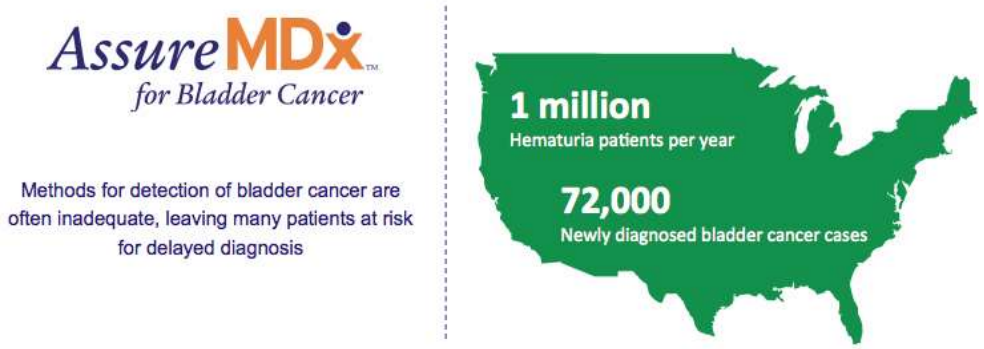
Consistent with our focus in the urology market, MDxHealth is accelerating the development of our AssureMDx for Bladder Cancer test. The test is a non-invasive, urine-based DNA methylation test designed to help rule out the presence of bladder cancer, sparing many patients unnecessary invasive and potentially harmful procedures, while aiding in the identification of high-risk patients requiring further examination.

The analytical validation study for AssureMDx for Bladder Cancer test was published in *The Journal of Urology* 2016. AssureMDx analyses DNA methylation of three genes (TWIST1, ONECUT2 and OTX1) in combination with mutation analyses of three others, was used to create an epigenetic profile of 154 urine

samples from haematuria patients without (n=80) and with (n=74) bladder cancer. The study demonstrated the test's high negative predictive value (99.2%) for the detection of bladder cancer in this cohort of haematuria patients.

Additionally, in the future we intend to validate our AssureMDx test to address the need for improved monitoring of diagnosed bladder cancer patients. More than 60% of early stage bladder cancer patients will have a recurrence following treatment and it is estimated that more than 500,000 Americans are currently under surveillance for recurrent bladder cancer, representing a total market potential of over $200 million.[11-12]

Background - Bladder cancer is the fourth most common cancer in men and the eight most common cancer in women. Over 170,000 cases are diagnosed every year in the US and EU, with over 50,000 deaths. Worldwide, the incidence of bladder cancer varies substantially, with over 400,000 cases each year, and the highest rates in Europe and North America and in areas (e.g. North Africa) endemic with the parasite Schistoma heamatobium. Annually in the US, we consider that there are approximately 7 million patients diagnosed with hematuria and 15,000 deaths[13]



More than 90% of bladder cancer patients in the EU and US have urothelial cell carcinoma (UCC), derived from the urothelium or lining of the bladder, most of whom initially present with superficial disease. These UCC's have a high chance of recurrence (60-80%), requiring extensive and long-term monitoring for progression to more invasive disease. There are an estimated 1 million individuals in the US and EU living with a diagnosis or history of bladder cancer that require this life-long surveillance.[12-13]

Hematuria is the most common sign of bladder cancer, with 90% of bladder cancer patients presenting with macro or micro hematuria, however only 15-35% of patients with hematuria are diagnosed with bladder cancer. In the US, over 7 million people are diagnosed with hematuria each year. Under today's standard of care, diagnosis and surveillance of bladder cancer consists of cystoscopy and cytology. A urine sample is obtained for cytopathology review to identify the cause of hematuria and to rule out bladder cancer. While cytopathology yields a high specificity of more than 90%, its sensitivity, at approximately 50%, is quite weak, leaving many patients without a definitive diagnosis and at risk for low-grade bladder tumors. When the cause of hematuria remains unclear, patients are referred to a urologist for further evaluation, leading to about 1 million patient referrals each year. Cytopathologic review is often repeated, and if equivocal, a cystoscopy procedure will be performed.21 AssureMDx market opportunity within the US urology marketplace alone, and at an estimated $350 per test, could initially represent a $500 million potential market opportunity.

Kidney and other Urologic Cancers

MDxHealth will continue to focus in urological oncology, and we intend to develop and validate tests for kidney cancer, also known as renal cell carcinoma. Early stage development work is underway with academic collaborators in the areas of diagnosis and prediction of response to therapy.

Biomarker Discovery and Development

With over a decade of cutting-edge epigenetics research and development experience, both internally and with a diverse range of academic and commercial collaborators, MDxHealth has amassed a proprietary portfolio of hundreds of epigenetic biomarkers and related expertise.

- **Non-core Cancers.** For cancer outside of our core urologic focus, we have sought to partner or out-license the commercialization of valuable biomarkers and technologies. The following represent certain of the key cancer types that MDxHealth has addressed:

  - *Colon:* In 2010, MDxHealth entered into an exclusive licensing 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 MDxHealth's NDRG biomarker in stool-based detection of colorectal cancer, as well as non-exclusive access to MDxHealth's MSP platform technology for use with those biomarkers. Exact Sciences has obtained FDA approval and CMS coverage, and launched its Cologuard® test in H2 2014.

  - *Brain:* MDxHealth holds exclusive rights to the MGMT biomarker, which has been extensively studied in glioblastoma and related brain cancers. Studies on thousands of clinical trial patients have demonstrated that methylation of MGMT can help oncologists identify newly diagnosed glioblastoma patients that are likely to respond to the most commonly used class of brain cancer drugs (alkylating agents). MDxHealth's PredictMDx for Glioblastoma (MGMT) test was included in the 2013 National Comprehensive Cancer Network (NCCN) Senior Adult Oncology Guidelines and has been awarded a Tier 1 reimbursement code, 81287, by American Medical Association (AMA), which provides a clear basis for comprehensive reimbursement. MDxHealth's strategy has been to partner with leading pathology service providers, such as the Laboratory Corporation of America (LabCorp) in the US, Teva Pharmaceutical Industries in Israel, and HistoGeneX in Belgium, to distribute the MGMT test to clinicians.

  - *Cervical:* In 2014, MDxHealth granted oncgnostics GmbH of Jena, Germany, a limited, non-transferable, non-exclusive, worldwide license for its patented methylation specific PCR (MSP) technology for diagnostic applications in cervical cancer. In return, MDxHealth will receive upfront and milestone payments, and royalties on net sales. oncgnostics will utilize MDxHealth's epigenetic technology for the accurate and sensitive assessment of DNA methylation markers included in its GynTect® test, which is intended for the early detection of cervical neoplasias that may progress to cancer.

- **Nextgen Sequencing.** MDxHealth, in collaboration with University of Gent in Belgium, has established the NXTGNT (Epi)genomics research joint-venture, which brings together researchers

with expertise in genomic and methylome sequencing and bioinformatics. The Laboratory for Bio-informatics and Computational Genomics (BIOBIX, FBW), the laboratory for Pharmaceutical Biotechnology (FFW), the IOF consortium *Biomarked*, together with a research team from MDxHealth are located within the Faculty of Pharmaceutical Sciences at University of Gent in Belgium. NXTGNT's core focus is the application of innovative technologies such as *NextGen* and *Deep Targeted Sequencing* for the discovery of novel biomarkers which improve the diagnosis and risk stratification of cancer patients, as well as the identification of potential targets for therapy. The mission is to accelerate the development and preclinical validation of new diagnostic and therapeutic products for personalized medicine.

- **EpiHealth.** Utilizing our experience in the development of methylation-specific deep sequencing technology, MDxHealth offers a discovery product to researchers and to pharmaceutical companies called EpiHealth. EpiHealth is a panel of hundreds of defined genes whose expression is controlled by DNA methylation. This concise panel allows collaborators to test xenografts, cell lines and primary material, and to focus on known published genes thereby decreasing the overall project development time. Knowledge gained from the profiles of the primary material allow for rapid downstream development of MSP assays for clinical application.

LABORATORY OPERATIONS

In 2015, MDxHealth received over 190,000 prostate biopsy samples, over 36% more biopsy samples than 2014. To support the volume increase, the Company has invested in robotic systems for certain specimen handling steps. All received samples are handled according to a defined process regulated under CLIA. For each step, standard operating procedures are in place. MDxHealth's laboratory process consists of the following steps:

- Distribution of collection kits
- Accessioning
- Processing
- Testing
- Reporting
- Client service

Collection kits are requested through Client Services, which we distribute nationwide using a third party vendor. Via overnight couriers, specimens are received by our laboratory in an MDxHealth specimen collection box, which include test requisition forms and appropriate specimen packaging. These specimens must be collected according to standards established by the Clinical and Laboratory Standards Institute (CLSI) and submitted by physicians and pathology labs.

The diagnostic workflow is separated into three main categories: pre-analytical, analytical and post-analytical. Specimen Accessioning begins the pre-analytical process where specimens are received, sorted, entered into the Laboratory Information System, labeled with unique barcoded identifiers and processed into the laboratory.

Processing a specimen may include collecting the tissue from a paraffin block or scraping the tissue from a glass slide. All patient biopsies are individually processed. Once the processing step has been completed, the specimens are forwarded on to the molecular testing section for testing.

Molecular testing begins the analytical phase, which involves removing the wax paraffin from the tissue, extracting the DNA, conducting a chemical conversion, purifying the DNA and performing methylation. Throughout the analytical process, quality controls are established to ensure accuracy and integrity of the specimens. All testing is executed on validated and calibrated instruments. Once molecular testing has been completed, licensed clinical laboratory scientists analyze the data using validated software programs.

Once patient results are made available, the post-analytical step concludes with reporting and the distribution of patient reports to the client. Reports are distributed by Client Services via facsimile, encrypted email, FedEx or secure web portal. Client Services bridges the communication with our sales force, our clients and the laboratory.

REIMBURSEMENT

ConfirmMDx testing revenues are derived from several different sources dependent on the billing and contractual arrangements, and applicable laws. Parties that reimburse for ConfirmMDx testing services include:

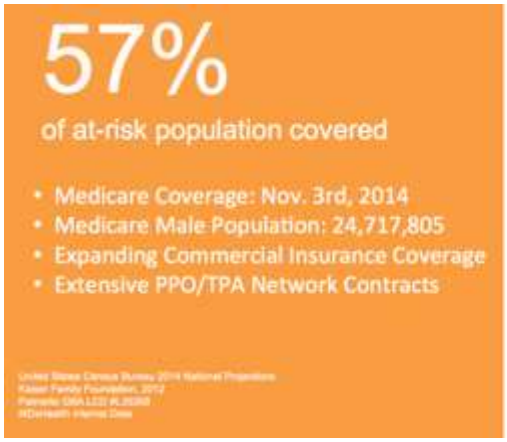
- third-party payors that provide coverage to the patient, such as insurance companies and managed care organizations; or
- government entitlement programs, such as Medicare, Medicaid, the Department of Defense, and the Veterans Affairs hospitals in the US; and other government agencies and laboratories, that order the testing service; and
- patients, to the extent responsible for a co-payment, co-insurance and / or deductible amount, and in cases where the patient has no insurance or coverage benefit, is underinsured or has insurance with cost sharing benefits whereby the insurance covers a percentage of testing costs.

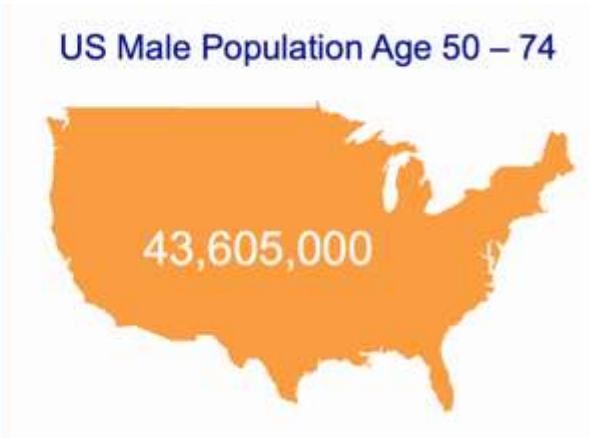
Where there is a private or governmental third-party payor coverage policy in place, MDxHealth bills the payor and/or the patient in accordance with the established policy, contractual terms and the law. For tests performed outside the scope of the payor's policy, and for tests performed where the payor has not adopted a coverage policy, MDxHealth pursues reimbursement on a case-by-case basis. If a reimbursement claim is denied, we generally pursue the appeals process for the particular payor.

Payors and Reimbursement

For the year ended December 31, 2015, we derived approximately 94.7% of our ConfirmMDx revenue from insurance companies, including managed care organizations and other health care insurance providers, and 5.3% from direct-bill patients. Where there is a coverage policy, contract or agreement in place, we bill the third-party payor, as well as the patient (for deductibles and coinsurance or copayments) in accordance with the policy or contractual terms. Where there is no coverage policy, contract or agreement in place, we pursue reimbursement on behalf of each patient on a case-by-case basis, based upon the explanation of benefits (EOB) and applicable billing standards.

In 2014, Palmetto GBA issued a Local Coverage Determination (LCD) for Medicare reimbursement of our ConfirmMDx for Prostate Cancer test under its Molecular Diagnostics (MolDX) program. Additionally, we continued to expand contracts with many of the largest preferred provider organizations (PPO) in the US, bringing the current total to 27 commercial managed care agreements. In aggregate, these managed care networks, combined with Medicare, represent approximately 214 million covered lives who now have access to the ConfirmMDx test.





COMMERCIAL AND PRIVATE PAYORS

MDxHealth's managed care team continues to pursue adoption of positive coverage policies and contracts by other commercial and private payors, preferred provider organizations and networks. We believe the clinical utility and actionability of our ConfirmMDx test, combined with our experience and knowledge of the factors needed to gain reimbursement, will enable us to expand coverage of ConfirmMDx among the private payor market. We continue to build upon our successful strategy, using our Medicare LCD, the recent inclusion of ConfirmMDx in the US National Comprehensive Cancer Network (NCCN) Guidelines for prostate cancer, and existing Preferred Provider PPO contracts as a foundation to secure additional contracts from major national and regional managed care organizations, insurance carriers, and self-insured employer groups. Several key factors will facilitate positive coverage policies from third-party private payors:

- additional clinical utility studies and peer-reviewed publications demonstrating the impact of ConfirmMDx test results on physician decisions for patient management and outcomes inclusion of ConfirmMDx in the American Urological Association (AUA), American Cancer Society (ACS), and other institutional guidelines
- widespread adoption of ConfirmMDx in routine clinic urology practice demonstrating utilization
- support of key opinion leading urologists within the academic and private physician communities
- patient advocacy organizations (e.g. PCEC), policy representatives, and industry coalitions.

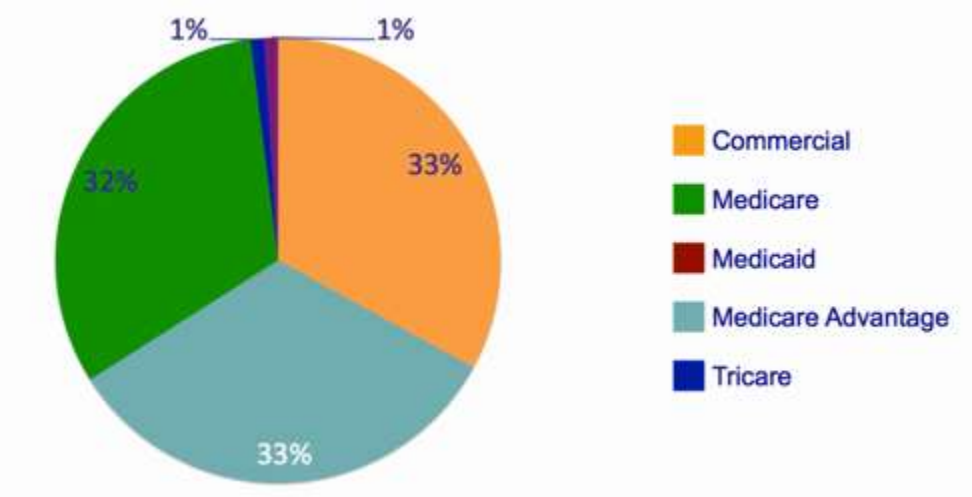
GOVERNMENTAL PAYORS

In 2014, a Medicare coverage determination (LCD) was issued by Palmetto GBA, administrator of the MolDX technology assessment program for the Centers for Medicare & Medicaid Services (CMS), for our ConfirmMDx for Prostate Cancer test. The LCD #L35368 became effective on November 3, 2014 and establishes ConfirmMDx for Prostate Cancer as "reasonable and necessary" under Section 1862(a)(1)(A) of the US Social Security Act. As part of an ongoing commitment to ensure that Medicare covers the appropriate use of the ConfirmMDx test, the LCD was issued under coverage with data development (CDD) requirements, stipulating that MDxHealth enroll providers into a Certification and Training Registry for ConfirmMDx . Under the LCD, coverage is initially limited to patients of physicians enrolled in the ConfirmMDx Registry. As one of the first companies to obtain a coverage determination with MolDX under its CDD program, MDxHealth continues to work closely with MolDX, administered by Palmetto GBA, in generating clinical utility evidence for ConfirmMDx. Based on input from Palmetto GBA, we have recently expanded the scope of the ConfirmMDx Registry to gather additional and more detailed clinical utility data in support of continued Medicare coverage. In addition to our expanded ConfirmMDx Registry, which is expected to collect a large pool of valuable clinical utility data potentially covering thousands of tested patients, MDxHealth has several retrospective and prospective, randomized and non-randomized clinical utility studies underway, including the on going PASCUAL study expected to conclude in 2017. The heavily weighted CTR and combination of clinical utility studies, and recent inclusion in the NCCN guidelines, are expected to add to the entire body of evidence in support of continued Medicare coverage.

With the issuance of the LCD, ConfirmMDx has an established price for government agencies and MDxHealth can pursue state-run Medicaid programs as well as US military providers for contracts. MDxHealth intends to pursue such contracts for Medicaid starting with Medi-Cal in California. Medi-Cal is California's Medicaid program and serves over 6 million residents. Medicaid is a medical assistance program established by Title XIX of the Social Security Act. The Medicaid program is a no-cost or low-cost public health insurance program that provides needed health care services for low-income and disabled individuals. Over the next few years, the Medi-Cal program is expected to expand further under the Affordable Care Act as those newly eligible for Medi-Cal are enrolled in managed care and as plans assume responsibility for additional covered services. With peer-reviewed health economic data demonstrating savings to payors covering ConfirmMDx, MDxHealth believes the California Department of Health Care Services (DHCS) leadership, and the public, will be receptive to contracting for the test. Once Medi-Cal coverge is established, MDxHealth intends to pursue Medicaid coverage in other US states, prioritizing each state program in order of ConfirmMDx utilization.

Beyond Medicaid programs, the military healthcare system, including the Veterans Affairs hospitals, military hospitals and Tricare healthcare providers, represent a significant opportunity for MDxHealth. These groups are estimated to be in excess of 20 million covered lives, with approximately 90% of beneficiaries being adult males. Likewise, the improved patient outcomes and health economic savings

delivered through utilization of the ConfirmMDx for Prostate Cancer test are expected to facilitate contracting discussions.



PATIENTS

MDxHealth bills payors directly for ConfirmMDx testing services or as suggested by the ordering physician. In many cases, payors will cover the entire cost of testing. The ConfirmMDx test falls under the Clinical Laboratory Fee Schedule, so there is no co-payment, co-insurance or deductible for patients covered under traditional Medicare. Patients covered by commercial insurance companies may be responsible for a co-payment, co-insurance, and/or deductible depending on the health insurance plan and individual patient benefit. The amount, if any, will depend on the specific level of benefits provided by the insurance plan the patient has chosen. MDxHealth understands that the costs associated with the diagnosis, treatment and management of prostate cancer can impose a financial hardship that may affect a patient's decisions on selecting testing and treatment options. Regardless of a patient's insurance coverage or financial status, MDxHealth's staff will assist the patient to obtain the testing needed. MDxHealth works closely with patients and healthcare providers on the timely and accurate filing of insurance claims and as needed, any appeals to mitigate out-of-pocket expense for the patient. MDxHealth offers a variety of financial assistance programs with options based on individual financial status. Some programs have certain eligibility requirements, so MDxHealth representatives assist in determining the right program for each patient.

In 2015, MDxHealth invested in managed care sales and marketing to ensure optimal coverage and reimbursement for ConfirmMDx testing. MDxHealth will continue to educate payors on the test's clinical value and its potential to reduce the overall cost of care. The key value proposition for payors will be focused on improved patient outcomes while delivering cost savings by reducing unnecessary, invasive and expensive biopsy procedures. We will leverage our managed care experience and base of contracted payors to obtain coverage for our future epigenetic test solutions in other cancers.

Billing

Billing for ConfirmMDx testing services is managed internally through our billing operations team utilizing specialized billing software for clinical laboratories and other healthcare organizations. Our billing department works closely with our third-party providers to ensure accuracy of billings, pursue timely collections, and to resolve discrepancies and process appeals as needed. Depending on our billing

arrangement with each third-party payor and applicable law, we are obligated to bill in the specific manner prescribed by physicians and various payors, such as private insurance companies, managed care companies, and governmental payors such as Medicare and Medicaid, and physicians, each of which may have different billing requirements. Often we are paid by these third-party payors at rates that are based on the applicable fee schedule associated with the patient's insurance plan.

Key factors to successful revenue cycle management include:

- understanding the coverage and information requirements among various payors;
- proactively capturing missing, incomplete or inaccurate billing information provided by ordering physicians;
- managing claims directed to out-of-network payors with whom we do not have contracts;
- negotiating with payors as to the appropriate level of reimbursement; and
- collection of patient receivables from copays, coinsurance or deductibles.

MDxHealth focuses on carefully preparing claim submissions to minimize missing or incorrect information to facilitate billing and claims processing, and our internal billing and collections department consistently appeals unpaid claims to mitigate patient out-of-pocket expenses.

We have established policies and audit requirements to ensure compliance with applicable laws and regulations as well as our internal compliance policies and procedures. Billing for ConfirmMDx testing services in connection with governmental payor programs is subject to numerous federal and state regulations and other requirements, including those related to: (1) adherence to procedures and processes required by governmental payor programs; (2) training and education of our employees and customers; (3) compliance and legal costs; and (4) managing medical necessity denials in the absence of advance beneficiary notices.

Both California law and CLIA requirements dictate that laboratory testing be performed only at the request of authorized persons, and the Medicare program's position is that laboratories are responsible for having sufficient processes and safeguards in place to ensure services are delivered only when ordered by a physician and for producing in an audit valid orders for all testing that they perform (*e.g.*, a requisition signed by a physician). Accordingly, while we do not believe that laboratories are strictly required to obtain physician signatures on test requisitions as a matter of law, it is a best practice for laboratories to take all reasonable steps to obtain physician signatures on their test requisitions, at least in connection with testing that is billed to the Medicare program. If not, a laboratory may be subject to the possibility of payment denials or recoupment actions if its Medicare contractor asks for documentation of a valid order and it is then unable to work with the ordering physicians to produce satisfactory documentation of orders from the medical records of the physicians.

SALES

MDxHealth's sales approach in the US focuses on the clinical and economic benefits of our ConfirmMDx for Prostate Cancer test as supported by extensive peer-reviewed literature covering the clinical validation and utility of our test. As of December 31, 2015, our sales and marketing team consisted of more than 50 employees, including molecular diagnostic specialists, reimbursement account managers, medical science liaisons and customer service personnel. All personnel are field based except for customer service, which are based in our California headquarters.

BUSINESS

MDxHealth's sales team is trained to address the clinical, economic and reimbursement questions associated with selling the ConfirmMDx for Prostate Cancer test. Our sales force focuses on educating its primary and secondary clientele, which consists of urologists and their clinical staff, including nurses, laboratory and pathology personnel, finance administrators and billing personnel, and secondarily the pathology and laboratory staff who fulfill ConfirmMDx test requests on behalf of their clinician clients.

MDxHealth's current US urology sales force consists of 33 direct sales representatives, 3 regional sales managers and the director of sales. Territories have been designed to strategically cover key geographic areas that have the highest concentrations of prostate cancer patients. We have recruited sales professionals with an average of 5-10 years of successful experience in clinical oncology, diagnostic testing, pharmaceutical and medical device sales from leading biopharmaceutical, pharmaceutical or specialty reference laboratory companies. MDxHealth plans to expand this specialized, uro-oncology-focused sales force to 40-50 direct representatives within two years, and to 60-80 direct representatives within five years.

Our sales efforts are directed towards increasing adoption and utilization of the ConfirmMDx for Prostate Cancer test in clinical practice. The strategy entails:

- working with community-based, large group practices and academic urologists to educate them on the clinical and economic benefits provided by ConfirmMDx;
- nurturing and strengthening relationships with key thought leaders in urology;
- supporting ongoing collaborations with leading universities and research institutions that have generated clinical validation data supporting ConfirmMDx;
- encouraging ongoing exploration and studies of expanded indications for the test; and
- continuing ongoing clinical utility studies with key collaborators and clients to demonstrate the impact of ConfirmMDx on physician decisions and patient management for the payor community.

MDxHealth's sales strategy for SelectMDx for Prostate Cancer in Europe consists of direct sales representatives in Benelux, Germany and Italy supported by European and global distributors and commercial lab partners. In the Netherlands and the Benelux Union region, the Company recently launched the SelectMDx test as a service product for hospitals, commercial labs and private clinics. The test is being performed in MDxHealth's state-of-the-art laboratory facility in Nijmegen, the Netherlands. In 2016, MDxHealth plans to launch the SelectMDx for Prostate Cancer test as a CE-marked in vitro diagnostic kit more broadly in Europe.

We also take advantage of customary marketing channels commonly used by the diagnostic and pharmaceutical industries, such as medical meetings, broad-based publication of our scientific and clinical

data, and the Internet. In addition, we provide easy-to-access information to our customers through our website and a data portal for physicians who wish to access test results electronically. Our customers value easily accessible information in order to quickly review their patients' information and begin developing a treatment protocol.

MARKETING

Successful penetration of the urology market and clinical adoption of ConfirmMDx has been achieved with a multi-faceted marketing approach to build brand recognition and raise awareness of the ConfirmMDx for Prostate Cancer test. Strategic drivers for success include :

Prostate Cancer Key Opinion Leader Support and Guidance

In any setting, industry leader support is a critical component to building brand recognition and gaining broad market adoption. Leveraging Key Opinion Leaders (KOLs) on a national and regional scale drives market awareness and lends credibility to the products utilized. As an organization, MDxHealth has forged relationships with the leading medical and scientific opinion leaders in urology. This was not quickly accomplished; as many KOLs work in the academic setting consider their largest asset to be their reputation, so most individuals are careful in selecting their associations with commercial enterprises. Gaining the support of KOLs was accomplished through building relationships, collaborating on studies and demonstrating the efficacy of our tests.

These thought leaders have provided valuable insights into the US urology marketplace and guidance on optimizing efforts for maximum impact and gained a better understand on their perspectives:

- opportunities and barriers to success in US market
- product differentiation and information requirements to maximize adoption and utilization
- effective methods to raise awareness and accelerate acceptance

Scientific Publications/Journal Articles

A major component to maximizing US marketplace acceptance has been supporting clinical studies for publication peer reviewed journals and abstracts at key scientific conferences. Such studies have further validated the science behind ConfirmMDx and highlighted the clinical impact on patient management and outcomes. This has been critical in demonstrating the clinical utility ConfirmMDx offers clinicians and their patients. Furthermore, such studies are a prerequisite for inclusion in the industry guidelines for patient management, as well as for obtaining Medicare and third-party payor coverage and reimbursement. To date MDxHealth and our collaborators have generated over 45 peer-reviewed publications covering the ConfirmMDx genes and assay performance characteristics.

Patient Advocacy

MDxHealth has been active with patient advocacy supporting an organization called Prostate Conditions Education Council (PCEC). PCEC serves as a source of unbiased information for prostate cancer patients

and their caregivers, advocates on behalf of patient needs and importantly provides patient awareness and free testing services for countless men across the US.

Objectives of these outreach efforts have included: 1) distribution of educational materials and networking among affiliates and members; 2) dissemination of ConfirmMDx test information on organizational websites; 3) direct educational programs by thought leaders at urological conferences nationwide; and 4) advocacy surrounding patient issues.

Strategic Marketing Partnerships

MDxHealth developed and leveraged strategic partnerships with leading pathology laboratories with large urology client bases to improve ConfirmMDx brand awareness, facilitate account access and accelerate assay adoption. The partnerships, and their sales teams, continue to serve as force-multipliers and contribute to nationwide promotion of the ConfirmMDx for Prostate Cancer test.

Marketing Collateral

MDxHealth has invested significant resources to build brand awareness and acceptance in the US urology marketplace through the development of marketing materials that clearly convey the value proposition that ConfirmMDx brings to clinicians and their patients. These marketing materials have been widely distributed through field sales efforts, strategic partners, advocacy groups and at industry conferences and company sponsored meetings.

Industry Conferences & Trade Shows

National and regional industry meetings have provided clinicians the opportunity to keep abreast of new data on ConfirmMDx that has been generated by MDxHealth and our collaborators. MDxHealth's participation in numerous strategic trade shows each year has also contributed to increased brand awareness.

Some of the major industry meetings MDxHealth routinely attends include:

- American Urological Association
- American Society of Clinical Oncology Genitourinary Meeting
- College of American Pathology
- Society of Urologic Oncology

Public Relations – Media Outreach

MDxHealth has made a concerted effort to drive awareness for ConfirmMDx through our public relations and media outreach, with frequent press releases and our efforts to secure media coverage at the national and local level. These efforts aid in raising patient awareness and driving clinical demand, while also providing valuable updates to the investor community.

Advertising

MDxHealth advertising goals have been two-fold: first, to raise awareness of the ConfirmMDx assay and, secon, to build brand recognition of MDxHealth with physicians who will utilize our tests. A series of strategic advertising campaigns have been placed in key industry trade, medical and scientific journals to educate urologists and pathologists treating prostate cancer patients. The ads have provided product information, including key positioning statements on clinical utility, references to clinical trial validation studies and methods to obtain testing for their patients.

COMPETITION

The molecular testing fields are intensely competitive both in terms of service and price, and continue to undergo significant consolidation, permitting larger clinical laboratory service providers to increase cost efficiencies and service levels, resulting in more intense competition. Some of our existing competitors and many potential competitors have substantially greater financial, selling, logistical and laboratory resources, more experience in dealing with third-party payors, and greater market penetration, purchasing power and marketing budgets, as well as more experience in providing diagnostic services.

As a specialized CLIA service lab, we provide reliable and accurate diagnostic services to our healthcare providers and physicians. We compete primarily based on the breadth, depth, speed and quality of testing, reporting and information systems, reliability in patient sample transport, ease-of-use and speed of our service, reputation in the medical community and new technologies and tests as they become available.

Several companies and institutions are developing blood based tests detecting proteins, nucleic acids or the presence of fragments of mutated genes that are associated with prostate cancer. For our ConfirmMDx for Prostate Cancer test, MDxHealth is aware of the presence of three 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. The PCA-3 test from Hologic, a urine-based test, is on the US market as an FDA approved test, which may provide a competitive advantage since the ConfirmMDx for Prostate Cancer test is not FDA approved. In 2013, OPKO, a NYSE listed company, launched the 4Kscore test, a blood based 4-plex test, which combines the results of the blood test with clinical information in an algorithm that calculates a patient's percent risk for aggressive prostate cancer prior to a biopsy. We expect additional competition and these competitors could have technological, financial, reputational and market access advantages over us.

COMMERCIAL COLLABORATORS

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. With the launch of licensee Exact Sciences' FDA-approved Cologuard test, MDxHealth expects to recognize a milestone fee and deferred license fees in excess of $0.5 million in the near term,

and is eligible to receive minimum annual maintenance fees of $100,000 per year, sales milestones of $300,000 after Cologuard attains net sales of $10 million, $750,000 after Cologuard attains net sales of $50 million, and $1 million after Cologuard attains net sales of $50 million in a single calendar year, as well as running royalties in the mid-single digit range. The license agreement is expected to remain in effect until the last of the licensed patents expires in 2028.

Exact Sciences completed the development of their Cologuard® test, which provides a more accurate, noninvasive 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. In August 2014, Exact Sciences received simultaneous US Food and Drug Administration (FDA) approval and a positive National Coverage Determination for Medicare coverage of their Cologuard test. Exact Sciences reported the completion of approximately 38,000 Cologuard tests during Q4 2015. As per the licensing agreement, Exact Sciences has commenced making certain milestone and royalty payments to us associated with net revenues on its Cologuard test.

Miraca Life Sciences (formerly PLUS Diagnostics)

MDxHealth continues to partner with Miraca Life Sciences on the promotion of ConfirmMDx for Prostate Cancer in the United States. Miraca Life Sciences, a leading US 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 ConfirmMDx for Prostate Cancer through its national network of urologists.

Bostwick Laboratories

MDxHealth maintains a strong partnership with Bostwick Laboratories to co-promote ConfirmMDx for Prostate Cancer in the United States. Bostwick Laboratories is a leading national, full-service laboratory specializing in anatomic and clinical pathology, with a focus on uropathology. Bostwick continues to help build awareness and provide access for ConfirmMDx within the urology community. Bostwick views MDxHealth's epigenetic test as providing additional clinical utility for their urology clients and patients.

LI PATH

MDxHealth partners with LI PATH an anatomical laboratory to co-promote ConfirmMDx for Prostate Cancer in the United States. LI PATH is a premier diagnostic and consultative company, located in East Setauket, New York, that has been serving the regional community for nearly 20 years. The Company is dedicated to provide top-level diagnostic pathology and clinical services in a cost effective and efficient manner.

Teva Pharmaceuticals Ltd

In January 2014, MDxHealth signed a partnership with Teva Pharmaceuticals Industries Ltd., a leading global pharmaceutical company, for commercialization of ConfirmMDx for Prostate Cancer and PredictMDx® for Glioblastoma tests in Israel. Teva Pharmaceuticals Industries is the exclusive distributor of both tests in Israel. Samples are sent to MDxHealth's CLIA-registered laboratory in Irvine, California for testing. Teva reimburses MDxHealth for all the testing services.

Summit Pharmaceutical Ltd. (a subsidiary of Sumitomo Corporation)

In July 2013, MDxHealth entered into a partnership with Summit Pharmaceuticals International Corporation (SPI), a subsidiary of Sumitomo Corporation, to gain access to the Japanese market with its pharmaco molecular diagnostic epigenetic technologies and products. The partnership aims to provide companion diagnostic solutions, or theranostics, to pharmaceutical companies in the Japanese market. Summit Pharmaceuticals International Corporation is a group of specialists in Japan that provides high-quality integrated services from drug discovery research to the production stage of pharmaceuticals and chemicals. SPI is a subsidiary of Sumitomo Corporation, which is a leading general trading company with 140 locations in 66 countries throughout the world.

HistoGeneX

On July 16, 2013, MDxHealth entered into a Pharmaco Molecular Diagnostic services collaboration agreement with HistoGeneX. The collaboration enables MDxHealth to combine its epigenetic technologies with HistoGeneX's well-established pharmaco diagnostic services to provide to pharmaceutical companies and oncologists with integrated molecular diagnostic testing services. HistoGeneX's laboratory in Belgium will also perform MGMT service testing on behalf of MDxHealth's current and future clients.

Veridex

In 2003, in connection with our acquisition of certain methylation markers and technology from Tibotec-Virco (a Johnson & Johnson Company), we entered into an agreement with Ortho-Clinical Diagnostics, Inc. (OCD, a Johnson & Johnson Company, the parent of Tibotec-Virco). Under the terms of this 2003 agreement, MDxHealth agreed to first offer to OCD (now Veridex LLC) 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 LabCorp a royalty bearing sublicense to the MGMT test (for the North American market only, of indefinite duration, and limited to service testing only). MDxHealth retained certain rights to develop and commercialize the MGMT test as a companion diagnostic on a worldwide basis. LabCorp began to commercialize the MGMT test in North America in 2008.

Ghent University

In December 2012, MDxHealth entered into a collaboration agreement with the University of Gent to establish 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

our pharmaceutical 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 University of Gent. NXTGNT, which is located at University of Gent within the laboratory of Pharmaceutical Biotechnology, houses MDxHealth's research team and laboratory for development of epigenetic tests. 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.

Oncgnostics GmbH

In January 2015, MDxHealth licensed a limited non-transferable and non-exclusive worldwide license for its patented methylation specific PCR (MSP) technology to oncgnostics GmbH in Jena, Germany. Founded as a spin-off from the University Women's Hospital Jena, oncgnostics GmbH focuses on in vitro diagnostic tests for the early detection of gynecological cancers, including cervical cancer. The initial product developed, GynTect^{R}, allows for the rapid and reliable detection of cervical precancerous lesions and cancer.

SouthGenetics, Inc.

In December 2015, MDxHealth established a partnership with SouthGenetics Inc., a Montevideo, Uruguay based beotechnology company to commercialize ConfirmMDx in Argentia, Bolivia, Chile, Columbia, Ecuador, Mexico, Peru, Dominican Republic, Panama, Paraguay, Uruguay, and Venezuela. SouthGenetics is a distribution company that focuses on providing access to the latest medical diagnostic services to Latin America where there are more than 160,000 cases of Prostate Cancer each year and the issues associated with false-negative biopsies are a significant concern.

INTELLECTUAL PROPERTY

MDxHealth believes that our patent portfolio places the Company in a competitive position in the realm of molecular cancer diagnostics. We own or hold exclusive rights to a range of issued and pending patents in multiple countries worldwide covering the epigenetics technology platform known as methylation specific PCR (MSP), nextgen epigenetics technology platforms, as well as multiple epigenetic markers. Many of our epigenetic technology patents are in-licensed from academic and commercial collaborators, including Johns Hopkins University, City of Hope, Epigenomics AG, Vrije Universiteit Medisch Centrum, and Erasmus University Medical Center Rotterdam. Through our internal R&D programs, together with our NXTGNT (Epi)genomics research joint-venture with University of Gent and other academic and commercial collaborations, MDxHealth continues to be at the forefront of researching and understanding the link between cancer and methylation (epigenetics), and how this link can be translated into meaningful clinical and pharmaco molecular diagnostic products and services. We consider patent protection of the technologies, on which our products are based, to be a key factor to our success. Our intellectual property portfolio 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.

The following is a selected summary of MDxHealth's patent portfolio, broken into two groups of patents. The first group includes foundational molecular technology patents certain of which have issued in the US, Japan, Canada, Israel and the major European countries. The second group includes cancer specific biomarker panels for tumor detection and profiling and includes over 20 granted patents and over 30 international pending patents.

Epigenetic Detection Technology – 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
SEQ-C-YR	Method for Predicting Clinically Significant Prostate Cancer	WO14/125421
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 patents on the MSP technology, which have been granted in key markets such as Europe, United States, Canada, and Japan, are exclusively in-licensed from Johns Hopkins University. The MSP patents will begin to expire as from this year, including expirations in the US in 2016 and in Europe in 2017. The MDxHealth methylation technology portfolio also comprises patent families on various improvements on MSP technology (*non-exclusive license from third parties where indicated). There are various patents covering methylation detection technologies 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. MDxHealth considers patent protection of the technologies, on which our products are based, to be a key factor to our success.

BioMarkers for Tumor Profiling

	TITLE
PROSTATE CANCER MARKERS	Genetic Diagnosis of Prostate Cancer
	Method of Detection of Prostate Cancer
	Tumor Suppressor Gene
	Characterizing Prostate Cancer
	Molecular Markers in Prostate Cancer
	Method for Predicting Clinically Significant Prostate Cancer
	Combinations of Molecular Markers in Prostate Cancer providing a Diagnostic Tool with Improved Sensitivity/Specificity
BLADDER CANCER MARKERS	Novel Markers for Bladder Cancer Detection (I)
	Novel Markers for Bladder Cancer Detection (II)
	Method of Diagnosing Bladder Cancer
	Molecular Markers in Bladder Cancer
CERVICAL CANCER MARKERS	Diagnosis and treatment of tumor-suppressor associated disorders
	Detection of HPV-induced invasive cancers and their precursor lesions with invasive potential
	Detection and prognosis of cervical cancer
	Improved Detection of Gene Expression
BRAIN CANCER MARKERS	Method of Predicting the Clinical Response to Chemotherapeutic Treatment with Alkylating Agents
	Improved Methylation Detection
COLON CANCER MARKERS	Epigenetic Change in Selected Genes and Cancer
	Improved methods of detecting colorectal cancer
LUNG CANCER MARKERS	Detection and Prognosis of Lung Cancer
	Methylation Markers and Methods of Use
OTHER BIOMARKERS	Methods of detecting mutations and epigenetic changes
	Methods and kits for correcting for bias in sequencing of polynucleotide samples
	Improved Detection of MAGE-A Expression
	Improved Detection of Gene Expression

At the date of this document and as far as MDxHealtlh is aware, our intellectual property has not been challenged otherwise than by patent offices in the normal course of examination of patent applications.

MDxHealth continually strives to develop new technologies and products, and we expend significant efforts and funds on research and development. We have obtained intellectual property through internal efforts and as a consequence of various research and development collaborations. Additionally, we have obtained from time to time, and may continue to obtain, licenses from third parties to use their technologies and know-how and to manufacture and sell their products (see "Business - Commercial Collaborators" above). We have granted from time to time, and may continue to grant, licenses to third parties to use certain patents and know-how of MDxHealth. The production technologies of MDxHealth typically incorporate specialised proprietary know-how. To preserve and enhance the value of our investments and assets, we

rely, inter alia, on the protection offered by the intellectual property laws of the jurisdictions in which we operate, and we have developed an active intellectual property strategy.

GROUP STRUCTURE / SUBSIDIARIES

MDxHealth SA is listed on the regulated market of Euronext in Brussels. The Company has two wholly-owned subsidiaries: MDxHealth B.V. with its principal address at Geert Grooteplein Zuid 34, 6524 GA Nijmegen, the Netherlands; and MDxHealth Inc., incorporated under the laws of the State of Delaware, US, with its principal office at 15279 Alton Parkway, Suite 100, Irvine CA 92618. Our US subsidiary operates a CLIA and ISO 9001:2008 certified, and CAP-accredited laboratory (13,444 sqft). Our Dutch subsidiary operates as a holding company, with two wholly-owned subsidiaries, including MDxHealth Servicelab B.V., which operates our commercial molecular diagnostics services lab, and MDxHealth Research B.V., which operates our molecular diagnostics research lab, each utilizing laboratory facilities resident in our 1,735 sqft (161m²) facility located on the Radboud University Medical Center campus in Nijmegen, the Netherlands.

HUMAN RESOURCES

On December 31, 2015, MDxHealth had 133 employees, 11% of whom contributed to research and development activities. The ratio of the number of women to men in the Company is 1 to 1. We select talented people to participate and drive our development programs. Our scientific staff has expertise in molecular biology, diagnostics, and oncology amongst other disciplines. The overall employment level of the Group is described as follows:

TOTAL HEADCOUNT EVOLUTION	DEC 31 2015	DEC 31 2014	DEC 31, 2013
TOTAL	*133*	*96*	*84*
HEADCOUNT EVOLUTION BY DEPARTMENT			
Research & Development	14	*12*	14
Sales, General, and Administrative	119	*76*	70
TOTAL	*133*	*88*	*84*
HEADCOUNT EVOLUTION BY GROUP ENTITY			
MDxHealth SA (Belgium)	7	8	11
MDxHealth B.V. (The Netherlands)	7		
MDxHealth Inc. (USA)	119	*88*	73
TOTAL	*133*	*96*	*84*

LEGAL PROCEEDINGS

At the date of this document and as far as MDxHealth is aware, the Company is not involved in any legal proceedings.

GOVERNMENT REGULATION

Currently, MDxHealth provides clinical testing services from its California-based laboratory facility, which focuses and the newly acquired laboratory in Nijmegen, the Netherlands. As of the end of 2015, primary is on sales to customers based in the United States, as well as from its laboratory facility located in Nijmegen,

the Netherlands, focusing on sales to customers based in the Benelux Union region. However initial testing at low volumes has started for patients in the Benelux countries, we have entered into distribution partnerships with Teva Pharmaceuticals to offer ConfirmMDx in Israel and with SouthGenetics Inc. to offer ConfirmMDx in Argentina, Bolivia, Chile, Columbia, Ecuador, Mexico, Peru, Dominican Republic, Panama, Paraguay, in Uruguay, and Venezuela. We for sales to twelve countries across Central and South America. Further we intend to investigate partnerships for our solutions in other regions.

In the European Union, each member state runs its own third-party or government reimbursement program. In situations involving physicians employed by state-funded institutions or national health care agencies of non-U.S. entities, violation of the local anti-kickback law may also constitute a violation of the US Foreign Corrupt Practices Act, or FCPA. In addition, prior to our being able to offer our medical devices in the European Economic Area (EEA), we would be required to comply with the essential requirements of the EU Medical Devices Directives. Compliance with these requirements would entitle us to affix the CE conformity mark to some of our medical devices (other than custom-made devices or devices for clinical investigations as described below), without which they could not be commercialized in the EEA. In order to demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark we would be required to undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. In November 2015, the Company fulfilled these requirements and has obtained the CE conformity mark for the SelectMDx test.

United States Regulations

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988

As a diagnostic service provider, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. As to federal certifications, in 1988, the US Congress passed the Clinical Laboratory Improvement Amendments of 1988, or CLIA, establishing quality standards for all clinical laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The Company's laboratory is CLIA certified. As to state laws, we are required to meet certain laboratory licensing and other requirements. Our laboratory holds the required licenses and accreditations obtained from the applicable state agencies in which we operate.

Under CLIA, a laboratory is defined as any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health. CLIA also requires that we hold a certificate applicable to the type of work we perform and comply with certain standards. CLIA further regulates virtually all clinical laboratories by requiring they be accredited by the federal government and comply with various operational, personnel, facilities administration, quality and proficiency requirements intended to ensure that their clinical laboratory testing services are accurate, reliable and timely. CLIA compliance and certification is also a prerequisite to be eligible to bill for services provided to governmental payor program beneficiaries. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by the regulated facilities, including certification and survey costs.

We are subject to survey and inspection every two years to assess compliance with program standards, and may be subject to additional unannounced inspections. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. In addition, a laboratory like ours that is certified as "high complexity" under CLIA may obtain analyte specific reagents, or ASRs, which are used to develop diagnostic tests that are developed and validated for use in

examinations the laboratory performs itself known as LDTs. Our laboratory is CLIA certified and under our CLIA certification, we were allowed to first use ConfirmMDx for Prostate Cancer in mid 2012.

In addition to CLIA requirements, we participate in the oversight program of CAP. Under CMS requirements, accreditation by the College of American Pathology, or CAP, is sufficient to satisfy the requirements of CLIA. Therefore, because we are accredited by CAP, we are deemed to also comply with CLIA. CLIA also provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory schemes. State laws may require that laboratory personnel meet certain qualifications, specify certain quality controls, or prescribe record maintenance requirements.

FDA

Pursuant to its authority under the federal Food, Drug and Cosmetic Act, or FDCA, the U.S. Food and Drug Administration, or FDA, has regulatory responsibility over instruments, test kits, reagents and other devices used to perform diagnostic testing by laboratories such as ours. Specifically, the manufacturers and suppliers of ASRs, which we obtain for use in diagnostic tests, are subject to regulation by the FDA and are required to, among other things, register their establishments with the FDA, to conform manufacturing operations to the FDA's Quality System Regulation, or QSR, and to comply with certain reporting and other record keeping requirements.

The FDA also regulates the sale or distribution, in interstate commerce, of products classified as medical devices under the FDCA, including in vitro diagnostic tests, or IVDs. Such devices must undergo premarket review by the FDA prior to commercialization unless the device is of a type exempted from such review by statute or pursuant to the FDA's exercise of enforcement discretion. LDTs are a class of IVD products that are developed, validated, manufactured, and offered within a single laboratory. Although most LDTs are subject to FDA regulation as IVD medical devices, FDA has historically exercised enforcement discretion to exempt LDTs from regulation, including the requirement for premarket clearance or approval. This initiative is noteworthy because while CLIA presently requires laboratories to establish that their LDTs accurately identify the specific substances that they purport to identify, regulation by the FDA would be expected to require a laboratory to also establish that its LDTs have the clinical significance in terms of patient care that the laboratory holds the tests out as having through its marketing activities.

Pursuant to the Food and Drug Administration Safety and Innovation Act, the FDA notified Congress on July 31, 2014 that the FDA intended to issue, on or after September 30, 2014, a draft guidance entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)," or the Framework Guidance, and a separate draft guidance entitled "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)," or the Notification Guidance. On October 3, 2014, the FDA issued the anticipated Framework Guidance and Notification Guidance. The Framework Guidance states that the FDA intends to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the existing classification of medical devices. Thus, the FDA plans to begin to enforce its medical device requirements, including premarket submission requirements, on LDTs that have historically been marketed without FDA premarket review and oversight.

The FDC Act classifies medical devices into one of three classifications based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. The classification of a medical device also generally determines the type of premarket review, if any,

required for the device. The FDA states its intention in the Framework Guidance to publish general LDT classification guidance within 18 months of the date on which the Framework Guidance is finalized.

Class I device are those for which reasonable assurance of safety and effectiveness can be provided by adherence to the FDA's general controls for medical devices, which include applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and device listing, reporting of adverse medical events and appropriate, truthful and non-misleading labeling, advertising and promotional materials. Many Class I devices are exempt from premarket review; however, some Class I devices require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are subject to the FDA's general controls, and any other special controls, such as performance standards, postmarket surveillance and FDA guidelines, deemed necessary by the FDA to provide reasonable assurance of the devices' safety and effectiveness. Unless exempt, the manufacturer of a Class I or II device must submit to the FDA a 510(k) premarket notification submission requesting clearance of the device for commercial distribution in the United States. Premarket notifications are subject to user fees, unless a specific exemption applies. To obtain a 510(k), the manufacturer must demonstrate that the device is "substantially equivalent" to a predicate device, which is either: a device that was legally marketed prior to May 28, 1976, for which the FDA has not yet called for the submission of a premarket approval, or PMA application, or to another commercially available, similar device that was cleared through the 510(k) process. In determining substantial equivalence, the FDA assesses whether the proposed device has the same intended use as the predicate device, and the same technological characteristics as the predicate device or different technological characteristics but the information submitted in the premarket notification demonstrates the device is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than the predicate device. The process for submitting a 510(k) premarket notification and receiving FDA clearance usually takes from three to twelve months, but it can take significantly longer and clearance is never guaranteed. The FDA may request additional information, including clinical data. If the FDA determines that the device is substantially equivalent to the predicate device, the subject device may be marketed in accordance with its 510(k) clearance. However, if the FDA makes a not substantially equivalent determination, then the device is regulated as a Class III device and may not be marketed without approval of a PMA.

Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices or devices deemed not substantially equivalent to a previously 510(k) cleared device are classified as Class III. These devices require submission and approval of a PMA application, which must demonstrate reasonable assurance of the safety and effectiveness of the device to the FDA's satisfaction. A PMA application must provide valid scientific evidence, typically extensive preclinical and clinical trial data and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications and supplemental PMA applications are subject to significantly higher user fees than are 510(k) premarket notifications. Some PMA applications, such as the first PMA submitted by a small business, are exempt from a user fee.

After a PMA application is submitted and found to be sufficiently complete, the FDA begins an in-depth review of the submitted information. During this review period, the FDA may request additional information or clarification of information already provided. The FDA also may convene an advisory panel of outside experts to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA generally will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the QSR. The FDA can delay, limit or deny approval of a PMA application for many reasons.

If the FDA's evaluation of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter authorizing commercial marketing or an approvable letter that usually contains a number of conditions that must be met in order to secure final approval. If the FDA's evaluations are not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The agency may determine that additional clinical trials are necessary, in which case the PMA approval may be delayed while the trials are conducted and the data acquired are submitted in an amendment to the PMA. Even with additional trials, the FDA may not approve the PMA application. The process for submitting and obtaining FDA approval of a PMA generally takes from one to three years, but may take longer and approval is not guaranteed.

A clinical trial may be required in support of a 510(k) submission and generally is required for a PMA application. These trials generally require an Investigational Device Exemption, or IDE, approved by the FDA for a specified number of patients, unless the device is exempt from IDE requirements or deemed a non-significant risk eligible for more abbreviated IDE requirements. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Clinical trials may begin 30 days after the submission of the IDE application unless the FDA disapproves the IDE or places the trial on clinical hold. Additionally, clinical trials may not begin until their protocol and informed consent receive approval from the appropriate institutional review boards, or IRBs, at the clinical trial sites. All clinical trials must be conducted in accordance with the FDA's IDE regulations.

If and when the Framework Guidance and Notification Guidance are finalized, we and the MDxHealth products could for the first time be subject to the FDA's enforcement of its regulatory requirements applicable to medical device manufacturers and medical devices, respectively. According to the Framework Guidance, devices that are already in use at the time the FDA initiates enforcement of the premarket review requirements will be permitted to remain in use – pending the FDA's review and consideration of the premarket submission – so long as a premarket submission is timely made. For the highest risk LDTs, the Framework Guidance provides that enforcement of the premarket submission requirements will begin 12 months after the guidance is finalized. For lower risk LDTs, enforcement of the premarket submission requirements are expected to be phased in over the following four to eight years.

Even if regulatory approval or clearance of a device is granted, the FDA may impose limitations on the uses and indications for which the device may be labeled and promoted, and the device remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved as the FDA prohibits promoting devices for "off-label" uses. Other regulatory requirements that apply include: facility registration and device listing; the Quality System Regulation, or QSR, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process and to have in place complaint handling and corrective and preventative action procedures; labeling regulations; the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and the reporting of certain field corrections and product recalls or removals. Additionally, if a manufacturer makes certain changes to its device, a new 510(k) or a PMA supplement may be required.

The FDA has broad post-market and regulatory and enforcement powers and it enforces its medical device requirements by various means, including inspection and market surveillance. Failure to comply with the

applicable US medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, consent decrees, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA's refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product applications and criminal prosecution.

The Physician Payment Sunshine Act, subject to specified exceptions, requires drug and medical device manufacturers to disclose to CMS any direct or indirect payments that they make to physicians and teaching hospitals or any direct or indirect ownership interests that physicians or their immediate family members hold in them. Given the position of non-enforcement that the FDA has historically taken with respect to LDTs and our position that our LDTs are not medical devices, we do not believe that we are currently subject to the requirements of the Sunshine Act, and we do not make reports under that law. Nevertheless, if the FDA decides to regulate our LDTs in the future, we may then be subject to the reporting requirements of the Sunshine Act. Even if the FDA decides to regulate our LDTs, the Sunshine Act may nevertheless not apply to us, as there is an exception under the Act for manufacturers of drugs or devices used solely by or within the manufacturer itself.

STATE LABORATORY LICENSING

In addition to our CLIA certification, licensure is required and maintained for our laboratory under the laws of certain states in the US from which we accept testing specimens. Such laws establish standards for the day-to-day operation of a clinical laboratory, qualifications for testing personnel, physical facilities requirements, equipment requirements, training and skills required of personnel and quality control. In addition, certain state laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for testing at our laboratory.

For example, we are subject to regulation of our laboratory operations under state clinical laboratory laws of California, where our facility is located. California's requirements for the qualifications of testing personnel are more rigorous than those of CLIA. Certain other states, such as Florida, Maryland, New York, Pennsylvania, and Rhode Island, each require that we obtain and maintain licenses to test specimens from patients residing in those states and additional states may require similar licenses in the future. Our ConfirmMDx test is currently approved in all states where approval is required. In particular, in 2013, our ConfirmMDx test was approved by the New York State Department of Health, which has a stringent, formal approval process for CLIA laboratory tests. CLIA does not preempt state laws that have established laboratory quality standards that are at least as stringent as federal law, which currently includes Washington and New York State. Potential sanctions for violation of state statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations. Although we believe that we are in compliance with all applicable laboratory requirements and that our laboratory locations are licensed, certified and accredited by the appropriate state agencies in the states in which we do business, no assurances can be given that the laboratory will pass future re-certification or accreditation inspections.

While we believe we are in compliance with applicable licensing laws, no assurance can be given that state licensing agencies would agree or that our laboratory will pass all future licensing inspection. We may become aware from time to time of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states do have such requirements or will have such requirements in the future. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

US FEDERAL AND STATE LAWS REGARDING PATIENT INFORMATION PRIVACY AND SECURITY

There are currently numerous federal and state laws addressing health information practices, patient privacy and electronic data security that apply to us. These federal and state health information, privacy and security laws require us to acquire, implement and maintain expensive computer systems, employee training programs and business policies and procedures to protect the privacy and security of each patient's health information consistent with the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Health Information Technology for Economic and Clinical Health Act, or HITECH, and the regulations promulgated thereunder. Federal regulations also require us to comply with standards for the format and content of certain electronic payment-related transactions that we conduct with health plans. These regulations have had and are expected to continue to have a considerable financial impact on the healthcare industry because they impose extensive new requirements and restrictions on the use and disclosure of identifiable patient information.

FEDERAL PRIVACY AND SECURITY LAWS

Under HIPAA and HITECH, the US Department of Health and Human Services, or HHS, has issued regulations that establish uniform standards governing the format and content of certain electronic payment-related transactions, and protecting the privacy and security of individually identifiable health information, also known as protected health information, or PHI, held by healthcare providers and other covered entities. Three principal sets of regulatory standards have been promulgated under HIPAA and HITECH: the Standards for Privacy of Individually Identifiable Health Information (referred to as the "Privacy Standards"), which restrict the use and disclosure of certain individually identifiable health information, and give individuals certain rights with respect to health information about them; the Standards for Electronic Transactions (referred to as the "Transaction Standards"), which establish standards for the format and content of common electronic payment-related transactions among health care providers and health plans, such as claims for payment by a provider, inquiries from a health care provider to a health plan concerning an individual's eligibility for benefits under the plan, and inquiries from a health care provider to a health plan concerning the status of a claim for payment; and the Security Rule, which require covered entities and their business associates to implement and maintain security measures to safeguard electronic PHI, including administrative, physical and technical safeguards to protect the confidentiality, integrity and availability of such information.

Penalties for violations of HIPAA and HITECH laws and regulations include civil and criminal penalties. HIPAA has a tiered system of money penalties, based on the degree of negligence or willfulness of the breach, and whether or not it was timely corrected. Possible penalties range up to $50,000 for each violation, subject to a $1.5 million maximum for identical violations during a calendar year. Criminal penalties may be imposed on any person who knowingly obtains or discloses PHI in violation of HIPAA. The penalties depend on intent; violations committed with intent to sell, transfer, or use the information for commercial advantage, personal gain, or malicious harm, carry the highest penalties—fines up to $250,000, imprisonment up to 10 years, or both.

The Office for Civil Rights of HHS, which enforces the HIPAA regulations, has been taking an increasingly rigorous approach to enforcement, and sometimes imposes penalties or settlements in excess of $1 million.

The Privacy Standards govern the use and disclosure of PHI by healthcare providers. These standards also set forth certain rights that an individual has with respect to his or her PHI maintained by a healthcare provider, including the right to access or amend certain records containing PHI, and to obtain an accounting of certain disclosures of PHI. HIPAA also governs patient access to laboratory test reports. Effective October 6, 2014, certain covered entity laboratories like us must provide individuals (or their personal representatives) with the right to access test reports directly from laboratories. We have implemented practices and procedures with the intent to comply with the requirements of the HIPAA Privacy Standards and applicable state privacy laws.

We have also implemented policies, procedures and standards with the intent to comply with the HIPAA Security Standards, which establish requirements for safeguarding the confidentiality, integrity and availability of electronic PHI. In addition, we have taken necessary steps to comply with HIPAA's Transaction Standards, which establish standards for common payment-related transactions among health plans and health care providers. In particular, we have completed conversion of our electronic fee-for-service claim transactions and our electronic fee-for-service remittance transactions to the HIPAA Transaction Standards, including the standards for billing claims, remittance advices, enrollment and eligibility verification inquiries.

In 2009, Congress passed the American Recovery and Reinvestment Act of 2009, or ARRA, which included HITECH. HITECH made significant changes to HIPAA, including increasing penalties for violations, providing the federal and state governments with additional enforcement capabilities, further restricting certain uses of PHI (particularly for commercial purposes), and extending some provisions of HIPAA to cover contractors of covered entities—known as business associates—directly.

Further, HITECH requires HIPAA covered entities, such as clinical laboratories, to provide notification to affected individuals and to the Secretary of HHS following discovery of a breach of unsecured PHI and imposes penalties on those that fail to do so. The 2013 final HITECH omnibus rule modified the breach reporting standard in a manner that will likely make more data security incidents qualify as reportable breaches. In some cases, HITECH also requires covered entities to provide notification to the media of breaches. In addition, in the case of a breach of unsecured PHI at or by a business associate of a covered entity, the regulations require the business associate to notify the covered entity of the breach. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney fees and costs associated with pursuing federal civil actions.

STATE PRIVACY AND SECURITY LAWS

HIPAA and HITECH and their implementing regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI. As a result, we are required to comply with both federal privacy and security regulations and state privacy and security laws, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

As one example, the Confidentiality of Medical Information Act, or CMIA, is California's statutory scheme governing the disclosure of medical information by providers of health care. Certain aspects of the CMIA are more stringent than the requirements of HIPAA, particularly with regard to the form used to obtain

authorization to disclose a patient's medical information. Like a number of other states, California also places special restrictions on the use and disclosure of particularly sensitive kinds of health information, such as information concerning alcohol and drug abuse, mental health, developmental disabilities, and HIV and genetic test results. Significant administrative penalties may be imposed for violation of any of these requirements. In addition, certain states have adopted information security requirements that apply to all businesses that store confidential personal information, including Massachusetts and California. Most states, including California, also have state breach notification laws that may be more onerous than the breach notification requirements under federal law. In addition to penalties that may be imposed by regulatory agencies, an individual whose medical information was the subject of a breach may also sue in some cases for statutory or actual damages.

ANTI-KICKBACK STATUTES

The federal healthcare program Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, referring an individual to a person for the furnishing, or arranging for the furnishing of, any item or service for which payment may be made, in whole or in part, under a federal health care program, including the Medicare and Medicaid programs or for the purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing or ordering, any such good, facility, item or service. The definition of "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests, and providing anything at less than its fair market value. The Anti-Kickback Statute may be violated if one purpose of a payment is to induce referrals, notwithstanding the fact that the payment may otherwise be for legitimate purposes and be at fair market value. The Anti-Kickback Statute is broad, and it prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, HHS has issued a series of regulatory "safe harbors." These safe harbor regulations set forth certain provisions, which, if met, will assure healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. The penalties for violating the Anti-Kickback Statute can be severe. These sanctions include criminal penalties and civil sanctions, including fines, imprisonment and possible exclusion from the Medicare and Medicaid programs. Further, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. Whistleblowers, known as qui tam relators, or the government may initiate False Claims Act litigation alleging that claims were tainted by violations of the Anti-Kickback Statute. Many states have also adopted statutes similar to the federal Anti-Kickback Statute, some of which apply to payments in connection with the referral of patients for healthcare items or services reimbursed by any source, not only governmental payor programs.

ANTI-MARKUP RULES

A number of states have anti-markup rules that prohibit physicians or certain other persons or entities from marking up clinical laboratory testing and, in some cases, require disclosures regarding the laboratory's charges for clinical laboratory testing. Depending on the particular facts, state and federal self-referral and anti-kickback laws also may be implicated when laboratories sell testing to a physician or an entity that the physician or entity then marks up.

California has an anti-markup statute as well as a self-referral law and anti-kickback statutes. California's self-referral law has been interpreted, in an opinion of the Office of Legislative Counsel, not to prohibit physician referrals to a laboratory insofar as the physician complies with the anti-markup rule, under the reasoning that the anti-markup statute is more specific than is the self-referral ban. However, if a California physician were to mark-up tests purchased from the Company, the physician would no longer be in compliance with the anti-markup rule, potentially subjecting the Company to penalties under California's self-referral law. This may be true even though the Company would have billed the physician, and not the patient or a third-party payor. Because the self-referral law is effectively a "strict liability" law, meaning no intent is required for penalties to be imposed, the Company potentially could be subject to penalties even in the absence of any intent to violate the law or induce referrals. Under the California self-referral law it is a crime to submit a claim that arises from a prohibited referrals and fines are capped at $15,000 per violation.

Also, California's anti-kickback laws have been interpreted by the state Attorney General to prohibit arrangements whereby a physician purchases laboratory services at a discount and then marks them up without passing the discount on to the patient or payor. However, referrals to the Company should be permitted under the California anti-kickback laws if the physicians are not marking up the tests and are making appropriate disclosures concerning the Company's charges for such tests. It can also be argued that such discounts should be governed by the more specific anti-markup law, and not the California anti-kickback law, even if a physician does not comply with the anti-markup law. However, no authority has addressed this issue. The Company is not aware of any enforcement actions that have been based upon this issue under California's anti-kickback laws.

CRIMINAL HEALTHCARE FRAUD AND FALSE STATEMENTS

In addition to the laws and regulations governing the privacy and security of PHI discussed above, HIPAA created two federal crimes: HIPAA healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from governmental payor programs such as the Medicare and Medicaid programs. The HIPAA false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment, as well as exclusion from one or more government payor programs.

FALSE CLAIMS ACT

Another development affecting the healthcare industry is the increased use of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam"

provisions. The False Claims Act imposes liability on any person or entity, who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal governmental payor program. The False Claims Act also applies if a provider knows that it has been overpaid by a federal health care program for a service, but fails to make a timely refund of the overpayment. The government has broad investigatory powers under the False Claims Act, and individuals and entities may incur significant costs in defending such investigations. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has defrauded the federal government by submitting a false claim to the federal government and permit such individuals to share in any amounts paid by the entity to the government in fines or settlement. The federal government has the right to intervene in a False Claims Act suit initiated by a qui tam relator and, when a qui tam suit is filed, it is filed under seal to provide the government an opportunity to investigate the matter before making a decision regarding intervention.

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties ranging from $5,500 to $11,000 for each separate false claim, exclusion from participation in federal healthcare programs, and criminal penalties. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, although many of these state laws apply where a claim is submitted to any third party payor and not merely a governmental payor program.

PHYSICIAN REFERRAL PROHIBITIONS

A federal law directed at physician "self-referral," commonly known as the "Stark Law," prohibits, among other things, physicians who personally, or through an immediate family member, have a financial relationship, including an investment, ownership or compensation relationship with an entity, from referring Medicare patients to that entity for designated health services, which include clinical laboratory services, unless an exception applies. "Immediate family member" is defined to mean husband or wife; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. In addition, the clinical laboratory is prohibited from billing for any tests performed pursuant to a prohibited referral. Recent court cases have extended the Stark law's prohibition to referral of Medicaid patients as well. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to $100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties of up to $15,000 per bill submission, an assessment of up to three times the amount claimed and possible exclusion from participation in federal governmental payor programs. Violations of the Stark Law can also be sanctioned under the False Claims Act. Bills submitted in violation of the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts. Many states, including California, also have anti- "self-referral" and other laws that are not limited to Medicare and Medicaid referrals.

Like the Anti-Kickback Statute, the Stark Law is broad in its application to healthcare transactions and arrangements. Accordingly, the Stark Law contains many exceptions, which protect certain arrangements and transactions from the Stark Law penalties. The Stark Law is a "strict liability" statute, so intent is irrelevant, i.e., a physician's financial relationships with a laboratory must meet an exception under the Stark law or the referrals are prohibited. Thus, unlike the Anti-Kickback Statute's safe harbors, if a laboratory's financial relationship with a physician does not meet a Stark Law exception's requirements,

then the physician is prohibited from making referrals to the laboratory, and any such referrals will result in overpayments to the laboratory and will subject the laboratory to the Stark Law's penalties. Laboratories that bill the Medicare and Medicaid programs for referrals that are in violation of the Stark Law may also be found liable under the False Claims Act. Many states have also adopted statutes similar to the Stark Law, some of which apply to payments in connection with the referral of patients for healthcare items or services reimbursed by any source, not only governmental payor programs.

Civil Monetary Penalties Law

Among other things, the Federal Civil Monetary Penalties Law prohibits the offering or giving of remuneration, including the provision of free items and services, to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a Federal or state governmental program. Violations could lead to civil money penalties of up to $10,000 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the Federal healthcare programs.

Corporate Practice of Medicine

Numerous states, including California, have enacted laws prohibiting business corporations, such as us, from practicing medicine and employing or engaging physicians to practice medicine. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed physician. This prohibition is generally referred to as the prohibition against the corporate practice of medicine. This doctrine does not have application to the extent that a laboratory only performs laboratory testing services in compliance with applicable laws. However, the doctrine may be implicated depending on the specifics of a laboratory's relationships with pathologists and, possibly, genetic counselors. Violation of this prohibition may result in civil or criminal fines, as well as sanctions imposed against us and/or the professional through licensing proceedings.

Other Requirements

Our laboratory is subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood and bone marrow samples and other human tissue. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste. Historically, our costs associated with handling and disposal of such wastes have not been material.

The Occupational Safety and Health Administration, or OSHA, has established extensive requirements relating to workplace safety for healthcare employers, including requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

OIG Compliance Program Guidance For Clinical Laboratories

The Office of Inspector General of HHS, or the OIG, first issued formal compliance guidance for laboratories in 1997, and then modified that guidance in 1998 through its "Compliance Program Guidance For Clinical Laboratories." The OIG's guidance, key parts of which are summarized below, covers a variety of issues that

are important to laboratories, including, but not limited to, medical necessity, notices to physicians, billing, and pricing to physicians.

In this guidance, the OIG takes the position that even though laboratories do not themselves make medical necessity determinations, they should advise physicians that Medicare will only pay for services that are medically necessary. The OIG believes that it is important for laboratories to design their test ordering forms in a manner that promotes the conscious ordering of tests by physicians or other authorized individuals. According to the OIG, the ordering form should include a statement that Medicare does not cover routine screening tests and laboratories should also provide notices to physicians on an annual basis that include the following: (i) any national and local medical review policies for laboratory testing, (ii) a statement that organ and disease panels will only be paid when all components are medically necessary; and (iii) a copy of the applicable Medicare fee schedule and a statement that Medicaid reimbursement will usually be equal to or less than that amount. Additional information is required for "custom" profiles, i.e. profiles that are put together for the convenience of particular physicians. The purpose of these disclosures is to provide physicians with greater information in making their determinations as to what testing is medically necessary.

The OIG's guidance also includes a discussion of the use of Advance Beneficiary Notice of Noncoverage, or ABNs, by laboratories. Where it is likely that a test will not be covered by Medicare, the laboratory may request that the beneficiary sign an ABN indicating the beneficiary's consent to be financially liable if payment is denied. The laboratory may ask the ordering physician to obtain the ABN, but it is the laboratory's responsibility to produce it, when necessary. According to the OIG, routine use of ABNs, or merely stating that denial of payment is possible, or that it is impossible to know when payment will be denied, is forbidden. The ABN must be in writing, must identify a specific service, and must explain the reasons that payment is believed likely to be denied.

According to the OIG, laboratories should also monitor test ordering to ensure that test ordering is not excessive, and the OIG's guidance set out methods for performing this analysis. The OIG also believes that laboratories should take steps to ensure that the CPT/HCPCS codes provided accurately describe the services furnished. Laboratories should not alter the physician's order in any way, either increasing or decreasing the number of services performed. According to the OIG, laboratories should ensure that the laboratory can support tests billed to Medicare with documentation from the physician ordering the test or other authorized person. According to the OIG, laboratories should not: (i) use information provided by the physician from earlier dates of service (other than standing orders); (ii) create diagnosis information that has triggered reimbursement in the past; (iii) use computer programs that automatically insert diagnosis codes without receipt from the ordering physician or other authorized person; or (iv) make up diagnosis information. Laboratories may, however, contact the ordering physician or other authorized person to obtain information if it was not provided and accurately translate narrative diagnoses obtained from the physician or other authorized person.

Where a test order is ambiguous, the OIG indicates that laboratories should not bill for testing until they have verified the tests that the physician actually wished to order. Similarly, where the test cannot be performed because of an accident or insufficient specimen, then the laboratory may not bill for the testing. The OIG's guidance includes a discussion of reflex testing (i.e. additional testing that is testing performed when initial results are positive or indicate the need for further testing). According to the OIG, laboratories should design their requisitions to only allow for reflex testing when necessary. The OIG also states that physicians should not provide inducements to obtain a physician's non-Medicare testing, and that it would

be an inducement to charge physicians a price below fair market value for their non-federal health care program testing.

We seek to conduct our business in compliance with all statutes and regulations applicable to our operations. To this end, we conduct in-depth reviews of procedures, personnel and facilities to ensure regulatory compliance throughout our operations. In addition, because compliance with government rules and regulations is a significant concern throughout our industry, in part due to evolving interpretations of these rules and regulations, we have established and maintain an internal compliance program. We provide periodic and comprehensive training programs to our personnel, which are intended to promote the strict observance of our policies designed to ensure compliance with the statutes and regulations applicable to our operations.

While current law does not expressly require laboratories to have a compliance program, the Affordable Care Act authorizes the Department of Health and Human Services, or HHS, to require certain providers and suppliers to establish a compliance program as a condition of enrollment in Medicare, Medicaid and other federal healthcare programs. HHS, in consultation with the HHS Office of Inspector General, is to establish the core elements of the required compliance plan and the implementation dates. HHS has not yet issued any final regulations but has issued detailed guidance on compliance requirements for nursing facilities, Medicare Advantage plans and Medicare prescription drug plans.

European and other International Regulations

Outside of the US, sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. In order to market our tests in other countries, we may be required to obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. The European Union/European Economic Area, or EU/EEA, requires a CE conformity mark in order to market medical devices. Many other countries, such as Australia, India, New Zealand, Pakistan and Sri Lanka, accept CE or FDA clearance or approval, although others, such as China, Brazil, Canada and Japan require separate regulatory filings.

Further, the advertising and promotion of our products in the EEA is subject to the laws of individual EEA Member States implementing the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State laws governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our tests to the general public and may impose limitations on our promotional activities with healthcare professionals.

Many countries in which we may in the future seek to offer our tests have anti-kickback regulations prohibiting providers from offering, paying, soliciting or receiving remuneration, directly or indirectly, in order to induce business that is reimbursable under any national health care program. In situations involving physicians employed by state-funded institutions or national health care agencies, violation of the local anti-kickback law may also constitute a violation of the US Foreign Corrupt Practices Act, or FCPA.

The FCPA prohibits any US individual, business entity or employee of a US business entity to offer or provide, directly or through a third party, including the distributors we rely on in certain markets, anything of value to a foreign government official with corrupt intent to influence an award or continuation of business or to gain an unfair advantage, whether or not such conduct violate local laws. In addition, it is

illegal for a company that reports to the FSMA to have false or inaccurate books or records or to fail to maintain a system of internal accounting controls. We are also required to maintain accurate information and control over sales and distributors' activities that may fall within the purview of the FCPA, its books and records provisions and its antibribery provisions.

The standard of intent and knowledge in the Anti-Bribery cases is minimal—intent and knowledge are usually inferred from that fact that bribery took place. The accounting provisions do not require intent. Violations of the FCPA's anti-bribery provisions for corporations and other business entities are subject to a fine of up to $2 million and officers, directors, stockholders, employees, and agents are subject to a fine of up to $100,000 and imprisonment for up to five years. Other countries, including the United Kingdom and other OECD Anti-Bribery Convention members, have similar anti-corruption regulations, such as the United Kingdom Bribery Act.

When marketing our tests outside of the United States, we are subject to foreign regulatory requirements governing human clinical testing, export of tissue and marketing approval for our products. These requirements vary by jurisdiction, differ from those in the United States and may require us to perform additional pre-clinical or clinical testing. In many countries outside of the United States, coverage, pricing and reimbursement approvals are also required. Reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. In the European Union, each member state runs its own third-party or government reimbursement program.

Prior to our being able to commercialize SelectMDx for Prostate Cancer in kit form in the European Economic Area, or EEA, we would be required to comply with the essential requirements of the EU Medical Devices Directives (Council Directive 93/42/EEC of June 14, 1993 concerning medical devices, as amended, and Council Directive 90/385/EEC of June 20, 2009 relating to active implantable medical devices, as amended). Compliance with these requirements would entitle us to affix the CE conformity mark to some of our medical devices (other than custom-made devices or devices for clinical investigations as described below), without which they could not be commercialized in the EEA. In order to demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark we would be required to undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the Medical Devices Directives, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization accredited by a Member State of the EEA to conduct conformity assessments. The Notified Body would typically audit and examine the quality system for the manufacture, design and final inspection of our devices before issuing a certification demonstrating compliance with the essential requirements. Based on this certification, we would be able to draw up an EC Declaration of Conformity, which would allow us to affix the CE label to our products. Devices for special purposes, such as custom-made devices or devices for clinical investigations are exempt from the CE marking but must be accompanied by a statement in accordance to the Medical Devices Directives. At the EU level, a revised regulation of medical devices could be enacted in the near future. While the content of the regulation is currently unknown, it may include controls and requirements that could impact our activities going forward.

MANUFACTURING AND SUPPLY

Many of the consumable supplies and reagents used as raw materials in our ConfirmMDx and SelectMDx for Prostate Cancer testing process are procured from a limited number of suppliers, some of which are sole-source. In addition, we rely on a limited number of suppliers, or in some cases a single supplier, for certain equipment with which we perform ConfirmMDx and SelectMDx testing services. To date we have acquired all of our equipment and the majority of our materials on a purchase order basis, and we do not have contracts with our suppliers and manufacturers that commit them to supply equipment and materials to us.

FACILITIES

The Company leases facilities in Belgium, in the Netherlands and in the US. We are unaware of any environmental issues that may affect our utilisation of the tangible fixed assets.

Belgium, Herstal & Gent

The Group's headquarters and MDxHealth's registered and corporate office is based in Herstal, Belgium. MDxHealth leases 452 sqft (42 m^2) of office space in the CAP Business Center.

MDxHealth SA leases 1808 sqft (168 m^2) research laboratories at the campus of the University of Gent, building FFW at the Ottergemsesteenweg 460, 3rd floor, 9000 Ghent.

United States, Irvine, CA

MDxHealth, Inc., the Company's US subsidiary, leases facilities located at 15279 Alton Parkway, Suite 100, Irvine, CA 92168. In the course of 2015, the Company entered into an additional leased building located adjacent to our Irvine CA US headquarters facility. The total space leased in Irvine is 20,797 sqft (1.932 m^2) of laboratory and office space. The lab facilities are CLIA and ISO 9001:2008 certified and CAP-accredited.

Nijmegen, the Netherlands

MDxHealth B.V., the Company's Dutch subsidiary, leases 1,735 sqft (161m^2) facility on the Radboud University Medical Center campus (Geert Grooteplein Zuid 34, 6525 GA Nijmegen, The Netherlands), which consists of 1,335 sqft clinical and research labs and 400 sqft office space.

QUALITY ASSURANCE

MDxHealth is committed to providing reliable and accurate diagnostic services to our customers. Accurate specimen identification, timely communication of diagnoses, and prompt correction of errors, is critical. We monitor and improve our performance through a variety of methods, including performance improvement indicators, proficiency testing, internal audits, external audits (CAP, ISO 9001:2008 and New York State) and satisfaction surveys. All quality concerns and incidents are subject to root cause analysis and our procedures are put through quarterly evaluation to ensure that we are providing the best services possible

to our patients and customers. Protection of patient results from misuse and improper access is imperative, thus electronic and paper results are guarded via password-protection and physical security procedures.

Testing components for our ConfirmMDx assay are subject to appropriate and strict, internal quality controls. Components that require pre-qualification are determined under our material classification program. Such critical material must be accompanied by certificates of analysis or conformity by the manufacture, as part of our acceptance criteria. We also have an extensive process of qualifying the components for our epigenetic testing to ensure lot consistency and variability. Analysis of all data which includes any changes or results that are not consistent with expectations are logged and then immediately reviewed by our team, including the Vice President Laboratory operations, Vice President of Product Development and Senior Director of Regulatory Affairs and Quality Systems. In cases where a manufacturing problem is suspected, an immediate discussion with the respective vendor is established.

EXTERNAL PROFICIENCY/ACCREDITATIONS

We participate in numerous externally-administered quality surveillance programs, and our laboratory is accredited by CAP. The CAP accreditation program involves both unannounced on-site inspections of the laboratory and participation in CAP's ongoing proficiency testing program for all testing categories. CAP is an independent non-governmental organization of board-certified pathologists which accredits, on a voluntary basis, laboratories nationwide, and which has been accredited by CMS to inspect clinical laboratories to determine adherence to the CLIA standards. A laboratory's receipt of accreditation by CAP satisfies the Medicare requirement for participation in proficiency testing programs administered by an external source, one of Medicare's primary requirements for reimbursement eligibility.

INTERNAL QUALITY CONTROL

We maintain internal quality controls by running samples with known diagnosis at the same time as patient samples are submitted for testing. We also have an internally-administered program of blind sample proficiency testing (i.e., the testing laboratory does not know the sample being tested is a quality control sample). In addition, our clinical staff and laboratory directors are an integral component of our focus on quality and are responsible for the review and quality of test reports and analyses to ensure its quality, completeness and consistency.

INFORMATION SYSTEMS

We have developed and implemented management information systems that support our operations as well as strategically position us for long-term growth in light of what we anticipate to be evolving market trends. We believe our information systems are secure and robust and we maintain an off-site backup of all our data and e-mail systems on a regular basis. We track the performance of our services real time and provide our customers with progress reports upon request. We have also created systems and processes to measure the performance of our business operations via daily monitoring individual variables that provide insight on quality, productivity, profitability, and performance-to-plan, customer buying patterns, customer communications, market share, suppliers and reimbursement.

INVESTMENT POLICY

MDxHealth has not made firm commitments on material investments. However, we have increased our capital expenditures in 2015 and intend to continue in 2016, primarily for the continued growth of our US-based commercial laboratory. Since 2012, we have invested about over $2.7 million in tangible assets to build our US-based laboratory. About $2.0 million was invested in laboratory equipment and $0.7 million was invested in IT equipment, leasehold improvements and selected furniture items. All these investments have been financed by both equity and bank loans. Further equipment will likely be needed for the handling of the prostate test volume and for handling service activities performed for pharmaceutical partners.

For further details on the principal investments made and amounts spent in investing activities during the period covered by the financial statements, reference is made to the section "MD&A - Liquidity, working capital and capital resources for the years ended December 31, 2015, 2014 and 2013".

MANAGEMENT'S DISCUSSION AND ANALYSIS

The following Management's Discussion and Analysis (MD&A) of financial condition and results of operations 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) as adopted by the EU ("IFAS"). The financial statements can be found below in the "Financials" section of this document.

RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2015 COMPARED TO YEAR ENDED DECEMBER 31, 2014

Revenues

Total Company revenues for the full year ended December 31, 2015, increased by 51% to $17.6 million, compared to total revenues of $11.7 million for the prior year. Revenue from ConfirmMDx for Prostate Cancer represented 86% of total Q4 revenues compared to 70% in the same quarter last year. Total revenues for Q4 2015 were $5.7 million compared to $3.4 million during the same period in 2014. The increase in Q4 2015 revenues compared to the prior period was due to increased sales of ConfirmMDx and royalty and milestone payments from Exact Sciences. For the full year, ConfirmMDx for Prostate Cancer accounted for 86% of the Company's revenue, compared to only 80% in 2014.

Substantially all of the Company's revenues have been derived from commercial license agreements, from pharmacogenomic contracts and from direct sales since 2012, but also from government grants. The commercial revenues include up-front fees and milestone fees (which are irregular in terms of timing and amounts), testing fees, contract research fees, and royalties on sales of products licensed to third parties. They also include the proceeds of direct sales of ConfirmMDx for Prostate Cancer.

Since the first sales of the ConfirmMDx for Prostate Cancer test in 2012, the Company's revenue recognition policy has limited the amount of revenue recognized. As the volume of historical reimbursement transactions from payors has grown, the basis to establish reasonable estimates of payment patterns by payor or claim categories has improved. As a result, a higher percentage of the transactional value sold is being recognized each year. Based on 2015 reported cases and historical average reimbursement amounts, the total estimated value of tests performed in 2015 was $36 million. Of this amount, $15.2 million was recognized as revenue, leaving uncollected outstanding unrecognized revenues of $20.8 million. The unrecognized and uncollected amount has been excluded from the Company's revenues in each year. 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 transactions per the Company's revenue recognition policy.

Cost of goods and services sold

The costs of goods include royalties that MDxHealth must pay to third parties and the costs associated with providing testing services to third parties. The cost of goods was higher in 2015 than in 2014, but thanks to

the process improvements in our services laboratory, the cost per case has been reduced. Total increase in the cost of goods is 7% compared to the 61% increase in sales for ConfirMDx for Prostate Cancer in 2015.

Research and development expenses

Research and development expenses were $3,257 thousand in 2015 compared to $2,387 thousand in 2014, an increase of 37%. The increase in the R&D expenditures in 2015 are the consequence of the following: (i) the launch of the capitalized intangible asset (reduction of $1.1 million of R&D expenses in 2014 versus $0.4 million in 2015); and (ii) the increase in collaborations and clinical trials expenses for our pipeline of new products.

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	*2015*	*2014*
Personnel costs	935	936
Lab consumables	358	344
External research and development collaborators	1,238	818
Depreciation & amortization	220	86
Other expenses	506	192
Total	**3,257**	**2,376**

Selling, general and administrative expenses

In 2015, selling, general and administrative expenses amounted to $22,358 thousand compared to $18,321 thousand in 2014, an increase of 22%. As in the previous years, the increase in costs is largely due to building US the sales, marketing, quality, and administrative functions in relation to the CLIA laboratory in California and the continuous hiring of the direct sales force for the commercialization of the ConfirmMDx for Prostate Cancer test. The detail of the administrative and selling expenses is as follows:

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	*2015*	*2014*
Personnel costs	12,865	10,658
Depreciation	502	260
Professional fees	1,994	2,495
Marketing expenses	1,885	1,395
Travel expenses	1,469	1,032
Other expenses	3,028	1,996
Patent expenses	615	485
Total	**22,358**	**18,321**

Financial results

In 2014, the Company ended the year with a net financial profit of $86 thousand while it recorded a financial loss of $91 thousand for the current year. MDxHealth earned $13 thousand of interest income and and recorded other financial losses for $99 thousand in 2015.

Net loss

The net loss was $14,473 thousand in 2015 compared to $15,256 thousand in 2014, a decrease of 5%. This decrease is due primarily to an increase in commercial revenues, while operating costs continue to increase in order to support the commercial development of the activity.

RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2014 COMPARED TO YEAR ENDED DECEMBER 31, 2013

Revenues

Total revenues increased by 55%, from $7,554 thousand in 2013 to $11,671 thousand in 2014. Revenues are derived from commercial product sales, services, or royalties and from grants. Commercial revenues in 2014 increased by 52%, from $7,554 thousand in 2013 to $11,479 thousand in 2014 mainly as a result of the success of the sale of ConfirmMDx for Prostate Cancer. For the full year, 82% of the Company's revenue came from ConfirmMDx for Prostate Cancer, compared to 50% in 2013. Grant revenue for 2014 was $194 thousand while no grant revenue was generated in 2013.

Substantially all of the Company's revenues have been derived from commercial license agreements, from pharmacogenomic contracts and from direct sales since 2012, but also from government grants. The commercial revenues include up-front fees and milestone fees (which are irregular in terms of timing and amounts), testing fees, contract research fees, and royalties on sales of products licensed to third parties. They also include the proceeds of direct sales of ConfirmMDx for Prostate Cancer.

Since the first sales of the ConfirmMDx for Prostate Cancer test in 2012, the Company's revenue recognition policy has limited the amount of revenue recognized. As the volume of historical reimbursement transactions from payors has grown, the basis to establish reasonable estimates of payment patterns by payor or claim categories has improved. As a result, a higher percentage of the transactional value sold is being recognized each year. Based on 2014 reported cases and historical average reimbursement amounts, the total estimated value of tests performed in 2014 was $19.1 million. Of this amount, $9.4 million was recognized as revenue, leaving uncollected outstanding unrecognized revenues of $9.6 million, consisting of $7.9 million from Medicare and $1.7 million from private payors. This compares to 2013 when the total estimated value of tests performed was $9.3 million, from which the Company recognized $3.8 million, leaving uncollected outstanding unrecognized revenues of $5.4 million, consisting of $2.9 million Medicare cases and $2.5 million non-Medicare cases. The unrecognized and uncollected amount has been excluded from the Company's revenues in each year. 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 transactions per the Company's revenue recognition policy.

At the end of 2014, MDxHealth received the Local Coverage Determination (LCD) for Medicare reimbursement of ConfirmMDx for Prostate Cancer through Palmetto GBA. The issuance of the LCD not only sets the reimbursement rate for Medicare patients, but also establishes reimbursement for Medicare Advantage patients covered by private commercial payors. By virtue of the Center for Medicare and

Medicaid Services policies, payors contracted to offer Medicare Advantage programs are legally obligated to honor the LCD. It is expected that reimbursements from Medicare and Medicare Advantage covered by private commercial payors can further increase the percentage of recognized revenue over the total transaction value of tests sold.

Cost of goods and services sold

The costs of goods include royalties that MDxHealth must pay to third parties and the costs associated with providing testing services to third parties. The cost of goods was higher in 2014 than in 2013, as a result of the higher sales of ConfirmMDx for Prostate Cancer.

Research and development expenses

Research and development expenses were $4,567 thousand in 2013 compared to $2,387 thousand in 2014, a decrease of 48%. The main reasons for the decrease in the R&D expenditures in 2014 are the following: (i) the capitalization of R&D expenses as intangible assets, for the development of the ConfirmMDx for Prostate Cancer; and (ii) the reduction of R&D activity in the course of 2013 in Belgium.

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	*2014*	*2013*
Personnel costs	936	1,957
Lab consumables	344	525
External research and development collaborators	818	1,203
Depreciation & amortization	86	452
Other expenses	192	430
Total	**2,387**	**4,567**

Selling, general and administrative expenses

In 2014, selling, general and administrative expenses amounted to $18,321 thousand compared to $13,219 thousand in 2013, an increase of 39%. The increase in costs is largely due to building US the sales, 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 commercialization of the ConfirmMDx for Prostate Cancer test. The detail of the administrative and selling expenses is as follows:

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	*2014*	*2013*
Personnel costs	10,658	8,611
Depreciation	260	248
Professional fees	2,495	1,862
Marketing expenses	1,395	1,408
Travel expenses	1,032	966
Other expenses	1,996	-369
Patent expenses	485	493
Total	**18,321**	**13,219**

Financial results

In 2014, the Company ended the year with a net financial profit of $86 thousand while it recorded a financial loss of $104 thousand in 2013. MDxHealth earned $14 thousand of interest income and financial gains in 2014 compared to $16 thousand in 2013. The net financial gain is mainly impacted by the currency exposure between Euros and USD.

Net loss

The net loss was $15,256 thousand in 2014 compared to $16,175 thousand in 2013, a decrease of 6%. This decrease is due primarily to an increase in commercial revenues, while operating costs continue to increase in order to support the commercial development of the activity.

LIQUIDITY, WORKING CAPITAL, AND CAPITAL RESOURCES FOR THE YEARS ENDED DECEMBER 31, 2015, 2014, AND 2013

Year ended December 31, 2015

MDxHealth closed the year 2015 with $31.7 million of cash and cash equivalent on hand. This corresponds to a net increase of $12.9 million. In 2015, the net cash used in operating activities amounted to $14.4 million and the net cash used in investing activities was $7.6 million, explained essentially by the acquisition of NovioGendix in The Netherlands and by large acquisitions of tangible assets for $1.6 million. The net proceed of cash from the capital increases in 2015 was $34.8 million. Excluding it from the calculation of the cash consumption, the Company burned $22 million of cash over the year.

Year ended December 31, 2014

At December 31, 2014, the cash and cash equivalents of MDxHealth amounted to $18.9 million compared to $24.7 million at the end of 2013. In 2014, net cash used in operating activities amounted to $18.5 million and net cash used by investing activities was $1.3 million. Excluding the net proceeds of $14.7 million generated from the private placement of new shares with institutional investors in November 2014, MDxHealth had a net cash burn of $20.5 million in 2014 compared to a net cash burn of $15.3 million in 2013. This 25% increase in cash used by the Company is a result of expanding operating activities supporting the commercialization of the ConfirmMDx for Prostate Cancer test, an increase in accounts receivables and the start of the PASCUAL clinical utility trial.

Year ended December 31, 2013

At December 31, 2013, the cash and cash equivalents of MDxHealth amounted to $24.7 million compared to $15.5 million at the end of 2012. In 2013, net cash used in operating activities amounted to $14.1 million and net cash used by investing activities was $1.3 million. Excluding the net proceeds of $24.3 million generated from the private placement of new shares with institutional investors in June 2013, the net cash consumption of the Company increased by $3.9 million mainly driven by the development of the US activity.

BOARD REPORT

MANAGEMENT REPORT

The following report has been established by the Board of Directors on February 17, 2016 for submission to the Annual General Shareholders' Meeting of May 27, 2016.

Dear MDxHealth Shareholder,

The present board report has been prepared in accordance with Articles 96 and 119 of the Belgian Company Code with respect to the consolidated financial statements and the statutory financial statements for the financial year ended December 31, 2015. In accordance with the Belgian Company Code 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 December 31, 2015, and this on a consolidated basis as well as a non-consolidated basis.

COMMENTS ON THE ANNUAL ACCOUNTS

Discussion and analysis of the consolidated financial statements of 2015, 2014 and 2013

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as developed and published by the International Accounting Standards Board (IASB) as adopted by the EU. They have been approved and authorized for issue by the members of the Board of Directors on February 17, 2016. Dr. Jan Groen, Executive Director, declares, in the name and on behalf of the Board of Directors, that to the best of the Board of Directors' knowledge, the consolidated financial statements of the Company prepared in accordance with IFRS, give a true and fair view of the Company and its subsidiaries' assets and liabilities, financial situation and results of operations, and that this management report presents a fair description of the Company's business evolution, results and situation, and main risks to which it is subject.

REVENUES

Total Company revenues for the full year ended December 31, 2015, increased by 51% to $17.6 million, compared to total revenues of $11.7 million for the prior year. Revenue from ConfirmMDx for Prostate Cancer represented 86% of total Q4 revenues compared to 70% in the same quarter last year. Total revenues for Q4 2015 were $5.7 million compared to $3.4 million during the same period in 2014. The increase in Q4 2015 revenues compared to the prior period was due to increased sales of ConfirmMDx and royalty and milestone payments from Exact Sciences. For the full year, ConfirmMDx for Prostate Cancer accounted for 86% of the Company's revenue, compared to only 80% in 2014.

Total revenues in 2015, 2014, and 2013 were $17.6 million, $11.7 million, and $7.6 million, respectively. The commercial revenues other than direct sales for ConfirmMDx for Prostate Cancer 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.

OPERATING CHARGES

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	2015	2014	2013
Research & development expenses	3,257	2,376	4,567
Selling, general and administrative expenses	22,358	18,321	13,219
Other operating expenses/(revenues)	-498	-137	46
Total Operating Charges	**25,117**	**20,560**	**17,832**

Total operating charges increased by 22% from $20.6 million in 2014 to $25.1 million in 2015, mainly due to the continuons development of the CLIA lab in California to support higher sales volume.

As a consequence, SG&A expenses increased by 22% from $18.3 million in 2014 to $22.4 in 2015, mainly due to the continuous buildup of US R&D, Marketing, Quality, and Administrative functions to support the development of the commercial operation in the US, while R&D expenses increased by 37% from $2.4 million in 2014 to $3.3 million in 2015.

NET RESULTS

EBITDA and net loss were $14.4 million, and $14.4 million in 2015 compared to $15.3 million, and $15.3 million in 2014.

CASH FLOW

The net cash balance increased by $12.8 million in 2015 due to the capital increases which generated a net proceed of $34.8 million to compensate the total cash burn of $22 million over the year.

BALANCE SHEET

The balance sheet at December 31, 2015 remained similar in terms of composition to previous years as evidenced by the following key ratios:

YEARS ENDED DECEMBER 31	2015	2014	2013
Cash & cash equivalents as a % of total assets	55%	61%	84%
Working capital as a % of total assets	59%	68%	78%
Solvency ratio (equity/total assets)	77%	77%	84%
Gearing ratio (Financial debt/equity)	**2%**	**0%**	**0%**

Cash and cash equivalents of $31.7 million account for 55% of total assets at December 31, 2015. The other major assets are intangible and tangible assets ($11.9 million or 21% of total assets), and receivables over the period 2015 ($11.3 million or 20% of total assets).

Total equity of $44.2 million accounts for 77% of the total balance sheet at December 31, 2015. The other major liabilities are trade payables ($6.6 million 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, 2015, the Company had net tax losses carried forward amounting to $170 million, implying a potential deferred tax asset of $58 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.

Comments on Approval of the Statutory Financial Statements

We submit for your approval the statutory financial statements for the fiscal year closed on 31 December 2015, which been approved and authorized for issue by the members of the Board of Directors on February 17, 2016. The statutory financial statements have been prepared in accordance with Belgian GAAP and give a true and fair view of the course of affairs of the Company during the past fiscal year. Dr. Jan Groen, Executive Director, declares, in the name and on behalf of the Board of Directors, that to the best of the Board of Directors' knowledge, the statutory financial statements of the Company prepared in accordance with Belgian GAAP, give a true and fair view of the Company's assets and liabilities, financial situation and results of operations.

The following can be noted on the basis of the annual accounts:

- Results of the fiscal year

The Company has closed its annual accounts with respect to the past fiscal year with a loss of €958,277.81 (USD equivalent $1,073,000). This loss results mainly from the costs related to the set-up of the US CLIA laboratory and team to support direct sales of tests since mid-2012.

- Statutory and non-distributable reserves

The Company has a corporate capital of €36,018,550.66. 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.

- Allocation of the results

We propose to carry forward the loss to the next fiscal year.

COMMENTS ON MATERIAL ITEMS

Material events that took place since the end of the fiscal year

In 2016, through the date of this document, the Company made the following normal course of business announcements:

- Published data in *The Journal of Urology* demonstrating that AssureMDx for Bladder Cancer delivers a high negative predictive value of 99.2% supporting the clinical potential of the Company's

urine-based epigenetic bladder cancer test to aid urologists in the management of patients presenting with haematuria (i.e., blood in urine).

- At American Society of Clinical Onclology (ASCO) Genitourinary Cancers Symposium In San Francisco, California, USA MDxhealth revealed data demonstrating that ConfirmMDx genes can aid in the detection of clinically significant prostate cancer, as well as difficult to detect anterior cancers, showing further the product's clinical utility for patients who may benefit from early detection and treatment .
- Frost & Sullivan granted MDxhealth the 2016 Global Prostate Cancer Diagnostics Technology Innovation Award.
- MDxHealth Provides Preliminary Update on Results, Reporting Strong Sales Trajectory for ConfirmMDx.
- MDxHealth's ConfirmMDx test is included in 2016 NCCN guidelines for prostate cancer early detection.

Significant change in the Company'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.

Recent Trends and Events

In 2016, we made the following normal course of business announcements:

- Frost & Sullivan granted MDxhealth the 2016 Global Prostate Cancer Diagnostics Technology Innovation Award.
- MDxHealth Provides Preliminary Update on 2015 Results, Reporting Strong Sales Trajectory for ConfirmMDx.

With regard to trends that are reasonably likely to have a material effect on MDxHealth in 2016, we believe the following can be noted:

- For the fiscal year 2016, we expect to see continued growth in test volumes and revenue driven by the increase in sales representatives, new payor contracts, introduction of the ConfirmMDx for Prostate Cancer likelihood profile and the launch of SelectMDx for Prostate Cancer on the EU and US market. With increasing product volumes and expanding coverage with payor contracts, both revenue and cash collections for 2016 are anticipated to improve. Importantly, increasing payor coverage is expected to improve days sales outstanding (DSO) for receivables.

- As we continue to establish MDxHealth as a market leader in molecular diagnostics for uro-oncology, the expansion of our portfolio with "liquid biopsy" tests such AssureMDx for Bladder Cancer, expected to launch later in 2016, allows us to address a larger segment of the urology market.

- We expect that operating expenses might increase primarily from the expansion of sales and marketing efforts in the US. Accordingly, 2016 net loss and cash burn are expected to increase versus 2015, while R&D are expected to remain at current levels.

Capital increases and issuance of financial instruments

The board of directors has used its powers under the authorised capital provided for in article 6.1., on June 23, 2015, up to four million, nine hundred and five thousand, eight hundred and fifty-five euros (€4,905,855), by the issuance of six million hundred fifty thousand (6,150,000) shares, and on September 18, 2015, up to eight hundred sixty-seven thousand, sixty-four euros and eighty cents (€ 867,064.80) by issuing 1,086,956 shares. As a result, the available amount for a share capital increase under the authorized capital is equal to six million, four hundred ninety-four thousand, nine hundred fifty-seven euros and seventy cents (€ 6,494,957.70).

Activities in the field of research and development

In 2015, 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 clinical trials. Extensive work was performed in development of the Company's clinical solutions for prostate and bladder cancers.

Obligations not reflected in the 2015 financial statements

All known obligations are reflected in the 2015 financial statements.

Branches of the Company

The Company has no branch.

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 2017.

Financial risks (article 96 8° Belgian Company Code)

Effective January 1, 2013, the Company changed the presentation currency of the consolidated financial statements from the Euro (EUR or €) to the US Dollar (USD or $). MDxHealth believes that this change provides greater alignment of the presentation currency with MDxHealth's most significant operating currency and underlying financial performance.

Effective July 1, 2014, the Company decided to change its functional currency from Euro to US Dollar.

Virtually all of the Company's currency risk currently relates to Euro. At this time, the Company does not use hedging instruments to cover the exchange rate risk.

Risk factors (article 96 1° Belgian Company Code)

In 2015, the Company was potentially subjected to the following risks:

- 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's financial results are largely dependent on sales of one test, ConfirmMDx for Prostate Cancer, and the Company will need to generate sufficient revenues from this and other future solutions to grow its business;
- The ability of the Company to execute its business strategy is dependent upon factors such as its ability to raise additional capital at acceptable terms in the future and to manage growth and international business development;
- 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'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 is dependent on intellectual property rights which could be challenged and the Company could be affected by new patents of 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 is subject to product liability risks;
- Foreign exchange rate fluctuations could impact the results of the Company.

In 2015, financial risk management involved primarily the following:

- Credit risk: At the end of 2015, the Company operated with more than 400 different customers, representing a significant reduction in credit risk when compared to prior periods. In 2013, the Company reduced its credit risk from the reliance on a small number of customers by generating 50% of its revenues related to ConfirmMDx for Prostate Cancer with a large range of customers. In 2015, the trend initiated in 2013 continued, with the consequence that the credit risk is highly reduced considering the high number or customers.
- Interest risk: The Company is not currently subject to material interest risk since its financial debts represent only 2% of its total equity.
- Currency risk: Considering the continuing development of the commercial activities in the US market, the Company has decided to change its presentation currency from the Euro to the US

Dollar as of January 1, 2013. The functional currency changed also from the Euro to the US Dollar as of July 1, 2014. In consequence, the currency risk is concentrated in Euros.

- Liquidity and investment risk: 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.

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 10,000 warrants in 2015 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 the May 2014 Stock Option Plan on June 23, 2014 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 below in "- Corporate Governance Statement; Board of Directors; Committees of the Board of Directors; Audit Committee".

Mrs. Ruth Devenyns meets the criteria of necessary competence in auditing and accounting: She has worked in the venture capital sector.

CORPORATE GOVERNANCE STATEMENT

GENERAL PROVISIONS

This chapter summarizes the main rules and principles of MdxHealth's Corporate Governance Charter. The complete Corporate Governance 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 Corporate Governance Charter forms an integral part of this Report of the Board of Directors. MdxHealth has adopted the 2009 Code as its reference code. It complies to a large extent with the provisions of the 2009 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 2009 Code, 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 2015 annual general shareholders' meeting have been awarded warrants.

- The performance and functioning of the Board of Directors, its committees, and the Executive Management team are summarized below.

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 6 Directors, of which 3 are Independent Directors and 3 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 is 1 female Director among a total of 6 Board members (representing a ratio of 17% female Directors against 83% male Directors). The Belgian Company Code provides that by January 1, 2017, at least one third of the members of the Board of Directors will have to be of the opposite gender.

The deadline to comply with this onligation is January 1, 2018 for companies that meet on a consolidated basis at least two of the following criterias: (a) an average number of employees of less than 250; (b) a balance sheet total of €43 million or less; and (c) an annual turnover of €50 million or less. The Company complies with at least two of these criterias. 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, the Board of Directors met 11 times throughout 2015. All Directors were present or represented at these 11 meetings, except for Valutesan Ltd., represented by its permanent representative, Dr. Rudi Pauwels, which was not represented at 3 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, Greenlands Consulting LLC, with Mr. Edward L. Erickson as permanent representative, 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 four Independent MDxHealth Directors listed in the table below meet at least the criteria set out in article 526ter of the Belgian Company Code, which can be summarized as follows:

- Not being an executive member of the board of directors, exercising a function as a member of the executive committee or as a person entrusted with daily management of the Company or a company or person affiliated with the Company, and not having been in such a position during the previous five years before his nomination.
- Not having served for more than three terms as a non-executive director of the board of directors, without exceeding a total term of more than twelve years.
- Not being an employee of the senior management (as defined in article 19, 2° of the Belgian Act of September 20, 1948 regarding the organisation of the business industry) of the Company or a company or person affiliated with the Company and not having been in such a position for the previous three years before his nomination.
- Not receiving, or having received, any significant remuneration or other significant advantage of a financial nature from the Company or a company or person affiliated with the Company, other than any bonus or fee (tantièmes) he receives or has received as a non-executive member of the board of directors.

- Not holding (directly or via one or more companies under his control) any shareholder rights representing 10% or more of the Company's shares or of a class of the Company's shares (as the case may be), and not representing a shareholder meeting this condition.
- If the shareholder rights held by the director (directly or via one or more companies under his control) represent less than 10%, the disposal of such Shares or the exercise of the rights attached thereto may not be subject to contracts or unilateral undertakings entered into by the director. The director may also not represent a shareholder meeting this condition.
- Not having, or having had within the previous financial year, a significant business relationship with the Company or a company or person affiliated with the Company, either directly or as partner, shareholder, member of the board of directors, member of the senior management (as defined in article 19, 2° of the aforementioned Belgian Act of 20 September 1948) of a company or person who maintains such a relationship.
- Not being or having been within the last three years, a partner or employee of the current or former statutory auditor of the Company or a company or person affiliated with the current or former statutory auditor of the Company.
- Not being an executive director of another company in which an executive director of the Company is a non-executive member of the board, and not having other significant links with executive directors of the Company through involvement in other companies or bodies.

Not being a spouse, legal partner or close family member (by marriage or birth) to the second degree of a member of the board of directors, a member of the executive committee, a person charged with the daily management, or a member of the senior management (as defined in Article 19, 2 of the aforementioned Belgian Act of September 20, 1948) of the Company or a company or person affiliated with the Company, or of a person who finds him or herself in one or more of the circumstances described in the previous bullets.

Composition of the Board of Directors

The table below describes the composition of the Board of Directors as of the date of this Annual Report.

NAME	*AGE ON DEC 31, 2015*	*POSITION*	*TERM START[1]*	*TERM END[2]*	*PROFESSIONAL ADDRESS*
Greenlands Consulting LLC, represented by **Mr. Edward L. Erickson**	69	Chairman, Non-Executive Independent Director	2013	2017	CAP Business Center Rue d'Abhooz, 31 4040 Herstal, Belgium
Dr. Jan Groen	56	Executive Director	2010	2017	CAP Business Center, Rue d'Abhooz, 31 4040 Herstal, Belgium
Gengest BVBA, represented by **Mr. Rudi Mariën**	70	Non-Executive Director	2011	2017	Karel van de Woestijnestraat 1-3, 9000 Gent, Belgium
Mrs. Ruth Devenyns	50	Non-Executive Independent Director	2011	2016	Kardinaal Sterckxlaan 47 - 1860 Meise, Belgium

Valiance Advisors LLP, represented by **Mr. Jan Pensaert**	44	Non-Executive Director	2014	2018	Lilly House 13 Hanover Square London W1S 1HN United Kingdom
Lab Dx L.L.C., represented by **Mr Walter Narajowksi**	62	Non-Executive Independent Director	2015	2018	CAP Business Center, Rue d'Abhooz, 31 4040 Herstal, Belgium

Notes:

1) Mr. Edward L. Erickson, presently serving as permanent representative of Greenlands Consulting LLC, was initially appointed as director of the Company in his individual capacity in 2010. As a result of the vacancy due to the resignation of LaurelWey Consulting LLC, represented by Mr. Mark Myslinski, as director of the Company, the Board nominated Lab Dx L.L.C., represented by its permanent representative Walter Narajowski. Subject to the provisions of Article 519 of the Belgian Companies Code, the director shall complete the term of the mandate of the resigning director who was appointed for a term continuing up to and including the annual general meeting to be held in 2018.

2) The term of the mandates of each Director will expire immediately after the annual general shareholders' meeting held on the last Friday of the month of May in the calendar year indicated.

Mr. Edward L. Erickson has over 30 years of executive, board-level and advisory experience in medical devices, therapeutics, and life science research products having served as chairman, president, CEO or a director of over a dozen companies in these industries. He was previously President and CEO of Saladax Biomedical, Inc., a diagnostics company developing and commercializing companion diagnostic and therapeutic dose management assays. 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 (IPOs) under his leadership. Earlier in his career, he held executive positions at The Ares-Serono Group (acquired by Merck KGaA) and Amersham International (acquired by GE). 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 US Navy's nuclear submarine force.

Dr. Jan Groen joined MDxHealth in 2010 and has over 30 years of executive and Board level experience in the clinical diagnostic and biotech industry, with a particular focus on emerging technologies, product development and commercialization. Dr. Groen was previously the president and COO of Agendia, a venture backed CLIA laboratory developing and commercializing proprietary genomic products and 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 private owned company focusing on infectious diseases and immunology, which was acquired by Quest Diagnostics in 2006. 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 board member of MyCartis BvBa. Dr. Groen holds a Ph.D. degree in medical microbiology from the Erasmus University

Rotterdam and published more than 125 papers in international scientific journals in the field of clinical diagnostics.

Mr. Rudi Mariën is President and Managing Director of Gengest BVBA and Biovest CVA. He was the Vice President of Cerba European Lab. Through his management company, Gengest BVBA, Mr. Mariën has Board mandates in different listed and private biotech companies. 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 including 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 is currently serving as Chief Financial Officer at EuroScreen S.A. 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 agro-biotech 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 member of FlandersBio, the biotech sector organization in Flanders.

Mr. Jan Pensaert is the founder and CEO/CIO of Valiance Advisors LLP, a specialist investment business with offices in London and Guernsey, formed in 2008. From 2003 to 2007, he was CEO of La Fayette Investment Management, a leading fund of hedge funds, where he was responsible for the overall business management of the firm, as well as second member of the investment committee. Prior to La Fayette, Mr. Pensaert was responsible for the European-based investment management and research activities of the Permal Group (assets under management of $10 billion at the time) from 2001-2003. Prior to that, he was active at Lazard in Corporate Finance M&A, where he advised on transactions with a total value of more than $40 billion. He holds a BA in Business Economics from the University of Gent, Belgium, and a Masters in Banking & Finance from the University of Aix-Marseille.

Mr. Walter Narajowski has over 25 years of executive and board level experience in the diagnostic industry. Until the end of 2015, Mr. Narajowski served as Senior Vice President and General Manager at Roka Bioscience (NASDAQ: ROKA) in San Diego. Previously, Mr. Narajowski was CEO of Pathway Diagnostics, a biomarker development and testing company, which was subsequently sold to Quest Diagnostics. Prior to Pathway, Mr. Narajowski served as Vice President and General Manager of Focus Diagnostics, an infectious disease CLIA reference laboratory and diagnostic product business.

The majority of Mr. Narajowski's career was with Abbott Laboratories where he served as Vice President, General Manager of critical care products, vice president, general manager of the infusion pump business, General Manager of physician office diagnostics, and a Director of research and development. Mr. Narajowski received his MS in bioengineering from the University of Utah, and his BS in electrical engineering from the Illinois Institute of Technology.

Litigation statement concerning the Directors or their permanent representatives

At the date of this Annual Report, none of the Company's Directors, or in case of corporate entities being Directors, none of their permanent representatives, other than those indicated in the paragraph below, for at least the previous five years:

- has any conviction in relation to fraudulent offenses;
- has 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:
  - 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 ;
  - Mrs. Ruth Devenyns, who was a director of two US companies that filed for bankruptcy, PR Pharmaceuticals in 2008 and Altea Therapeutics in 2011: and
  - Mr Rudi Mariën, who was, through his management company, a director of a Belgian company, Pharmaneuroboost, that filed for bankruptcy in 2013.
- 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

On January 8, 2009, updated 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 "Board of Directors" section of this Corporate Governance Statement above), and (iii) the appointment of and dismissal of statutory auditors (see "Statutory Auditor" section of this Corporate Governance Statement below).

- MDxHealth has had an audit committee in place since the Company's inception. According to applicable law, 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.

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 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.

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 follow-up 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; and
- 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 Non-Executive Directors were members of the audit committee in 2015: Mrs Ruth Devenyns (chairperson), Greenlands Consulting LLC, represented by Mr. Edward Erickson, and Valiance Advisors LLP, represented by Mr. Jan Pensaert. As requested by law, the chair of the audit committee is competent in accounting and auditing, as is evidenced her current role as chief financial officer of Euroscreen SA, and her previous roles.

The audit committee is a collegial body, and deliberates and makes decisions as such. The audit committee met 3 times in 2015. All members of the audit committee were present or represented at all meetings.

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 Non-Executive Directors were members of the nomination and remuneration committee : Lab Dx L.L.C., represented by Mr. Walter Narajowski (chairman of the committee) Independent Director, Greenlands Consulting LLC, represented by Mr. Edward Erickson, Independent Director, and Gengest BVBA, represented by 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 2 times in 2015. 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.

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 each Director's own performance and the performance of its 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.

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.

The key management positions in 2015 are illustrated below:

DR JAN GROEN
CEO

MR JOSEPH SOLLEE
EVP Corporate Development & General Counsel

MR CHRIS THIBODEAU
EVP and Chief Commercial Officer

MR FRANCIS OTA
EVP Finance

DR PHILIP GINSBURG
EVP and Chief Medical Officer

MS MIRIAM REYES
Sr VP of Laboratory Operations

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.

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.

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	AGE ON DEC 31, 2015	POSITION	PERMANENT ADDRESS
Dr. Jan Groen	56	Chief Executive Officer (CEO)	CAP Business Center Rue d'Abhooz, 31 4040 Herstal, Belgium
Mr. Joseph Sollee	51	Executive Vice President of Corporate Development & General Counsel (GC)	15279 Alton Pkwy, Ste 100 Irvine, CA 92618, USA
Mr. Christopher Thibodeau	45	Executive Vice President & Chief Commercial Officer (CCO)	15279 Alton Pkwy, Ste 100 Irvine, CA 92618, USA
Mr. Francis Ota	63	Executive Vice President of Finance	15279 Alton Pkwy, Ste 100 Irvine, CA 92618, USA
Dr. Philip Ginsburg	61	Executive Vice President & Chief Medical Officer	15279 Alton Pkwy, Ste 100 Irvine, CA 92618, USA
Ms. Miriam Reyes	43	Senior Vice President of Laboratory Operations	15279 Alton Pkwy, Ste 100 Irvine, CA 92618, USA

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

See *"Board of Directors - Composition of the Board of Directors".*

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. Mr. 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 & GENERAL COUNSEL

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 life sciences 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 (JD) and a Master's degree in International & Comparative Law (LLM) 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 & CHIEF COMMERCIAL OFFICER

Mr. Thibodeau joined MDxHealth in September 2010 and brings 20 years of commercial leadership experience, principally in the life sciences and diagnostics arena. As Chief Commercial Officer, he is responsible for MDxHealth's commercial operations. 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 US 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.

MR. PHILIP GINSBURG, MD, EXECUTIVE VICE PRESIDENT & CHIEF MEDICAL OFFICER

Dr. Ginsburg has over 20 years of commercial medical laboratory and urology experience. As Chief Medical Officer, he has overall responsibility for clinical strategy, including scientific and clinical affairs. Before joining the Company, Dr. Ginsburg was CMO at Toma Biosciences, Iris International, Inc. and President of Arista, a Personalized Medicine division of Iris acquired by Beckman Coulter, a subsidiary of Danaher Corporation. Prior to Iris International, he was CEO, Co-founder, and CMO of AlliedPath Inc., a CLIA certified molecular diagnostic laboratory, which was ultimately acquired by Iris International in 2010. Dr. Ginsburg also served as Senior Medical Director at Gen-Probe, Inc., where he was involved with the clinical development program for their PCA3 test for prostate cancer detection, and formerly served as a Medical Director at Quest Diagnostics. Dr. Ginsburg earned his medical degree at the University of Pretoria School

of Medicine, South Africa, later specializing in clinical pathology at the University of Witwatersrand and the South African Institute of Medical Research.

MS. MIRIAM REYES, SENIOR VICE PRESIDENT OF LABORATORY OPERATIONS

Ms. Reyes has over 20 years of experience in molecular diagnostics, specifically focused on R&D and lab operations. As Senior Vice President of Laboratory Operations, she is responsible for directing and managing all aspects of the California CLIA lab operations. Prior to joining MDxHealth, Ms. Reyes served as Director of Lab Operations at Agendia Inc. Ms. Reyes is a Certified Laboratory Specialist in Molecular Biology. She holds a Bachelor degree in Science as well as an MBA degree in Healthcare from the University of California in Irvine.

SHAREHOLDING STRUCTURE

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*
Alychlo NV	1,459,938	3.23%	Aug. 28, 2015	Aug. 31, 2015
Biovest Comm.VA.	6,156,525	13.63%	June 26, 2015	July 1, 2015
Valiance Asset Management	5,866,834	12.99%	June 30, 2015	July 3, 2015
Total of Notified Shares	12,023,359	26.63%		
Total Outstanding Shares	45,153,633	100.00%		

Biovest Comm. VA is an investment company owned and managed by Mr. Rudi Mariën. Mr. Mariën also serves as a permanent representative of Gengest BVBA on the Board of Directors of MDxHealth. Valiance Asset Management Ltd. is an investment company managed by Mr. Jan Pensaert. Mr. Pensaert also serves as a permanent representative of Valiance Advisors LLP on the Board of Directors of MDxHealth.

The voting rights of the major shareholders of the Company in no way differ from the rights of other shareholders in the Company.

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.

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 Board of Directors has established a Code of Business Conduct and Ethics to aid MDxHealth's directors, officers and employees in making ethical and legal decisions when conducting Company business and performing their day-to-day duties. The Code of Business Conduct and Ethics is available in its entirety on the Company's website (www.mdxhealth.com).

The risks that the Company is subject to are discussed at the beginning 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 or components for ConfirmMDx testing 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 Code of Business Conduct and Ethics and 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.

COMPLIANCE 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 2009 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 the 2009 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 the 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 Directors have been awarded warrants.

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).

STATUTORY AUDITOR

Services performed by the auditor and performance of exceptional activities or execution of special instructions (Article 134 Belgian Company Code)

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, was re-appointed on May 29, 2015 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 2018. BDO has been the statutory auditor since January 10, 2003. It is anticipated that BDO will be recommended by the Board of Directors for reappointment at the upcoming annual shareholder's meeting to be held on May 29, 2015. Mr. Gert Claes has represented BDO since May 29, 2015.

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.

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 Company expensed €123 thousand (USD equivalent $136 thousand) in fees to the auditor in 2015. The fees are broken down as follows:

- Audit fee for statutory and consolidated financials of €65 thousand ($72 thousand)
- Audit related services (comfort letter procedures, legal missions,…) €39 thousand ($43 thousand)
- Other missions €5 thousand (USD equivalent $6 thousand) and tax consulting services €4 thousand ($4 thousand)
- Specific review of Purchase Price Allocation NovioGendix €10 thousand (USD equivalent $11 thousand)

CONFLICTS OF INTEREST (ARTICLE 523 BELGIAN COMPANY CODE)

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 Belgian Company Code.

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 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 conflicts of interests have been reported in 2015, in each instance prior to the deliberations regarding proposals in relation to the remuneration of Dr. Jan Groen, Managing Director and CEO of the Company:

Minutes of the Meeting of the Board of Directors held on January 23, 2015

Prior to the deliberation and resolutions regarding the remuneration and personnel matters, Dr. Jan Groen, Managing Director and CEO of the Company, made the following declarations to the Board of Directors, as far as necessary and applicable in accordance with Article 523 of the Belgian Company Code. Dr. Jan Groen informed the meeting that the items to be discussed by the Board of Directors also concerned the remuneration of his mandate as CEO, and that he therefore had a financial interest that conflicts with the discussion and the deliberation by the Board of Directors with respect to the remuneration of his mandate as CEO. Dr. Jan Groen stated that he would inform the Statutory Auditor of the Company of the aforementioned conflict of interest in accordance with Article 523 of the Belgian Company Code. After having made the aforementioned statement, Dr. Jan Groen excused himself from the meeting and left the meeting.

Minutes of the Meeting of the Board of Directors held on June 15, 2015

Prior to the deliberations, Gengest BVBA represented by Rudi Mariën, informed the other members of the Board of Directors, as far as necessary and applicable in accordance with Article 523 of the Belgian Company Code, 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.

Some of the points at the agenda of the present Board meeting are related to the Private Placement through issuance of new shares. In order to make the shares directly available to the market after the transaction, Bioves Comm. VA will reach an agreement with Petercam NV/SA. 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 Belgian Company Code.

The financial consequences of the capital increase are further described in the notes to the financial statement of this Annual Report.

Minutes of the Meeting of the Board of Directors held on June 24, 2015

Prior to the deliberations, Gengest BVBA represented by Rudi Mariën, informed the other members of the Board of Directors, as far as necessary and applicable in accordance with Article 523 of the Belgian Company Code, 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.

Some of the points at the agenda of the present Board meeting are related to the Private Placement through issuance of new shares. In order to make the shares directly available to the market after the transaction, Bioves Comm. VA will reach an agreement with Petercam NV/SA. 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 Belgian Company Code.

The financial consequences of the capital increase are further described in the notes to the financial statement of this Annual Report.

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, 4 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 27, 2013, the Board of Directors has been expressly authorized to increase the share capital in one or more transactions with an amount of up to €15,000,000.00 (the "Authorized Capital"), subject to certain limitations and conditions described below.

The Board of Directors has used its powers under the Authorised Capital, on November 4, 2014, up to two million, seven hundred and thirty-two thousand, hundred and twenty-two euros, and fifty cents (€2,732,122.50), by the issuance of three million four hundred and twenty-five thousand (3,425,000) shares, and on June 23, 2015, up to four million, nine hundred and five thousand, eight hundred and fifty-five euros (€4,905,855.00), by the issuance of six million hundred fifty thousand (6,150,000) shares, and on September 18, 2015, up to eight hundred sixty-seven thousand, sixty-four euros and eighty cents (€867,064.80) by issuing 1,086,956 shares. As a result, the available amount for a share capital increase

under the Authorized Capital is equal to six million, four hundred ninety-four thousand, nine hundred fifty-seven euros and seventy cents (€6,494,957.70).

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 2016 which shall resolve on the annual accounts relating to the accounting year ending on December 31, 2015. This authorization may be renewed in accordance with the relevant legal provisions.

The capital increases that can be decided according to the Authorized Capital 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 27, 2013, 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.

REMUNERATION REPORT

The following report has been prepared by the nomination and remuneration committee and approved by the Board of Directors of MDxHealth on February 17, 2016. This report contains the remuneration report as referred to in Article 96, §3 of the Belgian Company Code (the "Remuneration Report"). 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, as supplemented by the relevant provisions of the 2009 Belgian Corporate Governance Code, and has prepared this Remuneration Report in accordance with the requirements contained therein.

PROCEDURE ADOPTED IN 2015

Procedure adopted to develop a remuneration policy

During 2015, MDxHealth has continued to apply the remuneration policy first adopted in 2012. 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 will be submitted to a vote by the annual general shareholders' meeting. The main recommendations seek to align the interests of the Board members with the goals of the Company, and 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 ten thousand (10,000) stock warrants to each Non-Executive Board member, under the terms of a Company warrant program.

These recommendations, as reflected in the remuneration policy, were first implemented in 2012 and, except for an increase in the fixed annual warrant grant from six thousand (6,000) to ten thousand (10,000) warrants, remained applicable for the accounting year 2015. The increase in annual warrants grants was first approved at the annual general shareholders' meeting held in May 2014.

Procedure adopted to determine the level of remuneration

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.

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 2015

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

DIRECTORS

The remuneration policy for Non-Executive and executive Directors was modified at the annual shareholders' meeting of May 25, 2012, and remained in effect for the accounting year 2015.

- 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.:
- €35,000 (USD equivalent $38,836[1]) for the Chair of the Board of Directors;
- €30,000 ($33,288[1]) for the Chair of the Audit Committee;
- €28,000 ($31,069[1]) for the Chair of the Nomination and Remuneration Committee; and
- €25,000 ($27,740[1]) 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 meetings of the Board of Directors, including committee meetings, is expected. In the event 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 2015, the two Non-Independent Directors, who have not held an executive position within the Company, agreed to waive their Director's 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.

[1] Exchange rate 1 €= 1.1096 $ (historical rate 2015)

- 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, 2°, b) of the Belgian Company Code, is provided below under the "Remuneration Amounts for the Reported Year" section of this Remuneration Report.

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 or 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, and (ii) 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 2015, all the members of the executive management 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 notice or

payment in line with market standards (see also above). 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 2015.

EXPECTED CHANGES WITH RESPECT TO ACCOUNTING YEAR 2016 AND THE FOLLOWING ACCOUNTING YEAR

No significant change to the remuneration policy of Directors and Executive managers is envisaged for 2016 or the following accounting year.

The bonuses of the management team members for 2016 and the following accounting year 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;
- meeting measurable operational targets, including specific product development and commercialization goals.

Remuneration amounts for the reported year

REMUNERATION EARNED BY THE NON-EXECUTIVE DIRECTORS FOR THE REPORTED YEAR

The following table provides the 2015 compensation of the Non-Executive Directors in function at the date of this document :

REMUNERATION REPORT

NAME[1]	POSITION[2]	PRO-RATA OF ANNUAL RETAINER FEE (€K)	OTHER SERVICES (€K)	TOTAL[3] (€K)
Mr. Erickson	NED – Board Chair, member AC & NRC	35	0	35
Mrs Devenyns	NED – AC Chair	30	0	30
Mr. Mariën	NED – member NRC	0	0	0
Mr. Pensaert	NED – member AC	0	0	0
Mr. Narajowski	NED – NRC Chair (as from October 2015)	6	0	6
TOTAL for Non-Executive Board members		71	0	71

Notes:

[1]: Mr. Edward Erickson serves on the Board as a permanent representative of Greenlands Consulting, LLC. Mr. Rudi Mariën serves on the Board as a permanent representative of Gengest BVBA. Mr. Jan Pensaert serves on the Board as a permanent representative of Valiance Advisors LLP. Mr Mark Myslinski served on the Board as a permanent representative of LaurelWey Consulting LLC.

[2]: "NED" = Non-Executive Director, "AC" = Audit Committee, "NRC" = Nomination & Remuneration Committee.

[3]: Excludes expense reimbursement and warrants. No other form of remuneration exists for Directors.

During the course of 2015, the composition of the Board of Directors changed.

During the course of 2015, the Company has not deviated from its remuneration policy for the Non-Executive Directors. The total remuneration of the Board of Directors (including the Executive Director) in 2015, 2014, and 2013 was €671,000 ($745,000), €634,000 ($842,000), and €639,000 ($850,000) respectively (excluding VAT, stock-based compensation and expenses reimbursement).

On May 23, 2006, the Board of Directors decided, with application of Article 523 of the Belgian Company Code, that the Company would 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 2015. Additionally, the Company's US subsidiary, MDxHealth, Inc., has 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, US-associated activities of the US subsidiary or of the Company, including any claims based on a theory of derivative liability in the right of the US 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 of 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 €22,000,

linked to his capacity to manage human resources costs. Excluding the value of warrants, the remuneration and benefits provided to the CEO in 2015 were composed as follows :

	EURO (€)	$ EQUIVALENT
Fixed gross remuneration[1]:	413,155	458,437
Bonuses paid and awarded[2] (gross) :	104,756	116,237
Pension benefits:	15,024	16,671
Other benefits[3]:	50,812	56,380
TOTAL	583,747	647,725

Notes:

1: Total cost to the Company, including employer social security contributions and vacation pay accrual.

2: Excludes value of 350,000 warrants already created, issued, and accepted (under several warrants plans).

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 2015, 2014 and 2013 were €583,000 €546,000, and €514,000, respectively (in USD equivalent $648,000, $726,000 and $683,000 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.

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 €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 €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, with the following characteristics:

- Exercise price of €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 €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:

- €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 of the date of their grant.

The IFRS share-based compensation of the above 45,000 warrants granted in 2012 amounts to €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:

- €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 of the date of their grant.

The IFRS share-based compensation of the above 45,000 warrants granted in 2013 amounts to €52,000.

At the Board meeting of January 27, 2014, the non-conflicted members of the Board of Directors agreed to the following bonus for the performance of Dr. Jan Groen in 2013:

- €75,800 cash bonus
- 50,000 new warrants (employee stock options) formally granted on March 12, 2014 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 of the date of their grant.

The IFRS share-based compensation of the above 50,000 warrants granted in 2014 amounts to €86,900.

At the Board meeting of January 22, 2015, the non-conflicted members of the Board of Directors agreed to the following bonus for the performance of Dr. Jan Groen in 2014:

- €105,797 cash bonus
- 50,000 new warrants (employee stock options) formally granted on February 9, 2015 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 of the date of their grant.

The IFRS share-based compensation of the above 50,000 warrants granted in 2015 amounts to €104,750.

At the Board meeting of February 4, 2016, the non-conflicted members of the Board of Directors agreed to the following bonus for the performance of Dr. Jan Groen in 2015:

- €104,756 cash bonus
- 50,000 new warrants (employee stock options) formally granted on February 4, 2016 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 of the date of their grant.

The IFRS share-based compensation of the above 50,000 warrants granted in 2016 amounts to €78.050.

REMUNERATION REPORT

During the course of 2015, the Company has not deviated from its remuneration policy for the Executive Director.

REMUNERATION EARNED BY OTHER EXECUTIVE MANAGERS

The 2015 combined remuneration package of the 5 other executive management team members (excluding the CEO) - i.e. Christopher Thibodeau, Joseph Sollee, Francis Ota, Philip Ginsburg and Miriam Reyes - including employer taxes, was €1,266,000.

	EURO (€)	*$ EQUIVALENT*
Fixed gross remuneration[1]:	980,157	1,087,581
Bonuses paid and awarded[2] (gross) :	209,830	232,827
Pension benefits:	37,214	41,293
Other benefits[3]:	38,313	42,513
TOTAL	1,265,514	1,404,214

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 2015, 2014 and 2013 was € 1.3 million, €1.2 million and €1.2 million, respectively (USD equivalent $1.4 million, $1.6 million and $1.5 million respectively) (gross amount, excluding VAT and stock based compensation). In the aforementioned figures, the service fees of the managers hired on the basis of a service agreement are included with the salaries of the other management team members.

At the Board meeting Februray 4, 2016, cash bonuses were awarded to certain executive management team members for their performance in 2015 as follows (amounts exclude employer taxes):

- CEO €104,756 ($116,237)
- Other Executive Management €209,829 ($232,827)

The primary performance objectives for the bonuses of the above management team members in 2015 were the following:

- respect of the Board-approved annual budget, with a focus on cash-flow management
- meeting measurable operational targets, such as the commercialization of its ConfirmMDx for Prostate test and attainment of revenue targets

In the course of 2015, 222,187 warrants were exercised; Dr Jan Groen exercised 202,187 warrants, Joseph Sollee exercised 20,000 warrants.

REMUNERATION REPORT

During the course of 2015, the Company has not deviated from its remuneration policy for the executive managers.

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. At the meeting of the Board of Directors on December 4, 2013, the Board directed the nomination and remuneration committee to review and assess the remuneration of members of the executive management against industry standards. Following its review and assessment, the nomination and remuneration committee prepared a report and proposal on January 16, 2014, recommending to the Board that certain changes to the existing remuneration terms and levels be implemented. Upon the advice and recommendation of the nomination and remuneration committee, the non-conflicted members of the Board of Directors approved on January 27, 2014, that a number of changes be implemented, including notably an extension of the severance notice or payment, and a retention bonus to encourage employee retention in the event of certain events. Inclusive of the aforementioned changes, the special contractual provisions with each member of executive management include the following terms:

- 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 eighteen (18 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 nine (9) 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 six (6) months gross remuneration and benefits; and
- 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 six (6) months gross remuneration and benefits.
- the employment contract with Dr. Philip Ginsburg provides that if the employment contract is terminated for a reason other than serious misconduct, he will be entitled to a severance pay of six (6) months gross remuneration and benefits.
- the employment contract with Ms. Miriam Reyes provides that if the employment contract is terminated for a reason other than serious misconduct, she will be entitled to a severance pay of three (3) months gross remuneration and benefits.

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.

2015 SHARE-BASED COMPENSATION OF DIRECTORS AND EXECUTIVE MANAGERS

During the course of 2015, the following share-based compensation was given to Directors of MDxHealth:

- Each Non-Executive Director received 10,000 new warrants
- Dr. Jan Groen, CEO and Executive Director, received 50,000 new warrants
- The 5 other current members of the Executive management team received a total of 160,000 new warrants

In reference to the 10,000 new warrants received by each Non-Executive Director in 2015, each Non-Executive Director received:

- 10,000 new warrants at the annual general shareholders meeting of May 29, 2015, with the following characteristics:
  - Exercise price of €4.91 (one stock option (warrant) gives right to buy one share)
  - Cliff vesting over 1 year for all beneficiaries
  - Duration of options: 10 years

A total of 230,000 warrants were granted to executive management in 2015, as follows:

- 155,000 warrants were granted based on a decision of the Board of Directors on January 22, 2015, with the following characteristics:
- Exercise price of €4.49 (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
- 75,000 warrants were granted based on a decision of the Board of Directors on January 22, 2015, with the following characteristics:
  - Exercise price of €4.20 (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

An additional 180,000 warrants were granted to executive management in 2016, based on a decision of the Board of Directors on February 4, 2016, with the following characteristics:

- Exercise price of €3.78 (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

REMUNERATION REPORT

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

Done on April 18, 2016
On behalf of the Board of Directors

GENERAL INFORMATION

THE COMPANY

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 Cap Business Center, Rue d'Abhooz 31, 4040 Herstal, Belgium. The Company's phone number is +32 4 364 20 70 (Belgium) and +1 949 812 6979 (US).

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).

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 into 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.

CAPITAL AND SHARES

The descriptions provided below are only a summary and do not purport to give a complete overview of the Company's articles of association nor all relevant provisions of Belgian law. Neither should it be viewed as legal advice regarding the shares.

HISTORY OF SHARE CAPITAL

At the end of 2015, the issued capital of MDxHealth amounted to € 36,018,550.66 represented by 45,153,633 common shares without nominal value.

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 of shares issued	Issue price per share		Capital increase (000 €)	Share Capital after transaction (000€)	Share Capital after transaction (000$)	Aggregate # of shares after capital increase
			share (EUR)	post stock-split (EUR)				
Jan. 10, 2003	Incorporation	202,975	0.3	0.06	62	62		202,975
Phase I Financing Round December 20, 2002 (Preferred A Shares)								
Feb. 7, 2003	Capital increase in cash	197,025	20	4	3,941	4,002		400,000
Jun. 30,2003	Capital increase in cash	33,333	20	4	667	4,669		433,333
Sep.30,2003	Capital increase in cash	218,139	22.31	4.46	4,867	9,535		651,472
Jun. 20,2004	Capital increase in cash	195,504	23.87	4.77	4,667	14,202		846,976
Phase II Financing Round October 19, 2005 (Preferred B Shares)								
Oct. 28,2005	Capital increase in cash	375,000	24.00[7]	4.80[7]	9,000	23,202		1,221,976
Mar.31,2006	Capital increase in cash	193,548	31	6.2	6,000	29,202		1,415,524
Stock Split								
May23,2006	Stock split 5/1	/	/	/	/	/		7,077,620
Initial Public Offering and Exercise of Over-Allotment Warrants								

Jun. 30,2006	Capital increase in cash	2,933,334	7.5		7.5	22,000	51,202	10,010,954
Jun. 30,2006	Capital decrease	/	/		/	-10,218	40,984	10,010,954
Jun. 30,2006	Capital increase through exercise of warrants	440,000	7.5		7.5	1,817	42,801	10,450,954
Exercise of Warrants								
Apr. 18,2007	Capital increase through exercise of warrants	182,560	4.7		4.7	748	43,549	10,633,514
Private Placement								
Oct. 19,2007	Capital increase in cash	1,063,351	10		10	4,355	47,904	11,696,865
Exercise of Warrants								
Oct. 25,2007	Capital increase through exercise of warrants	50,837	4.73		4.73	208	48,112	11,747,702
Exercise of Warrants								
Apr. 24,2008	Capital increase through exercise of warrants	61,120	4.59		4.59	250	48,363	11,808,822
Nov.5 , 2008	Capital increase through exercise of warrants	19,375	4.73		4.73	79	48,442	11,828,197
Private Placement								
Dec.18,2008	Capital increase in cash	1,332,877	6.29		6.29	5,459	53,901	13,161,074
Exercise of Warrants								
Apr. 17,2009	Capital increase through exercise of warrants	24,540	4.49		4.49	101	54,001	13,185,614
Reduction of Share Capital								
Jun. 21,2010	Share Capital reduction	/	/		/	/	10,518	13,185,614
Private Placement								
Apr. 8, 2011	Capital increase in cash	5,436,713	1.5		1.5	4,337	14,855	19,921	18,622,327

Private Placement								
Jul. 4, 2012	Capital increase in cash	6,891,113	1,45	1,45	5,497	20,352	26,852	25,513,440
Private Placement								
Jun. 25,2013	Capital increase in cash	8,797,863	2,05	2,05	6,970	27,322	37,860	34,251,303
Private Placement								
Nov. 7, 2014	Capital increase in cash	3,425,000	3,60	3,60	2,732	30,054	40,727	37,676,303
Exercise of Warrants								
Apr. 30,2015	Capital increase through exercise of warrants	172,187	2.01	2.01	137	30,191	40,881	37,848,490
Private Placement								
Jun. 26,2015	Capital increase in cash	6,150,000	4.5	4.5	4,906	35,097	46,370	43,998,490
Private Placement								
Sep.18,2015	Capital increase in cash	1,086,956	4.14	4.14	867	35,964	47,341	45,085,446
Exercise of Warrants								
Nov.27,2015	Capital increase through exercise of warrants	68,187	1.7	1.7	54	36,018	47,399	45,153,633
Per statutory accounts						€ 36,018	$ 47,399	45,153,633
Per IFRS consolidated accounts						€ 32,337	$ 42,791	

CAPITAL AND SHARES

At incorporation, **on January 10, 2003**, the Company issued 202,975 common shares in consideration for a contribution in cash of €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 €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 **June 30, 2003** approved the issuance of 33,333 new series A preferred shares in consideration for a contribution in cash of €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 **September 30, 2003** approved the issuance of 218,139 new series A preferred shares in consideration for a contribution in cash of €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 **June 30, 2004** approved the issuance of 195,504 new series A preferred shares in consideration for a contribution in cash of €4,666,680.

On July 12, 2005, 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 €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 **March 31, 2006** approved the issuance of 193,548 new series B preferred shares in consideration for a contribution in cash of €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 €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 May 23, 2006, 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 €10,217,809) without cancellation of any shares. The capital decrease was completed on June 30, 2006.

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 with an amount of €1,817,200 through exercise of 440,000 over-allotment warrants and the issuance of 440,000 new ordinary shares. An amount of €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 April 18, 2007, 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 €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 €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 €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 October 15, 2007, 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 €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 €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 €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 €24 per warrant, (iv) 187 warrants issued by the Board of Directors on November 8, 2006 (Warrants November 2006) at an exercise price of €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 €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 April 25, 2008, 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 €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 €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 November 5, 2008, 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 €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 €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 €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 December 18, 2008, 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 €5,458,797.75 and the issuance of 1,332,877 new common shares was completed on December 18, 2008.

On April 17, 2009, 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 €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 €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 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 €43,483,535.37, bringing the share capital per the statutory accounts from €54,001,197.27 to €10,517,661.90. This transaction caused the share capital under IFRS to be reduced from €51,089,000 to €10,518,000.

On April 8, 2011, 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 €1.50 per share, resulting in an increase of the share capital for an amount of €4,336,865.96 (with the remaining balance allocated to issuance premium).

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. 6,819,113 new common shares were issued at €1.45 per share, resulting in an increase of the share capital for an amount of €5,497,040.84 (with the remaining balance allocated to issuance premium).

On June 25, 2013, the Board of Directors decided to increase the Company's share capital in connection with a private placement with qualified institutional investors. 8,737,683 new common shares were issued at €2.06 per share, resulting in an increase of the share capital for an amount of €18,000,000.

On November 7, 2014, the Board of Directors decided to increase the Company's share capital in connection with a private placement with qualified institutional investors. 3,425,000 new common shares were issued at €3.60 per share, resulting in an increase of the share capital for an amount of €12,330,000.

On April 30, 2015, a share capital increase was recorded in the amount of hundred thirty seven thousand three hundred and fifty three euros and fifty-seven cents (EUR 137,353.57) by the issuance of hundred seventy-two thousand and hundred eighty seven (172,187) shares, fully paid-up, through contribution in cash, further to the exercise of 172,187 warrants, amongst which 140,000 had been issued in the framework of the May 2010 Sotck Option Plan, 30,000 had been issued in the framework of the April 2011 Stock Option Plan and 2,187 had been issued in the framework of the May 2012 Stock Option Plan.

On 26 June 2015, it was acknowledged that the capital increase, in the framework of the authorised capital, resolved by the board of directors on June 23, 2015, was realised in the amount of four million nine hundred and five thousand and eight hundred fifty-five euros (€4,905,855), through the issuance of six million hundred fifty thousand new shares, entirely paid-up, through a contribution in cash, issued at the price of four euros and fifty cents (€ 4.50) per share, including the fractional value of existing shares, i.e. 0,7977 euro per share, increased with an issuance premium for the balance.

On September 18, 2015, the Board of directors increased the share capital, in the framework of authorized capital, up to eight hundred sixty-seven thousand, sixty-four euros and eighty cents (€ 867,064.80) by issuing one million, eighty-six thousand, nine hundred and fifty-six (1,086,956) fully paid up new shares by a contribution in kind, issued at a price of 4.14 euros per share, including the fractional value of the existing shares, i.e., 0.7977 euro per share, increased by an issue premium for the balance.

On November 27, 2015, a share capital increase was recorded in the amount of fifty four thousand three hundred and ninety-two euros and seventy-seven cents (EUR 54,392.77) by the issuance of sixty eight thousand and hundred eighty seven (68,187) shares, fully paid-up, through contribution in cash, further to the exercise of 68,187 warrants, amongst which 20,000 had been issued in the framework of the April 2011 Stock Option Plan, 42,187 had been issued in the framework of the March 2012 Stock Option Plan and 6,000 had been issued in the framework of the June 2012 Stock Option Plan.

AUTHORIZED CAPITAL

By virtue of the resolution of the extraordinary general shareholders' meeting held on June 27, 2013, 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 15,000,000.00 (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 on May 27, 2016 which shall resolve on the annual accounts relating to the accounting year ending on December 31, 2015. 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 27, 2013, 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 November 4, 2014, up to two million, seven hundred and thirty-two thousand, hundred and twenty-two euros, and fifty cents (€2,732,122.50), by the issuance of three million four hundred and twenty-five thousand (3,425,000) shares,
- on June 23, 2015, up to four million, nine hundred and five thousand, eight hundred and fifty-five euros (€4,905,855), by the issuance of six million hundred fifty thousand (6,150,000) shares,
- and on September 18, 2015, up to eight hundred sixty-seven thousand, sixty-four euros and eighty cents (€ 867,064.80) by issuing 1,086,956 shares.

As a result, the available amount for a share capital increase under the Authorized Capital is equal to six million, four hundred ninety-four thousand, nine hundred fifty-seven euros and seventy cents (€ 6,494,957.7).

RIGHTS ATTACHED TO SHARES

Dividend Rights

All shares entitle the holder thereof to an equal right to participate 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 statutory audited 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 declare interim dividends on profits of the current financial year subject to the terms and conditions of the Belgian Company Code.

The Company's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of the Company's statutory unconsolidated financial statements rather than its consolidated financial statements. In particular, 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 non-consolidated financial statements (i.e., summarized, the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all 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 (or, if higher, the issued 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.

The Company has never declared or paid any dividends on its shares and does not anticipate paying any dividends in the foreseeable future. At December 31, 2015, there were no profits available for distribution under Belgian law.

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 existing shareholders have a preferential right to subscribe, pro rata, to the new shares, convertible bonds or warrants. The general shareholders' meeting may decide to limit or cancel this preferential subscription right, subject to special reporting requirements. Such decision by the shareholder's meeting needs to satisfy the same quorum and majority requirements as the decision to increase the Company's share capital. The shareholders may 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.

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 may be mainly 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%, 7.5%, 10%, 15%, 20% and any further 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, in the event that the relevant shareholder has not notified the Company and the FSMA at least 20 days prior to the date of the general shareholders' meeting in accordance with the applicable rules on disclosure of major shareholdings; and
- of which the voting right was suspended by a competent court or the FSMA.

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 may, whenever 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; (ii) 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.

RIGHT TO ASK QUESTIONS

Within the limits of article 540 of the Belgian Compagnies Code, shareholders have the right to ask questions to the Directors in connection with the report of the Board of Directors or the items on the agenda of such shareholders' meeting. Shareholders can also ask questions to the statutory auditor in connection with its report. Such questions can be submitted in writing prior to the meeting or can be asked at the meeting. Written questions must be received by the Company by mail at its registered office or by e-mail no later than the sixth day prior to the 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 attend the meeting, as explained under "Registration for the meeting" above.

QUORUM AND MAJORITIES

In general, there is no quorum requirement for a shareholders' meeting and decisions are generally passed with a simple majority of the votes of the shares present and represented. However, capital increases (other than those decided by the Board of Directors pursuant to 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 shareholders' meeting, which 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 shareholders' meeting may validly deliberate and decide regardless of the number of shares present or represented. The special majority requirements, however, remain applicable.

DISCLOSURES WITHIN THE FRAMEWORK OF THE TAKEOVER DIRECTIVE

Capital structure

At the end of 2015, the issued capital of MDxHealth SA amounted to €36,018,550.66 represented by 45,153,633 fully paid-up common 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 above in "Board Report; Corporate Governance Statement; Shareholding Structure" 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 Company 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.

Significant agreements which take effect alter or terminate upon a change of control of the Company 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 18 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.

NOTIFICATION OF IMPORTANT PARTICIPATIONS

The Belgian Company Code, applicable legislation and article 14 of 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.

WARRANTS

This section provides an overview of the outstanding warrants as of December 31, 2015. The warrants were created within the context of stock based incentive plans for employees, directors and consultants of the Company.

The Company has created several pools of warrants under stock option plans for grant to eligible employees, Directors, and consultants. On May 12, 2004 (30,000), July 12, 2005 (15,000), March 22, 2006 (66,700), November 8, 2006 (47,500), April 18, 2007 (55,100), May 25, 2007 (50,000), May 30, 2008 (61,000), January 2, 2009 (120,500), June 21, 2010 (145,000), May 27, 2011 (225,000), March 15, 2012 (195,000), June 15, 2012 (700,000), June 23, 2014 (1,500,000) in aggregate 3,210,800 warrants were issued, subject to warrants being granted to and accepted by the beneficiaries. Of these 3,210,800 warrants, (i) 422,515 warrants were terminated or lapsed, (ii) 308,310 warrants were exercised, (iii) 1,378,475 warrants were granted but not yet exercised, and (iv) 1,101,500 warrants were not yet granted by the Company. As a result, as at December 31, 2015, there are 1,378,475 warrants outstanding, entitling their holders to subscribe to 1,507,627 shares of the Company (given that 32,288 of these outstanding warrants each entitle to subscribe to 5 shares per warrants, whereas all other warrants entitle to subscribe to 1 share per warrant).

The warrants are granted to employees, consultants or Directors of the Company and its subsidiaries. The warrants have been granted free of charge. Except for the warrants issued on March 22, 2006 that entitle their holders to subscribe to five common shares per warrant, each warrant entitles its holders to subscribe to one common share of the Company at a subscription price determined by the Board of Directors, within the limits decided upon at the occasion of their issuance.

The warrants issued have generally a term of ten years as of issuance, except for the warrants issued on May 12, 2004, July 12, 2005, May 25, 2007, June 21, 2010 which have a term of five years as of issuance. Upon expiration of their term, the warrants become null and void.

In general, the warrants vest in cumulative tranches of 25% per year, provided that the beneficiary has provided at least one year of service. However, there are certain exceptions to this rule which are, if applicable, specified in the relevant stock option plans. The 30,000 warrants granted under the May 2011 Stock Option Plan to the CEO became vested immediately on the date of grant (i.e. December 7, 2010). The warrants granted under the May 2012 Stock Option Plan and under the June 23, 2014 Stock Option Plan to Directors all vest on the date of the annual meeting that takes place in the calendar year following the calendar year in which they were granted, provided that the mandate of the relevant director has not ended or been terminated. The warrants granted under the May 2012 Stock Option Plan and under the June 23, 2014 Stock Option Plan to beneficiaries who are not Directors all vest in installments of 25% per year, the first trenche of 25% vesting on the first anniversary date of the date of grant and the following trenches vesting on a quarterly basis.

OUTSTANDING FINANCIAL INSTRUMENTS

The table below provides an overview of the issued and outstanding voting financial instruments at December 31, 2015. The numbers below take into account the stock split (shares and warrants) decided upon by the shareholders' meeting of May 23, 2006.

CAPITAL AND SHARES

	Number of voting rights
(A) Actual voting rights attached to:	
Shares issued at December 31, 2015	45,153,633
Total A	45,153,633

(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	
Warrants issued on July 12, 2005	
Warrants issued on March 22, 2006	161,440
Warrants issued on November 8, 2006	9,500
Warrants issued on April 18, 2007	13,000
Warrants issued on May 25, 2007	0
Warrants issued on May 30, 2008	25,500
Warrants issued on January 27, 2009	22,000
Warrants issued on June 21, 2010	0
Warrants issued on May 27, 2011	105,000
Warrants issued on March 15, 2012	169,063
Warrants granted on August 15, 2012	30,000
Warrants granted on September 14, 2012	70,624
Warrants granted on December 1, 2012	4,063
Warrants granted on January 1, 2013	116,875
Warrants granted on February 1, 2013	2,375
Warrants granted on April 1, 2013	3,438
Warrants granted on May 1, 2013	10,313
Warrants granted on May 31, 2013	30,000
Warrants granted on March 12, 2014	135,000
Warrants granted on April 1, 2014	4,875
Warrants granted on May 30, 2014	36,000
Warrants granted on June 1, 2014	0
Warrants granted on July 1, 2014	5,625
Warrants granted on April 1, 2015	0
Warrants granted on June 23, 2014	24,000
Warrants granted on October 10, 2014	4,375
Warrants granted on February 9, 2015	29,063
Warrants granted on May 29, 2015	-
Warrants granted on April 1, 2015	-
Warrants granted on May 1, 2015	-
Warrants granted on June 1, 2015	-
Warrants granted on July 1, 2015	-
Warrants granted on August 1, 2015	-
Warrants granted on September 1, 2015	625
Warrants granted on October 1, 2015	-
Warrants granted on November 1, 2015	-

Warrants granted on December 1, 2015	-
Total B	1,012,754
Total (A)+(B):	46,166,387

(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	0
Warrants issued on June 21, 2010	0
Warrants issued on May 27, 2011	0
Warrants issued on March 15, 2012	937
Warrants granted on August 15, 2012	0
Warrants granted on September 14, 2012	6,250
Warrants granted on December 1, 2012	937
Warrants granted on January 1, 2013	12,063
Warrants granted on February 1, 2013	0
Warrants granted on April 1, 2013	1,562
Warrants granted on May 1, 2013	4,687
Warrants granted on May 31, 2013	0
Warrants granted on March 12, 2014	116,000
Warrants granted on April 1, 2014	5,625
Warrants granted on May 30, 2014	0
Warrants granted on June 1, 2014	0
Warrants granted on July 1, 2014	9,375
Warrants granted on April 1, 2015	0
Warrants granted on June 23, 2014	0
Warrants granted on October 10, 2014	13,125
Warrants granted on February 9, 2015	125,937
Warrants granted on May 29, 2015	50,000
Warrants granted on April 1, 2015	0
Warrants granted on May 1, 2015	20,000
Warrants granted on June 1, 2015	6,000
Warrants granted on July 1, 2015	4,000
Warrants granted on August 1, 2015	4,000
Warrants granted on September 1, 2015	84,375
Warrants granted on October 1, 2015	8,000
Warrants granted on November 1, 2015	4,000
Warrants granted on December 1, 2015	18,000
Total C	494,873

Totaal (A) + (B) + (C)……	46,661,260

FINANCIALS

AUDITED CONSOLIDATED FINANCIAL STATEMENTS

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 of the Annual Report have been approved and authorized for issue by the Board of Directors at its meeting of February 17, 2016. 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 27, 2016.

Consolidated statement of comprehensive income

THOUSANDS OF $ EXCEPT PER SHARE AMOUNTS / YEARS ENDED DECEMBER 31	*NOTES*	*2015*	*2014*	*2013*
Product and service income	4	15,752	10,896	6,955
Royalties	4	1,715	583	599
Government grant income	4/24	173	192	-
Revenues		**17,640**	**11,671**	**7,554**
Cost of goods & services sold	4	6,905	6,453	5,793
Gross profit		**10,735**	**5,218**	**1,761**
Research and development expenses	5	3,257	2,376	4,567
Selling, general and administrative expenses	5	22,358	18,321	13,219
Other operating income		498	139	147
Other operating expenses		-	2	193
Total operating charges		**25,117**	**20,560**	**17,832**
Operating Loss (EBIT)		**-14,382**	**-15,342**	**-16,071**
Financial income	7	13	109	114
Financial expenses	7	104	23	218
Loss before taxes		**-14,473**	**-15,256**	**-16,175**
Income taxes		-	-	-
Net Loss for the year from continuing operations		**-14,473**	**-15,256**	**-16,175**
Loss for the year from discontinued operations		-	-	-
Loss for the year		**-14,473**	**-15,256**	**-16,175**
Other comprehensive income		**-**	**-**	**-**
Items that will be reclassified to profit or loss				
Exchange differences arising on translation of foreign operations		-289	-81	16
Total comprehensive loss for the year (net of tax)		**-14,762**	**-15,337**	**-16,159**
Basic earnings per share (EPS) $	9			
Using weighted average number of shares		-0.35	-0.44	-0.54
Using end of period number of shares		-0.32	-0.40	-0.47

Consolidated statement of financial position

Assets

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	*NOTES*	*2015*	*2014*	*2013*
Goodwill	10.1	1,145	-	-
Intangible assets	10.2	10,030	2,011	981
Property, plant and equipment	11	1,888	724	781
Grants receivable (> 1 year)	14	33	105	-
Non-current assets		**13,096**	**2,840**	**1,762**
Inventories	12	1,427	860	171
Grants receivable (< 1 year)	14	180	139	23
Trade receivables	13	10,978	7,500	1,997
Prepaid expenses and other current assets	13	381	717	748
Cash and cash equivalents	15	31,680	18,897	24,683
Current assets		**44,646**	**28,113**	**27,622**
TOTAL ASSETS		**57,742**	**30,953**	**29,384**

Liabilities & Shareholders' Equity

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	NOTES	2015	2014	2013
Share capital	17	42,791	37,825	35,483
Issuance premium	17	83,118	53,273	41,694
Accumulated profit/(loss)		-71,153	-55,897	-39,646
Result of the year		-14,473	-15,256	-16,175
Share-based compensation	22	4,701	4,264	3,864
Translation reserves		-722	-433	-683
Total equity		**44,262**	**23,776**	**24,537**
Deferred tax liabilities		842	-	-
Grants payable (> 1 year)		15	83	-
Long-term liabilities	3	1,390	-	-
Loans and borrowings	18/19	408	-	-
Non-current liabilities		**2,655**	**83**	**-**
Loans and borrowings	18/19	440	-	-
Trade payables	20	6,610	5,264	3,271
Grants payable (< 1 year)		104	110	-
Other current liabilities	20	2,801	1,720	1,576
Short-term liabilities	3	870	-	-
Current liabilities		**10,825**	**7,094**	**4,847**
TOTAL EQUITY AND LIABILITIES		**57,742**	**30,953**	**29,384**

Consolidated cash flow statement

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	*NOTES*	*2015*	*2014*	*2013*
CASH FLOWS FROM OPERATING ACTIVITIES				
Operating Profit/(Loss)		**-14,382**	**-15,342**	**-16,071**
Depreciation, amortization and impairment results	10/11	881	333	418
Share-based compensation	22	437	437	312
(Gain)/Loss on disposal of fixed assets		-	-1	60
Interests paid	7	-5	-	-
Change in inventories	12	-567	-688	-171
(Increase)/decrease in accounts receivable (1)	13	-3,111	-5,693	467
Increase/(decrease) in account payable (2)	20	2,353	2,441	880
Total adjustments		-12	-3,171	1,966
Net cash provided by/(used in) operating activities		**-14,394**	**-18,513**	**-14,105**
CASH FLOWS FROM INVESTING ACTIVITIES				
Acquisition of subsidiary, net of cash acquired		-5,389	-	-
Proceed from sale of fixed assets		-	-	70
Interest received	7	13	14	8
Other financial profit/(loss)	7	-99	72	-112
Purchase of property, plant and equipment	11	-1,577	-264	-257
Purchase of intangible assets	10	-524	-1,078	-960
Net cash provided by/(used in) investing activities		**-7,576**	**-1,256**	**-1,251**
CASH FLOWS FROM FINANCING ACTIVITIES				
Payments on long-term obligations		-617	-	-
Proceeds from long-term obligations		1,036	-	-
Payments on loans and borrowings		-188	-	-
Proceeds from issuance of shares (net of issue costs)	17	34,811	14,666	24,280
Net cash provided by/(used in) financing activities		**35,042**	**14,666**	**24,280**
Net increase/(decrease) in cash and cash equivalents		**13,072**	**-5,103**	**8,924**
Cash and cash equivalents at beginning of year		18,897	24,683	15,455
Effect on Exchange rate changes		-289	-683	304
Cash and cash equivalents at end of period	15	31,680	18,897	24,683

Notes:

1) Long term grants receivable + short term grants receivable + trade receivables + prepaid expenses and other current assets.

2) Advance on royalties + long term grants payable + trade payables + short term grants payable + other current liabilities.

Consolidated statement of changes in shareholders' equity

		ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY				
THOUSANDS OF $	NUMBER OF SHARES	SHARE CAPITAL & ISSUANCE PREMIUM	RETAINED EARNINGS	SHARE-BASED COMPENSATION	TRANSLATION RESERVES	TOTAL EQUITY
Notes	17	17		22		
Balance at January 1, 2013	**25,513,440**	**50,607**	**-37,621**	**3,387**	**-386**	**15,987**
Total comprehensive income	-	-	-16,175	-	16	-16,159
Issuance of shares	8,737,863	24,824	-	-	-	24,824
Deduction of SPO costs	-	-543	-	-	-	-543
Share-based compensation	-	-	-	324	-	324
Currency translation adjustments	-	2,289	-2,025	153	-313	104
Balance at December 31, 2013	**34,251,303**	**77,177**	**-55,821**	**3,864**	**-683**	**24,537**
Balance at January 1, 2014	34,251,303	77,177	-55,821	3,864	-683	24,537
Total comprehensive income	-	-	-15,256	-	-81	-15,337
Issuance of shares	3,425,000	15,392	-	-	-	15,392
Deduction of SPO costs	-	-726	-	-	-	-726
Share-based compensation	-	-	-	437	-	437
Currency translation adjustments	-	-745	-76	-37	331	-527
Balance at December 31, 2014	**37,676,303**	**91,098**	**-71,153**	**4,264**	**-433**	**23,776**

THOUSANDS OF EUR	NUMBER OF SHARES	SHARE CAPITAL & ISSUANCE PREMIUM	RETAINED EARNINGS	SHARE-BASED COMPENSATION	TRANSLATION RESERVES	TOTAL EQUITY
Balance at January 1, 2015	**37,676,303**	**91,098**	**-71,153**	**4,264**	**- 433**	**23,776**
Net loss	-	-	- 14,473	-	-	- 14,473
Other comprehensive income	-	-	-	-	- 289	- 289
Total comprehensive income	**-**	**-**	**- 14,473**	**-**	**- 289**	**- 14,762**
Issuance of shares	7,477,330	36,517	-	-	-	36,517
Deduction of SPO costs	-	- 1,706	-	-	-	- 1,706
Share-based compensation	-	-	-	437		437
Balance at December 31, 2015	**45,153,633**	**125,909**	**- 85,626**	**4,701**	**- 722**	**44,262**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 : General information

MDxHealth SA is a limited liability company incorporated in Belgium.

MDxHealth is a molecular diagnostics company that develops and commercializes advanced epigenetic tests for cancer assessment and the personalized treatment of patients. Applying our patented DNA methylation platform and biomarkers, we help address a large and growing unmet medical need for better cancer diagnosis and treatment information.

Using our extensive scientific expertise and our patented DNA-based methylation technology, MDxHealth focuses on providing high value molecular diagnostics (MDx) products that address significant unmet clinical needs and can be used in clinical laboratory testing.

Our mission is to develop and commercialize advanced molecular diagnostic products for personalized cancer treatment. This will be achieved with products that provide physicians with tools to aid in the diagnosis and or prognosis of cancers, aid in the physician's ability to predict disease progression and or response to therapy. We have an innovative and broad MDxHealth product pipeline covering major cancer areas such as prostate, bladder, kidney, colon, lung and brain cancer.

We develop MDxHealth products based on our patented DNA methylation platform integrating our proprietary DNA biomarkers. These assays deliver highly accurate analytical results and can be performed on a variety of sample types including formalin-fixed paraffin embedded (FFPE) tissue, fresh/frozen tissue, urine, plasma, serum, sputum, broncho-alveolar lavages and stool using commercially available PCR equipment.

MDxHealth has a lab in Gent, Belgium, and offers its products in North-America through a CLIA Certified, ISO 9001 Acredited and CAP accredited service laboratory. Since September 2015, with the acquisition of NovioGendix, MDxHealth operates also in The Netherlands and offers its products in Europe through its laboratory in Nijmegen.

The MDxHealth group of companies has its parent company, MDxHealth SA (formerly OncoMethylome Sciences as established in 2003), headquarters in Belgium, but also operates in the United States and in the Netherlands. MDxHealth's registered and corporate office is based in Herstal, Belgium (Cap Business Center, Rue d'Abhooz 31, 4040 Herstal). MDxHealth, Inc., the Company's US subsidiary, is located at 15279 Alton Parkway – Suite 100 – Irvine, CA 92618, United States. MDxHealth B.V., the Company's Dutch subsidiary, is located at Geert Grooteplein-Zuid 34, 6525 GA NIJMEGEN (The Netherlands).

Considering the continuing development of the commercial activities in the US market, the Company has decided to change its presentation currency from the EURO to the US Dollar as of January 1, 2013. As per IAS 21, the Functional currency is the currency of the primary economic environment in which the entity operates. The primary economic environment in which an entity operates is normally the one in which it primarily generates and expends cash. In adherence to IAS 21 the Company changed its functional currency from the EURO to the US Dollar from July 1, 2014, the transition date. We refer to Note 2 : Accounting policies for further explanations.

NOTE 2 : Accounting policies

BASIS OF PREPARATION AND STATEMENT OF COMPLIANCE

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, 2015.

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 US Dollars ($) unless otherwise indicated, rounded to the nearest $1,000.

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, as adopted by the European Union up to December 31, 2015, that are relevant to its operations and effective for the accounting year starting on January 1, 2015. The Group has not applied any new IFRS requirements that are not yet effective as per December 31, 2015.

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

- Annual Improvements to IFRSs 2011-2013 Cycle (issued by the IASB in December 2013)
- IFRIC 21 – Levies (May 2013)

The adoption of these new standards and amendments has not led to major changes in the Group's accounting policies.

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

The Group elected not to early adopt the following new Standards, Interpretations and Amendments, which have been issued and adopted but are not yet effective as per December 31, 2015.

- Annual Improvements to IFRSs 2010-2012 Cycle (issued by the IASB in December 2013)
- Annual Improvements to IFRSs 2012-2014 Cycle (issued by the IASB in September 2014)
- IAS 1 - Presentation of Financial Statements — Amendments resulting from the disclosure initiative (December 2014)
- IAS 16 – Property, Plant and Equipment — Amendments regarding the clarification of acceptable methods of depreciation and amortization (May 2014)
- IAS 16 – Property, Plant and Equipment — Amendments bringing bearer plants into the scope of IAS 16 (June 2014)
- IAS 19 - Employee Benefits — Amendments relating to Defined Benefit Plans: Employee Contributions (November 2013)
- IAS 38 – Intangible Assets — Amendments regarding the clarification of acceptable methods of depreciation and amortization (May 2014)

The Group elected not to early adopt the following new Standards, Interpretations and Amendments, which have been issued but not yest endorsed by the European Union as per December 31, 2015.

- IFRS 9 - Financial Instruments — Classification and Measurement (Original issue July 2014, and subsequent amendments) *
- IFRS 10 – Consolidated Financial Statements — Amendments regarding the sale or contribution of assets between an investor and its associate or joint venture (September 2014)*
- IFRS 10 – Consolidated Financial Statements — Amendments regarding the application of the consolidation exception (December 2014)*
- IFRS 12 – Disclosure of Interests in Other Entities — Amendments regarding the application of the consolidation exception (December 2014)*
- IFRS 15 - Revenue from Contracts with Customers (Original issue May 2014)*
- IAS 39 – Financial Instruments: Recognition and Measurement — Amendments for continuation of hedge accounting (fair value hedge of interest rate exposure) when IFRS 9 is applied (November 2013)*

It is not expected that the initial application of the above mentioned IRFS standards, interpretations and amendments will have a significant impact on the consolidated financial statemetns, except for the application of IFRS 15 for which the Company is assessing the impact.

BASIS OF CONSOLIDATION

The consolidated financial statements incorporate the financial statements of MDxHealth SA (Belgium legal entity), MDxHealth Inc. (United States legal entity), and MDxHealth BV (The Netherlands) for each fiscal year ending on December 31st.

In 2003, MDxHealth SA (Belgium) incorporated MDxHealth Inc. (US) as a wholly-owned subsidiary. MDxHealth SA fully acquired NovioGendix on September 18, 2015 and this Dutch entity is now integrated under the name of MDxHealth BV. 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

On January 1, 2013, the Company changed its presentation currency from the EURO to the US Dollar based on the continuing development of the commercial activities in the US market. Given the further shift to US centric activities in 2014, effective July 1, 2014, The Company took the next step to change its functional currency from the EURO to the US Dollar.

For the purpose of change in functional currency, the Company converted on July 1, 2014 (transition date) all non-monetary assets and liabilities at the rate of 1,3658 corresponding to the exchange rate at June 30, 2014, this rate being from then on considered as the new historical rate of these non-monetary items.

As from that date (July 1, 2014) and on a continuing basis, the Company has been converting all transactions and balance sheet items in accordance with IAS 21.21 and IAS 21.23 :

- all transactions under the statement of comprehensive income are converted at the rate of 1,1096 USD/EUR corresponding to the average rate for the related period (January 1, 2015 until December 31, 2015);
- monetary assets and liabilities at the date of the balance sheet are converted at the rate of 1,0887 corresponding to the exchange rate at December 31, 2015;
- non-monetary assets and liabilities that are measured in terms of historical cost in a foreign currency are translated using the exchange rate of the month during which the transaction takes place.

Transactions and balances

Transactions in currencies other than USD 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 items that are measured in terms of historical cost in a foreign currency shall be translated using the exchange rate at the date of the transaction; and non-monetary items that are measured at fair value in a foreign currency shall be translated using the exchange rates at the date when the fair value was measured.

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.

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.

USE OF ESTIMATES AND JUDGMENTS

MDxHealth makes 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. Estimates and judgments are continually evaluated based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. In the future, actual experience may differ from these estimates and assumptions. 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:

- Note 3: Business Combination – The Company determines and allocates the purchase price of an acquired business to the assets acquired and liabilities assumed as of the business combination date. The purchase price allocation process requires the Company to use significant estimates and assumptions that determine the present value of future cash flows. The multi-period excess earnings method, a variation of the income approach, estimates an intangible asset's value based on the present value of the incremental after-tax cash flows (or "excess earnings") for each identifiable assets and liabilities. including:
    - Developed technologies;
    - In process research and development;
    - Defined earn outs;
    - Deferred tax liabilities;
    - Goodwill;
    - Estimated fair value of property, plant and equipment
- Note 4: 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;
  5) Percentage claims collected versus percentage claims billed should be 50% or more, and
  6) The trend of percentage collected versus billed should not be declining over the months.

  Health insurers and other third-party payors may decide not to cover or to revoke coverage of, or may provide inadequate reimbursement for, our existing or future solutions, which could jeopardize our commercial prospects. We refer to the Risks section of the document for further details.

  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. In case the Company does not respect the conditions of the grants, there is a risk that the governement grants may have to be reimbursed.

- Note 7: The losses of the Company in the last three years imply that no income taxes are payable for these years. On December 31, 2015, the Company had net tax losses carried forward amounting to $170 million, implying a potential deferred tax asset of $58 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. The Company can realize and capitalize the accumulated net tax losses when there is sufficient evidence that The Company will achieve sustainable taxable profits. Conservatively, The Company will need to have at least four consecutive quarters of profitability.

- Note 10-1 : Goodwill – The Company has recognized Goodwill in relation with the acquisition of NovioGendix. At each balance sheet date and at each interim reporting date, the Company reviews the carrying amount of the goodwill to determine whether there is any indication that it has suffered an impairment loss. If any such indication exists, the recoverable amount of the goodwill is estimated in order to determine the extent of the impairment loss (if any). Any goodwill with an indefinite useful life is tested for impairment annually and at each interim reporting date, and whenever there is an indication that it might be impaired.

- Note 20: Warrant plans - The Company has created several pools of warrants under stock option plans for grant to eligible employees, Directors, and consultants. Generally, the warrants have been granted free of charge and have a term of ten years as of issuance and become null and void after the term has ended. In general, the warrants vest in cumulative tranches of 25% per year, provided that the beneficiary has provided at least one year of service. However, there are certain exceptions to this rule which are, if applicable, specified in the relevant stock option plans. The exceptions are addressed in note 20. The fair value of each warrant is estimated on the date of grant using the Black-Scholes methodology. The details of the granted warrants, the vested and outstanding warrants, and the valuation of the warrants are detailed in note 20.

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 the out-licensing of the Company's patented DNA methylation platform and biomarkers. On an ancillary and opportunistic basis, the Company may engage in contracting out its R&D and scientific expertise to commercial and non-commercial entities. The Company is not organized nor does it operate along business lines and all functions can support all the Company's commercial endeavors. In 2015, the Company earned 99% of its revenue from the clinical laboratory testing service and out-licensing of intellectual property. The remaining 1% came from a R&D grant in Belgium and in The Netherlands. In 2015, the clinical laboratory testing in the US CLIA laboratory represented 86% of the Company's revenue, while the out-licensing of intellectual property revenue and grant income in Europe represented the remaining 14%. In 2014, 61% of revenues were derived from clinical laboratory testing services, while 39% came from R&D services. The majority of the R&D services were for pharmaceutical companies evaluating the biomarkers of MDxHealth as potential companion diagnostic tests. In 2013, 50% of the revenue was earned in Belgium, while the remaining 50% was generated through the US CLIA laboratory.

At the end of 2015, 98% of the non-current assets (other than financial instruments, deferred tax assets, post-employment benefit assets, rights arising under insurance contracts and intangible assets derived from Business Combination – see note 3) were located in the US and the remining 2% in Belgium, and a negligible and immaterial amount in the Netherlands. At the end of 2014, 94% of the non-current assets were located in the United States, and the remaining 6% composed by equipment located in Belgium, Europe.

REVENUE RECOGNITION

Substantially all of the Company's revenues are generated from the sale of clinical laboratory testing services, technology out-licensing deals, research and development service fees, and government grants. Most commercial agreements include up-front fees, milestone fees, and royalty fees.

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; and
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 is updated at least each quarter for each payor 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, meaning that revenues will not be recognized until actual cash payment is received from the payor. Deferred revenue represents amounts received prior to revenue being earned.

Since the first sales of the ConfirmMDx for Prostate Cancer test mid 2012, the Company's revenue recognition policy has limited the amount of revenue recognized. As the volume of historical reimbursement transactions from payors has grown, the basis to establish reasonable estimates of payment patterns by payor or claim categories has improved. As a result, a higher percentage of the transactional value sold is being recognized each year. Based on 2015 reported cases and historical average reimbursement amounts, the total estimated value of tests performed in 2015 was $36 million. Of this amount $15.2 million was recognized as revenue, leaving uncollected outstanding unrecognized revenues of $20.8 million, consisting of $1.7 million from Medicare and $19.1 million from private payors. This compares to 2014 when the total estimated value of tests performed was $19.1 million, from which the Company recognized $9.4 million, leaving uncollected outstanding unrecognized revenues of $9.6 million consisting of $7.9 million Medicare cases and $1.7 million non-Medicare. The unrecognized and uncollected amount has been excluded from the Company's revenues in each year. 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 transactions per the Company's revenue recognition policy.

At the end of 2014, a Local Coverage Determination (LCD) for Medicare reimbursement of ConfirmMDx for Prostate Cancer was issued by Palmetto GBA, the administrative contractor for Medicare. The issuance of the LCD not only sets the reimbursement rate for all US Medicare patients, but also establishes reimbursement for all Medicare Advantage patients in the US covered by private commercial payors. By virtue of the Center for Medicare and Medicaid Services policies, payors contracted to offer Medicare Advantage programs are legally obligated to honor the LCD. It is expected that reimbursements from Medicare and Medicare Advantage covered by private commercial payors can further increase the percentage of recognized revenue over the total transaction value of tests sold.

License fees are recognized when the Company has fulfilled all conditions and obligations. A 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 from 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.

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

EXTERNALLY ACQUIRED INTANGIBLE ASSETS

Intangible assets are recognized on business combinations if they are separable from the acquired entity or give rise to other contractual/legal rights. The amounts ascribed to such intangibles are arrived at by using appropriate valuation techniques (see section related to the use of estimates and judgments and see also note 3 related to business combinations).

Externally acquired patents and software licenses are initially recognized at cost and are subsequently 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
- Developped technology : 10 years
- In-Process Research and Development: indefinite until the completion or abandonment of the associated research and development effort.
- The amortization expense on intangible assets with finite lives is recognized in the consolidate income statement based on its function which may be “Research and Development expenses” and “General and administrative expenses”.

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.

INTERNALLY GENERATED INTANGIBLE ASSETS (DEVELOPMENT COSTS)

Generally, 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 if it can be demonstrated that:

- It is technically feasible to develop the product for it to be sold;
- Adequate resources are available to complete the development;
- There is an intention to complete and sell the product;
- The Company is able to sell the produc t;
- Sale of the product will generate future economic benefits, and;
- Expenditures on the project can be measured reliably.

The Company capitalized internally generated development costs related to the enhancement of the ConfirmMDx for Prostate assay amounting to $2,355,000. The improved ConfirmMDx test has been launched in production in the course of 2015.

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). 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.

An intangible asset not yet available for use is tested for impairment annually by comparing its carrying amount with its recoverable amount. This impairment test may be performed at any time during an annual period, provided it is performed at the same time every year. Different intangible assets may be tested for impairment at different times. However, if such an intangible asset was initially recognised during the current annual period, that intangible asset shall be tested for impairment before the end of the current annual period.

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 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.

The depreciable amount of an intangible asset with a finite useful life shall be allocated on a systematic basis over its useful life. Amortisation shall begin when the asset is available for use, ie when it is in the location and condition necessary for it to be capable of operating in the manner intended by management. Amortisation shall cease at the earlier of the date that the asset is classified as held for sale (or included in a disposal group that is classified as held for sale) in accordance with IFRS 5 and the date that the asset is derecognised. The amortisation method used shall reflect the pattern in which the asset's future economic benefits are expected to be consumed by the entity. If that pattern cannot be determined reliably, the straight-line method shall be used. The amortisation charge for each period shall be recognised in profit or loss unless this or another Standard permits or requires it to be included in the carrying amount of another asset.

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.

INVENTORIES

Inventories are initially recognized at cost, and subsequently 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 amortized cost.

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. This note is to be read together with the note related to Revenue recognition.

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

Current tax assets and liabilities for the current period are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted, at the reporting date.

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.

Deferred tax liabilities are recognized for all taxable differences. Deferred tax assets are recognized for all deductible temporary differences, carry forward of unused tax credits and unused tax losses, to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilized.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilized. Unrecognized deferred tax assets are reassessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realized or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Deferred tax assets and deferred tax liabilities are offset, if a legally enforceable right exists to set off current tax assets against current income tax liabilities and the deferred taxes relate to the same taxable entity and the same taxation authority.

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. Transaction costs related to equity transactions are accounted for as a deduction from equity ('capitalized in equity'). Only the portion of costs that relate to new shares being issued are accounted for as a deduction from equity.

DERIVATIVE INSTRUMENTS

The Company has not used any derivative financial instruments.

FINANCIAL ASSETS

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.

NOTE 3 : Business Combination

ACQUISITION IN 2015

NovioGendix

The Company signed a sale and purchase agreement on September 18, 2015 to acquire all shares and voting interests of NovioGendix, an entity incorporated in The Netherlands.

NovioGendix, a privately held company based in Nijmegen (The Netherlands), is a molecular diagnostic research and service company providing an expert-based, integrated approach in developing advanced and clinically useful molecular diagnostic assays for the uro-oncological practice. The Company is now active in the discovery and subsequent (clinical) validation and further product development and commercialization of biomarker-based diagnostic tests for prostate- bladder- and kidney cancer.

Under the terms of the agreement, MDxHealth purchased all outstanding shares of NovioGendix Holding B.V. in a combined share and cash transaction for an aggregate purchase price of $8.7 million (or €7.75 million), of which $5.1 million (or €4.5 million) was payable in new MDxHealth shares, $0,3 million (or €250,000) in cash, and up to an additional $3.3 (or €3.0 million) in cash shall, subject to meeting certain milestones, be payable in six milestone payments. In addition, MDxHealth granted NovioGendix a bridge loan of $680,000 (or €0.6 million) to repay outstanding debts of NovioGendix. As part of the consideration that was paid for the shares in NovioGendix, the Company issued 1,086,956 new shares at an issue price of EUR 4.14 representing the average closing price of the Company's shares on Euronext Brussels during a period of 30 days ending on September 17, 2015. MDxHealth has full control of the acquired entity and meets the definition of a business combination.

The fair values of the identifiable assets and liabilities acquired, purchase consideration and goodwill at the date of the acquisition were as follows:

ASSETS	Carrying Value at acquisition date	Fair Value adjustments	Fair value at acquisition date
Intangible assets	-	7,800	7,800
Property plant and equipment	16	-	16
Non-current assets	16	7,800	7,816
Trade and other receivables	153	-	153
Cash and cash equivalents	40	-	40
Current assets	193	-	193
TOTAL ASSETS	209	7,800	8,009
EQUITY AND LIABILITIES			
Long-term liabilities	-	1,390	1,390
Deferred tax liabilities	-	842	842
Non current liabilities	-	2,232	2,232
Trade payables	12	-	12
Other current liabilities	769	-	769
Short-term liabilities	-	820	820
Current liabilities	781	820	1,601
TOTAL EQUITY AND LIABILITIES	781	3,052	3,833
Total identified assets and liabilities other than goodwill			4,176
Goodwill			1,145
Acquisition price paid in cash and shares			5,321

The cash flow from the business combination is as follows:

Cash and cash equivalents	40
Acquisition price paid in cash	(280)
Total cash flow	(240)

Since the acquisition date, NovioGendix has contributed $131,000 to the Company's group revenues and $ 274,000 to the Company's group result (net losses). If the acquisition had occurred on 1 January 2015, the total revenue generated by NovioGendix for the full-year of 2015 is $280,000 (€250,000) and the net loss for the same period is $811,000 (€724,000).

Contingent Considerations or future earn outs:

The valuation of the contingent liability related to defined earn out was developed based on the probability of attainment, the estimated time to attainment, and application of various discount rates. The contingent liability valued as of December 31, 2015 is $2,260,000, which is the valuation of the future earn out based on the defined milestones.

Intangible Asset Valuation:

Given that NovioGendix
has innovated and developed unique and potentially proprietary technology, the value of the Company is in part derived from the technology already developed and technology in the process of being developed.

Developed Technologies – Intangible Asset:

MDxHealth has acquired as part of the NovioGendix acquisition the following developed technologies:

- Design and development of SelectMDx, a urinary 3-gene RNA panel for the identification of patients with clinically significant Prostate Cancer and also with low serum PSA values utilizing existing qPCR processing.
- SelectMDx is fully validated assay by NovioGendix and documented to outperform the current IVD PCA3 test

The multi-period excess earnings method, a variation of the income approach, estimates an intangible asset's value based on the present value of the incremental after-tax cash flows (or "excess earnings") attributable only to the intangible asset. This method was used to value the existing Developed Technology as of the effective date, September 18, 2015. Based on this method, the indicated value for the developed technology (SelectMDx) is calculated to be $4,500,000.

In-process Research and Development – Intangible Asset:

In-process research and development ("IPR&D") can be broadly defined as acquired research and development assets that have been initiated, achieved material progress, but have not yet resulted in a technologically feasible or commercially viable project.

The AssureMDx Bladder cancer assay is in the process of development with the expected to be completed in late 2016 to early 2017.

- The AssureMDx Bladder assay is a similar test to the SelectMDx assay for Prostate cancer in its positioning to assist in the early diagnosis of Bladder cancer and as a diagnostic tool to assist urologist to identify potential Bladder cancer patients who are negative and not in need of repeat cystoscopies. AssureMDx is an invasive urine based assay that will be easy for urologist to adopt. Into their practice. The estimated market size for AssureMDx is over $500 million.

Similar to the valuation method used for the developed technology, the multi-period excess earnings method was applied to assess the value for the in-process research and development intangible. Based on this method, the indicated value for the in-process research and development asset (AssureMDx) is calculated to be $3,300,000.

Residual Value of Goodwill prior to Deferred Tax Liability Adjustment:

The residual value of goodwill taking into account the intangible assets, the developed technology (SelectMDx) at $4.5 million and the in-process research and development asset (AssureMDx) at $3.3 million, and the tangible assets of $209,000, relative to the purchase consideration is $303,000. The material value of the acquisition is attributable to the acquired technology and minimally to goodwill.

Deferred Tax Liability Adjustment:

NovioGendix since 2006 had generated net operating losses (NOLs) of €4,353,946 which would have become a Deferred Tax Asset, once it became a profitable entity. The value of the NOLs at the tax rate of 20% for the first $220,000 and 25% thereafter would yield a tax benefit of $1,108,252. Conversely, the Deferred Tax Liability on the Intangible Asset value of $7,800,000, the $4,500,000 for the developed technology and the $3,300,000 for the in-process research and development asset at the aforementioned tax rate would yield a value of $1,950,000. Since the deferred tax liability is greater than the deferred tax asset value by $841,748, the residual goodwill $303,000 is adjusted to $1,144,748.

NOTE 4 : Product and Service Income and Cost of goods sold

PRODUCT AND SEVICE INCOME

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	***NOTES***	***2015***	***2014***	***2013***
Product and service income		15,752	10,896	6,955
Royalties		1,715	583	599
Government grant income	24	173	192	-
Total		**17,640**	**11,671**	**7,554**

Total revenues in 2015, 2014 and 2013 were $17.6 million, $11.7 million, and $7.6 million, respectively. The commercial revenues other than direct sales for ConfirmMDx for Prostate Cancer were primarily generated from royalties' payments and from services provided to large Pharmaceutical companies.

COST OF GOODS & SERVICES SOLD

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	2015	2014	2013
Cost of goods & services sold	6,905	6,453	5,793
Total	**6,905**	**6,453**	**5,793**

The costs of goods include the costs associated with providing testing services to third parties. During the year the current year, the amount of inventories recognized as an expense is $3,885,000.

NOTE 5 : Operating result

RESEARCH AND DEVELOPMENT EXPENDITURES

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	NOTES	2015	2014	2013
Personnel costs	6	935	936	1,957
Lab consumables		358	344	525
External research and development collaborator fees		1,238	818	1,203
Depreciation and amortization		220	86	452
Other expenses		506	192	430
Total		**3,257**	**2,376**	**4,567**

After the downsizing of research and development activities in Belgium since 2013 which have decreased the research and development expenditures in the past. As a result of the business combination with NovioGendix research and development expenses have increased again.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	NOTES	2015	2014	2013
Personnel costs	6	12,865	10,658	8,611
Depreciation		502	260	248
Professional fees		1,994	2,495	1,862
Marketing expenses		1,885	1,395	1,408
Travel expenses		1,469	1,032	966

Offices & facilities expenses	974	778	826
Royalties to third parties	1,379	786	512
Other expenses	675	432	-1,707
Patent expenses	615	485	493
Total	**22,358**	**18,321**	**13,219**

SG&A expenses mainly represent general management costs, consulting, selling and marketing costs. The increasing trend is mainly driven by Sales & Marketing to support the development of the ConfirMDx for Prostate Cancer in the US. In 2013, the allocation of overhead in our Cost of Good Sold was transferred in one line direcly from other expenses.

NOTE 6 : Personnel costs

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	*2015*	*2014*	*2013*
The number of employees at the end of the year was:			
Management (headcount)	6	4	4
Laboratory staff (headcount)	14	9	14
SG&A staff (headcount)	113	83	72
Total	133	96	84
Their aggregate remuneration comprised:			
Wages and salaries	10,714	8,855	8,416
Social security costs	823	812	713
Pension costs	377	349	292
Health insurance expenses	822	769	592
Share-based compensation	444	438	312
Other costs	620	371	333
Total	**13,800**	**11,594**	**10,658**

The personnel numbers in the table reflect year-end numbers. The year-end headcount in 2015 was higher than in 2014, and the total personnel costs continued to increase in 2015 because of the increase in headcount during the year.

NOTE 7 : Finance income / (expenses)

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	2015	2014	2013
Interest on bank deposits	13	14	16
Foreign exchange gain/(loss)	-5	95	-100
Other financial gain/(loss)	-99	-23	-20
Net financial results	**-91**	**86**	**-104**

The financial results is composed of realized exchange losses from exposure to €/$ and of bank service charges.

NOTE 8 : Taxes

CURRENT TAX

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.

DEFERRED TAX ASSETS

	INCOME STATEMENT		
THOUSANDS OF $/ YEARS ENDED DECEMBER 31	2015	2014	2013
Loss for the year	-14,473	-15,256	-16,175
Income tax expense	-	-	-
Loss before income tax	-14,473	-15,256	-16,175
Tax using the MdxHealth's domestic tax rate of 33,99%	-4,919	-5,186	-5,498
Effect of unused tax losses not recognized as deferred tax assets (*)	4,919	5,186	5,498

Total tax expense

The losses of the Group in the past imply that no income taxes were payable. On December 31, 2015 the Group had under IFRS a net tax loss carried forward amounting to USD 170 million (2014: USD 156 million, and 2013 : USD 146 million), implying a potential deferred tax asset of USD 58 million (respectively USD 53 million in 2014 and USD 50 million in 2013).

The tax losses do not have an expiry date for the Belgian part.

It is probable that the Company will not have taxable profits in the near future to allow all or part of the deferred tax asset to be utilized and no deferred tax asset will be recognized in 2015.

DEFERRED TAX LIABILITIES

	In the consolidated statement of financial position			*In the consolidated income statement*		
THOUSANDS OF $/ YEARS ENDED DECEMBER 31	***2015***	***2014***	***2013***	***2015***	***2014***	***2013***
Developed Technology	486	-	-	-	-	-
In-process research and development	356	-	-	-	-	-
Total	**842**	**-**	**-**	**-**	**-**	**-**

In the context of the business combination with NovioGendix, the Company recognized a deferred tax liability of $1.9 million relating to the recognition of the intangible assets of NovioGendix at the acquisition date. At the same time (i.e. the acquisition date) a deferred tax asset was recognized for the tax losses carried forward of NovioGendix amounting to $1.1 million.

(*) Permanent differences between accounting and tax books are included in the unused tax losses not recognized as deferred tax assets given their insignificant nature.

NOTE 9 : 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 $ EXCEPT PER SHARE AMOUNTS / YEARS ENDED DECEMBER 31	***2015***	***2014***	***2013***
Result for the purpose of basic loss per share, being net loss	-14,473	-15,256	-16,175
Number of shares	41,275,611	34,758,015	30,037,977
Weighted average number of shares for the purpose of basic loss per share (assuming stock split in all periods)			
Basic loss per share (in $)	-0.35	-0.44	-0.54

At December 31, 2015, 2014, and 2013, 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.

NOTE 10.1 : Goodwill

The goodwill has been allocated to the Cash Generating Unit (CGU) as follows :

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	2015	2014	2013
CGU : NovioGendix	1,145	-	-
Total Goodwill	**1,145**	**-**	**-**

The goodwill allocated to the CGU NovioGendix relates to the goodwill from the acquisition of the Company NovioGendix in September 2015. The details about the calculation of the goodwill are presented under Note 3.

The Company has performed an impairment test based on a discounted cashflow model including cashflows derived from the 10-year budget plan.

The main assumptions include a discount rate of 13% for the developed technology and 40% for the in-process R&D and include the year-on-year growth rate of the revenues, gross margin and operating costs which has been determined by the management based on past experience and the valuation difference between the deferred tax value of the valued intangibles and the historical accumulated net operating losses of the acquired entity..

It was concluded that the recoverable amount of $9 million is higher than the carrying-value of the CGU of $8.9 million.

NOTE 10.2 : Intangible assets

THOUSANDS OF $	INTELLECTUAL AND PROPERTY RIGHTS & SOFWARE LICENSES	DEVELOPMENT ASSETS	TOTAL
Gross value			
At January 1, 2013	3,426	-	3,426
Additions – internally developed	-	924	924
Disposals	-	-	-
Impairment	-	-	-
Currency translation adjustments	192	-	192
Gross value at December 31, 2013	3,618	924	4,542
Accumulated amortization			
At January 1, 2013	-3,389	-	-3,389
Additions	-18	-	-18
Disposals	-	-	-
Impairment	-	-	-
Currency translation adjustments	-154	-	-154
Accumulated amortization at December 31, 2013	-3,561	-	-3,561
Net value at December 31, 2013	**57**	**924**	**981**

THOUSANDS OF $	INTELLECTUAL AND PROPERTY RIGHTS & SOFWARE LICENSES	DEVELOPMENT ASSETS	TOTAL
Gross value			
At January 1, 2014	3,618	924	4,562
Additions– internally developed	-	1,078	1,078
Disposals	-	-	-
Impairment	-	-	-
Currency translation adjustments	-68	-	-68
Gross value at December 31, 2014	3,550	2,002	5,552
At January 1, 2014	-3,561	-	-3,561
Additions	-12	-	-12
Disposals	-	-	-
Impairment	-	-	-
Currency translation adjustments	32	-	32
Accumulated amortization at December 31, 2014	-3,541	-	-3,541
Net value at December 31, 2014	**9**	**2,002**	**2,011**

THOUSANDS OF $	INTELLECTUAL AND PROPERTY RIGHTS & SOFWARE LICENSES	DEVELOPMENT ASSETS	DEVELOPPED TECHNOLOGY	IN-PROCESS R&D FROM	TOTAL
Gross value					
At January 1, 2015	3,550	2,002	-	-	5,552
Additions– externally acquired	171	-	-	-	171
Additions– internally developed	-	353	-	-	353
Additions– acquired through business combination	-	-	4,500	3,300	7,800
Disposals	-	-	-	-	-
Impairment	-	-	-	-	-
Currency translation adjustments	-	-	-	-	-
Gross value at December 31, 2015	3,721	2,355	4,500	3,300	13,876
Accumulated amortization					
At January 1, 2015	-3,541	-	-	-	-3,541
Additions	-24	-118	-163	-	-305
Disposals	-	-	-	-	-
Impairment	-	-	-	-	-
Currency translation adjustments	-	-	-	-	-

Accumulated amortization at December 31, 2015	-3,565	-118	-163	-	-3,846
Net value at December 31, 2015	**156**	**2,237**	**4,337**	**3,300**	**10,030**

The intangible asset consists of intellectual property rights, software licenses and development assets.
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.
Intangible assets derived from internal development are depreciated over 5 years and will be fully amortized in 2020. In the meantime, intangible assets related to Developped Technology (from Business Combination) are amortized over 10 years, starting 2015.

NOTE 11 : Property, plant and equipment

THOUSANDS OF $	LABORATORY EQUIPMENT	FURNITURE	IT EQUIPMENT	LEASEHOLD IMPROVEMENTS	TOTAL
Gross value					
At January 1, 2013	2,934	249	684	391	4,258
Additions	197	14	46	0	257
Disposals	-521	-110	-543	-188	-1,362
Impairment	-	-	-	-	-
Currency translation adjustments	104	2	24	8	138
Gross value at December 31, 2013	2,714	155	211	211	3,291
Accumulated amortization					
At January 1, 2013	-2,254	-143	-559	-247	-3,203
Additions	-236	-46	-39	-86	-407
Disposals	452	108	541	125	1,226
Impairment	-	-	-	-	-
Currency translation adjustments	-96	-5	-23	-2	-126
Accumulated amortization at December 31, 2013	-2,134	-86	-80	-210	-2,510
Net value at December 31, 2013	**580**	**69**	**131**	**1**	**781**

THOUSANDS OF $	LABORATORY EQUIPMENT	FURNITURE	IT EQUIPMENT	LEASEHOLD IMPROVEMENTS	TOTAL
Gross value					
At January 1, 2014	2,714	155	211	211	3,291
Additions	163	1	31	69	264
Disposals	-1	-	-	-	-1
Impairment	-	-13	-	-	-13
Currency translation adjustments	-27	-2	1	-	-28
Gross value at December 31, 2014	2,849	141	243	280	3,513
Accumulated amortization					
At January 1, 2014	-2,134	-86	-80	-210	-2,510
Additions	-192	-45	-58	-23	-318

Disposals	-	-	-	-	-
Impairment	-8	18	-	-	10
Currency translation adjustments	31	0	-1	-1	29
Accumulated amortization at December 31, 2014	-2,303	-113	-139	-234	-2,789
Net value at December 31, 2014	546	28	104	46	724

THOUSANDS OF $	*LABORATORY EQUIPMENT*	*FURNITURE*	*IT EQUIPMENT*	*LEASEHOLD IMPROVEMENTS*	*LEASING*	*TOTAL*
Gross value						
At January 1, 2015	2,849	141	243	280	-	3,513
Acquired through business combinations	163	-	-	-	-	163
Additions	1,194	2	76	20	285	1,577
Disposals	-	-	-	-	-	-
Impairment	-	-	-	-	-	-
Gross value at December 31, 2015	4,206	143	319	300	285	5,253
Accumulated amortization						
At January 1, 2015	-2,303	-113	-139	-234	-	-2,789
Additions	- 390	- 23	- 88	- 35	- 40	- 576
Disposals	-	-	-	-	-	-
Impairment	-	-	-	-	-	-
Accumulated amortization at December 31, 2015	- 2,693	- 136	- 227	- 269	- 40	- 3,365
Net value at December 31, 2015	**1,513**	**7**	**92**	**31**	**245**	**1,888**

NOTE 12 : Inventories

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	*2015*	*2014*	*2013*
Raw materials and consumables	1,427	860	171
Total Inventories	**1,427**	**860**	**171**

Inventories are recognized at cost or not realizable value.

NOTE 13 : Trade and other receivables

TRADE RECEIVABLES

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	2015	2014	2013
Trade accounts receivable	10,978	7,500	1,997
Total trade accounts receivable	**10,978**	**7,500**	**1,997**

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

In 2015, the trade accounts receivable balances were mainly composed of services for ConfirmMDx for Prostate Cancer for $9,613,000. The average Days Sales Outstanding for this balance is 229 days in 2015. The remaining balances were related to services provided to pharmaceutical companies as at end of previous years.

PREPAID EXPENSES AND OTHER CURRENT ASSETS

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	2015	2014	2013
Prepayments	214	317	365
Deposits	79	43	44
Recoverable VAT	48	354	214
Other	40	3	125
Total prepaid expenses and other current assets	**381**	**717**	**748**

The Company considers the carrying amount of other receivables approximates their fair value.

NOTE 14 : Grants receivable

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	2015	2014	2013
NL Efro : Ultrasense	30	-	-
NL CTMM : PCMM	36	-	-
NL CTMM : ProCaMolMed	46	-	-
BE Wallonia: Eurostars - Cervix	-	-	23
BE Flanders : IWT	101	244	-
Total grants receivables	**213**	**244**	**23**
More than one year	33	105	-
Less than one year	180	139	23
Total grants receivables	**213**	**244**	**23**

When the Company acquired NovioGendix in September 2015, two subsidies from CTMM and one from EFRO were still running. Two of these project are terminated at December 2015 and a balance of $67,000 is to be received.

In 2014, the Company entered into a new project with IWT related to immunotherapy. The project is running on 36 months and was retroactive to October 1, 2013.

In 2013, the Company fulfilled all its obligation related to subsidies. The remaining balance related to the Eurostars grant is expected to be received in 2014.

We refer to note 24 Significant agreements, commitments and contingencies with respect to the main grant conditions.

NOTE 15 : Cash and cash equivalents

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	*2015*	*2014*	*2013*
Cash at bank and in hand	31,680	18,897	24,683
Total cash and cash equivalents	**31,680**	**18,897**	**24,683**

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.

The Company has restricted cash for an amount of $1,160 thousand representing a guarantee with respect to the ING loan. The group has no other restriced cash.

NOTE 16 : 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

At the end of 2015, the Company operated with more than 400 different customers, representing a significant reduction in credit risk when compared to prior periods. In 2013, the Company reduced its credit risk from the reliance on a small number of customers by generating 50% of its revenues related to ConfirmMDx for Prostate Cancer with a large range of customers. In 2014, the trend initiated in 2013 continued, with the consequence, the credit risk has been substantially reduced considering the large and diverse customer base.

In the US healthcare system, and particularly within the molecular diagnostic CLIA laboratory industry, where there is rapid technological advances in diagnostic services, companies provide services to healthcare professionals and their patients, while being reimbursed from commercial and governmental insurance systems. Often these services are provided out of network and without supplier contracts. As a result, there is

reimbursement risk, separate from credit risk that is characterized by uncertainty in reimbursement value, delays in payment, and ultimately non-payment. This impacts the Company's revenue recognition and cash collections discussed above in NOTE 2 : Accounting Policies and Revenue Recognition. Discussion regarding the progress made in revenue recognition and collections are noted in the Revenue Recognition section.

In addition to reimbursement risk associated with commercial third party payors, there is in some cases a new credit risk associated with amounts due directly from patients. In many cases, payors will cover the entire cost of testing. The ConfirmMDx test falls under the Clinical Laboratory Fee Schedule, so there is no co-payment, co-insurance or deductible for patients covered under traditional Medicare. However, patients covered by commercial insurance companies may be responsible for a co-payment, co-insurance, and/or deductible depending on the health insurance plan and individual patient benefit. Patients who cannot meet their co-payment or deductible portions can create a credit risk that is new to the Company.

Customer's compliance with agreed credit terms is monitored regularly and closely. No major overdue trade accounts receivable are identified and the year-end 2015 balance was $10,978,000.

Receivables related to research grants from the Belgian government ($213 thousand at December 31, 2015) 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 $31,680,000 (€29,099,000) is limited given that the counterparties are banks with high credit scores attributed by international rating agencies.

INTEREST RISK

The group is subject to interest risk in regards of the bank loans agreements entered during 2015. In reference to note 18, the Group has contracted bank loans for a total of $750,800 with ING for which the interest rate charged is equivalent to LIBOR + 1.20%.

Despite the non-materiality of the amounts, the Group has performed a sensitivity analysis in order to report the exposure to variations in interest rates of +2% and -2%. As a consequence, the Group is exposed to additional interests' charges of $23 thousand if LIBOR increases by 2%, and to a reduction of $4 thousand if LIBOR is lowered at its minimal value, meaning 0%.

CURRENCY RISK

Considering the continuing development of the commercial activities in the US market, the Company has decided to change its presentation currency from the EURO to the US Dollar as of January 1, 2013. The functional currency changed also from the EURO to the US Dollar as of July 1, 2014. In consequence, the currency risk is concentrated on European operations.

The monetary items at December 31, 2015 in Euros are composed of cash on hand of € 4,771,000.

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

The exposure of operations to the currency risk is limited to the net amount of €4.5 million (€0.2 million revenue and €4.7 million costs), giving a potential loss of €502,000 in case of an increase of the USD/Euro exchange rate by 10%, and a potential gain of €411,000 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 four loan agreements with banks and one financial least at December 31, 2015 (see note 18) 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.

NOTE 17 : 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	*2015*	*2014*	*2013*
Common shares	45,153,633	37,676,303	34,251,303
Total outstanding shares	**45,153,633**	**37,676,303**	**34,251,303**

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

	THOUSAND OF $/			*THOUSANDS OF €/*		
YEARS ENDED DECEMBER 31	*2015*	*2014*	*2013*	*2015*	*2014*	*2013*
Share Capital as per statutory accounts	47,399	40,727	37,680	36,019	30,054	27,322
IPO Costs & Capital Increase costs	-4,608	-2,902	-2,197	-3,682	-2,138	-1,393
Share capital under IFRS	42,791	37,825	35,483	32,337	27,916	25,729
Issuance premium	83,118	53,273	41,694	66,503	39,831	30,233
Share capital and issuance premium	125,909	91,098	77,177	98,980	67,747	55,962

The share capital and issuance premium increased in 2015 as a result of the private placement with institutional

investors of 6,150,000 new shares on June 26, 2015 issued at €3.60 per share, but also with the creation of 1,086,956 for the acquisition of NovioGendix, and two other capital increases related to warrants exercise.

A detailed history of the Share Capital can be found in "General Information; Capital and Shares".

EXTERNALLY IMPOSED CAPITAL REQUIREMENTS

None of the current contracts of the Company imposes 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 €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.

NOTE 18 : Loans and Leases payables

				OUTSTANDING AT DECEMBER 31		
		INTEREST RATE	MATURITY	2015	2014	2013
$ 303,000.00	bank loan	LIBOR + 1.20%	31/07/2017	227	-	-
$ 75,000.00	bank loan	LIBOR + 1.20%	31/12/2017	75	-	-
$ 220,000.00	bank loan	LIBOR + 1.20%	31/12/2017	220	-	-
$ 152,800.00	bank loan	LIBOR + 1.20%	31/12/2017	153	-	-
$ 285,964.61	obligations under finance lease finance lease (third parties)	3.50%	30/07/2018	173	-	-
				848	-	-

All bank loans, for a total of $750.800 have been used to finance the acquisition of laboratory equipment of the US facilities in Irvine. They have a maturity of 2-years, with reimbursement period of 3 months. The interest rate applicable each quarter is fixed by the LIBOR rate in USD with a margin of 1.20%. These loans are secured with a cash pledge. We refer to note 16 Financial Risks Management – interest risk where we provide a sensitivity analysis.

The Company has one finance lease obligation with Cisco Systems Capital Corporation. The lease has a term of 3 years and a purchase option for the equipment. The Company has determined that this lease is a finance lease because (i) the purchase option is assumed to be significantly lower than the fair value of the equipment and (ii) it was very likely at inception of the lease that the Company would exercise its purchase option. The amount outstanding as of December 31 2015 is $173,000 and the interest expense for the year 2015 is $2,000.

NOTE 19: Operating lease obligations

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	2015	2014	2013
Outstanding commitments for future minimum rent payments, which fall due as follows :			
Within one year	464	535	409
In the second to fifth year	1,087	562	510
After five years	165	-	-

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.

NOTE 20 : Trade and other payables

TRADE ACCOUNTS PAYABLE

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	2015	2014	2013
Trade accounts payable	5,152	4,236	2,313
Accruals for invoices to be received	1,458	1,028	958
Total trade accounts payable	**6,610**	**5,264**	**3,271**

OTHER CURRENT LIABILITIES

THOUSANDS OF $/ YEARS ENDED DECEMBER 31	2015	2014	2013
Payroll	2,800	1,720	1,577
Other accruals	1	-	-
Total other current liabilities	**2,801**	**1,720**	**1,577**

The trade accounts payable and other current liabilities balances have increased mainly because MDxHealth incurred costs related to the increasing activity of its CLIA lab facility in Irvine, California. See also Note 5 for further details on payroll expenses.

NOTE 21 : 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 $377,000 in 2015 (respectively $349,000 and $292,000 in 2014 and in 2013) 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 obligation of the Company with respect to the retirement benefit scheme is to make the specified contributions.

Because the Company has to guarantee the statutory minimum return on these plans, not all actuarial and investment risks relating to these plans are transferred to the insurance company or pension fund managing the plans. The Company has considered the potential impact of the employer's obligation to guarantee a minimum return and that this was assessed not to be significant.

By law, defined contribution pension plans in Belgium are subject to minimum guaranteed rates of return. Hence, strictly speaking, those plans classify as defined benefit plans. The IASB recognised that the accounting for such so-called "contribution-based plans" in accordance with the currently applicable defined benefit methodology is problematic. Considering as well the uncertainty with respect to the future evolution of the minimum guaranteed rates of return in Belgium, the Company adopted a retrospective approach whereby the net liability recognized in the statement of financial position is based on the sum of the positive differences, determined by individual plan participant, between the minimum guaranteed reserves and the accumulated contributions based on the actual rates of return at the closing date (i.e. the net liability is based on the deficit measured at intrinsic value, which is not significant).

NOTE 22 : Stock Option plans (warrants)

This section provides an overview of the outstanding warrants as of December 31, 2015. The warrants were created within the context of stock based incentive plans for employees, directors and consultants of the Company.

The Company has created several pools of warrants under stock option plans for grant to eligible employees, Directors, and consultants. On May 12, 2004 (30,000), July 12, 2005 (15,000), March 22, 2006 (66,700), November 8, 2006 (47,500), April 18, 2007 (55,100), May 25, 2007 (50,000), May 30, 2008 (61,000), January 2, 2009 (120,500), June 21, 2010 (145,000), May 27, 2011 (225,000), March 15, 2012 (195,000), June 15, 2012 (700,000), June 23, 2014 (1,500,000) in aggregate 3,210,800 warrants were issued, subject to warrants being granted to and accepted by the beneficiaries. Of these 3,210,800 warrants, (i) 422,515 warrants were terminated or lapsed, (ii) 308,3010 warrants were exercised, (iii) 1,378,475 warrants were granted but not yet exercised, and (iv) 1,101,500 warrants were not yet granted by the Company. For the year 2015, 16,438 warrants were terminated or lapsed, 240,374 warrants were exercised and 67,188 warrants were vested. As a result, as at December 31, 2015, there are 1,378,475 warrants outstanding, entitling their holders to subscribe to 1,507,627 shares of the Company

(given that 32,288 of these outstanding warrants each entitle to subscribe to 5 shares per warrants, whereas all other warrants entitle to subscribe to 1 share per warrant).

	Number of potential shares from outstanding warrants
At January 1, 2015	1,403,439
Number of warrants cancelled/forfeited during the year	- 16,438
Number of warrants exercised during the year	- 240,374
Number of warrants granted during the year	361,000
At December 31, 2015	**1,507,627**

The warrants are granted to employees, consultants or directors of the Company and its subsidiaries. The warrants have been granted free of charge. Except for the warrants issued on March 22, 2006 that entitle their holders to subscribe to five common shares per warrant, each warrant entitles its holders to subscribe to one common share of the Company at a subscription price determined by the board of directors, within the limits decided upon at the occasion of their issuance.

The warrants issued have generally a term of ten years as of issuance, except for the warrants issued on May 12, 2004, July 12, 2005, May 25, 2007, June 21, 2010 which have a term of five years as of issuance. Upon expiration of their term, the warrants become null and void.

In general, the warrants vest in cumulative tranches of 25% per year, provided that the beneficiary has provided at least one year of service. However, there are certain exceptions to this rule which are, if applicable, specified in the relevant stock option plans. The 30,000 warrants granted under the May 2011 Stock Option Plan to the CEO became vested immediately on the date of grant (i.e. December 7, 2010). The warrants granted under the May 2012 Stock Option Plan and under the June 23, 2014 Stock Option Plan to directors all vest on the date of the annual meeting that takes place in the calendar year following the calendar year in which they were granted, provided that the mandate of the relevant director has not ended or been terminated. The warrants granted under the May 2012 Stock Option Plan and under the June 23, 2014 Stock Option Plan to beneficiaries who are not directors all vest in installments of 25% per year, the first trenche of 25% vesting on the first anniversary date of the date of grant and the following trenches vesting on a quarterly basis.

The table below presents the outstanding warrants and their exercise price at the end of each accounting year covered by the financial statements:

	Warrants	Weighted average exercise price (€)	Potential shares from exercise of warrants	Weighted average exercise price per potential share (€)
Granted in 2013	245,000	2.04	245,000	2.04
Outstanding 31 December 2013	962.163	3.17	1,091,315	2.79
Granted in 2014	361,500	3.70	361,500	3.70
Outstanding 31 December 2014	1,274,287	3.35	1,403,439	3.04
Granted in 2015	361,000	4.33	361,000	4.33
Outstanding 31 December 2015	1,378,475	3.85	1,507,627	3.52
Exercisable at 31 December 2015	883,102	3.69	1,012,754	3.22

The following table provides an overview of the outstanding potential shares from warrants per personnel category at December 31, 2015:

Category	Number of potential shares from outstanding warrants
Executive Director	147,813
Non-Executive Directors	190,000
Management team (excluding the Executive Director)	567,500
Other employees, consultants, and former service providers	602,314
Total outstanding at December 31, 2015	1,507,627

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 statement of comprhansive income as such is given below as is the cumulated amount as per the consolidatet statement of financial position:

Thousands of $/ Years ended December 31	2015	2014	2013
Share-based compensation	443	437	312
Cumulated Share-based compensation	4,701	4,264	3,864

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 €3.52 ($conversion 3.83 at December 31, 2015). The weighted average remaining contractual life of all outstanding warrants at the end of 2015 is 4.77 years.

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

Dates	Number of warrants granted		Exercise price (€)	Expected dividend Yield	Expected stock price volatility	Risk-free interest rate	Expected duration (months)	
	to Belgian benef.	to other benef.					to Belgian benef.	to other benef.
12-May-04	28,750	120,000	€ 4.46	-	51.00%	3.25%	51.70	48.10
12-Jul-05	50,00	25,000	€ 4.77	-	51.00%	3.25%	43.70	40.70
22-Mar-06	201,250	132,250	€ 4.80	-	51.00%	3.25%	88.40	54.40
08-Nov-06	19,00	28,000	€ 7.72	-	65.00%	4.41%	84.00	72.00
04-Jan-07	32,100	23,000	€ 10.87	-	65.00%	4.41%	87.00	68.90
25-May-07	15,000	35,000	€ 11.42	-	65.00%	4,41%	55.30	37.20
30-May-08	12,000	37,000	€ 9.10	-	52.30%	4.92%	82.10	61.10
02-Jan-09	63,400	53,200	€ 6.32	-	57.24%	3.98%	74.08	62.88
21-Jun-10	135,000	10,000	€ 2.07	-	76.17%	3.40%	51.35	33.34
27-May-11	100,000	125,000	€ 1.71	-	68.81%	4.15%	76.21	58.19
15-Mar-12	75,000	120,000	€ 1.72	-	67.74%	3.43%	78.57	60.56
15-Aug-12	12,000	24,000	€ 1.52	-	54.50%	2.57%	73.54	61.54
14-Sep-12	-	85,000	€ 1.65	-	55.58%	2.59%	72.56	60.56
01-Dec-12	-	10,000	€ 2.19	-	57.13%	2.19%	75.98	57.99
01-Jan-13	65,000	107,000	€ 2.00	-	57.13%	2.09%	80.97	62.92
01-Feb-13	-	23,000	€ 2.26	-	49.99%	2.39%	79.96	61.91
01-Apr-13	-	5,000	€ 2.30	-	51.52%	2.18%	78.02	59.97
01-May-13	-	15,000	€ 2.13	-	49.75%	1.93%	77.03	58.98

31-May-13	12,000	18,000	€ 2.05	-	49.62%	2.22%	76.04	57.99
12-Mar-14	76,000	177,000	€ 3.60	-	47.75%	2.24%	72.69	54.67
01-Apr-14	-	12,000	€ 4.32	-	48.82%	2.21%	72.03	54.02
30-May-14	18,000	18,000	€ 4.25	-	48.68%	1.86%	70.09	52.08
01-Jun-14	-	4,000	€ 4.24	-	48.81%	1.86%	70.03	52.01
01-Jul-14	-	15,000	€ 4.02	-	48.58%	1.72%	69.04	51.02
1-avr-15	-	4,000	€ 5.02	-	47.42%	0.40%	60.03	47.97
23-juin-14	12,000	12,000	€ 4.13	-	48.12%	1.78%	75.32	63.29
10-oct-14	-	17,500	€ 4.01	-	46.93%	1.01%	69.73	57.70
9-févr-15	60,000	95,000	€ 4.49	-	46.75%	0.62%	79.73	61.71
29-mai-15	20,000	30,000	€ 4.91	-	46.52%	0.81%	64.14	52.11
1-avr-15	-	3,000	€ 5.02	-	47.42%	0.40%	72.03	54.02
1-mai-15	-	20,000	€ 5.05	-	46.59%	0.62%	71.05	53.03
1-juin-15	-	6,000	€ 4.90	-	46.58%	0.81%	70.03	52.01
1-juil-15	-	4,000	€ 4.62	-	47.02%	1.27%	69.04	51.02
1-août-15	-	4,000	€ 4.64	-	46.54%	0.98%	68.02	50.01
1-sept-15	-	85,000	€ 4.24	-	49.31%	1.15%	73.02	48.99
1-oct-15	-	8,000	€ 4.20	-	48.99%	0.90%	72.03	54.02
1-nov-15	-	4,000	€ 3.81	-	50.88%	0.92%	71.01	52.99
1-déc-15	-	18,000	€ 3.89	-	51.18%	0.85%	70.03	52.01

The above inputs for the Black-Scholes model have been determined based on the following:

- The dividend return is estimated by reference to the historical dividend payment of the Group. Currently, this is estimated to be zero as no dividends have been paid since inception.
- The expected volatility was determined using the average volatility of the stock over the last two years at the date of grant.
- Risk-free interest rate is based on the interest rate applicable for the 10Y Belgian government bond at the grant date

NOTE 23 : Related parties

Transactions between MDxHealth SA, MDxHealth Inc. and MDxHealth B.V. which are related parties, have been eliminated in consolidation and are not disclosed in this note. Since 2012, the intercompany services relate to royalties paid by MDxHealth Inc. to MDxHealth SA and to interest on intercompany loans. In 2015, the services charged by the parent company to the subsidiary amounted to $4.0 million.

Transactions between the Company and its employees, consultants or Directors are described below. There were no other related party transactions.

REMUNERATION OF KEY MANAGEMENT PERSONNEL

At December 31, 2015, the executive management team comprises 2 additional members compared to prior years, and counts now 6 members:

1. Chief Executive Officer and Executive Director, Dr. Jan Groen
2. Executive Vice President of Corporate Development & General Counsel, Mr. Joseph Sollee
3. Executive Vice President of Finance, Mr. Francis Ota
4. Executive Vice President of Sales & Chief Commercial Officer, Mr. Christopher Thibodeau
5. Executive Vice President and Chief Medical Officer, Mr. Philip Ginsburg M.D.
6. Senior Vice President of Laboratory Operations, Ms. Miriam Reyes

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)[3]:

THOUSANDS OF $ EXCEPT PER PERSONNEL, WARRANTS & SHARE AMOUNTS YEARS ENDED DECEMBER 31	*2015*	*2014*	*2013*
Number of management members and Executive Directors	6	4	4
Short-term employee benefits	1,895	1,537	1,441
Post-employment benefits	58	47	47
Other employment costs	99	90	53
Total benefits	2,052	1,674	1,541
IFRS share-based compensation expense	217	183	136
Outstanding receivables from persons	-	-	-
Outstanding payables to persons	-	-	-
Shares owned	-	-	-

[3] Years prior to 2015 show data for the Executive Management Team at that period, meaning 4 members.

Number of warrants offered	210 ,000	157,500	120,000
Cumulative outstanding warrants	715,313	672,500	515,000
Exercisable warrants	434,689	451,251	328,139
Exercised warrants	222,187	-	-

In 2015, as an aggregate for the group comprised by the 6 executive managers, 222,187 warrants were exercised, 210,000 new warrants were granted and accepted (for an annualized IFRS cost of $ 217 thousands), and no shares were sold.

In 2014, as an aggregate for the group comprised by the 4 executive managers, no warrants were exercised, 157,500 new warrants were granted and accepted (for an annualized IFRS cost of $89 thousands), and no shares were sold.

In 2013, 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 $70 thousands), 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-Independent Directors do not receive a fee payment for attending and preparing for Board meetings or for assisting the Company with Board matters. They receive reimbursement for expenses directly related to the Board meetings, totaling $23,000 in 2015.

The Independent Directors receive a fee for attending and preparing meetings of the Board of Directors and for assisting the Company with Board matters, and they receive reimbursement for expenses directly related to the Board meetings. In 2015, 2014, and 2013, respectively $97,000, $178,000 and $179,000 were paid as fees and expense reimbursement to independent members of the Board of Directors.

A total of 50,000 warrants were granted to Non-Executive Directors in 2015. A total of 10,000 warrants were exercised in 2015.

NOTE 24 : Significant agreements, commitments and contingencies

FAIR VALUE OF EARN OUT

MDxHealth on September 18, 2015 acquired NovioGendix, a Dutch molecular diagnostic research and service company with expertise in the urological oncology. The terms of the acquisition consisted of initial consideration paid in 1,086,956 shares of MDxHealth common stock, issued at €4.14 representing the average closing price of the Company's shares on Euronext Brussels during a period of 30 days ending on September 17, 2015. In addition to this equity an additional cash payment of €250,000 cash paid. On top of the acquisition price, MDxHealth is committed to pay future milestone fees to third-parties. The fair value of the earn out as of December 31, 2015 is estimated at $2,260,000 over the period 2015-2019.

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.

MDxHealth collaborates on research and clinical development with many of the world's leading academic and government 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. MDxHealth's collaborators include such prestigious institutions as Johns Hopkins University Medical Institutions (US), Duke University Medical Center (US), Harvard Medical School (US), Cleveland Clinic (US), University of Colorado (US), University of California at Los Angeles (US), Erasmus University (The Netherlands), University of Edinburgh (UK), and University of Gent (Belgium) among others.

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.

COMMERCIAL AND INTELLECTUAL PROPERTY SUB-LICENSING AGREEMENTS

The Company has entered into numerous partnering and sub-licensing agreements. We refer to "Facts & Figures; Business; Commercial Collaborators" for detailed information.

LITIGATION

As of the date of this document and as far as MDxHealth is aware, the Company is not involved in any legal proceedings.

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 €9.6 million in grants ($10,5 million conversion at December 31, 2015 at EUR/USD rate of 1.0887) and has received grant payments for a total of €9.5 million. A total of €9.5 million has already been recognized as revenues in the period 2004-2015. The revenues generated by grants recognized in 2015 were $173k.

The active grants are the following:

(1) Name (2) Source (3) Description (4) Applicability	Start Date	End Date	Amount Approved (€)	Amount Received (€)	Main Conditions
(1) IWT (2) Belgian government (Flanders), (3) R&D for cervix cancer (4) covers mainly personnel and sample collection costs	1/10/2013	30/09/2016	272	108	Respect plans and budget.
(1) UltraSense NMR (2) EFRO (EU), (3) R&D for a UltraSense NMR platform (4) covers all personell and material cost, at a subsidy rate of 59%	1/12/2010	1/12/2015	109	81	Respect plans and budget.
(1) ProCaMolMed (2) CTMM (3) R&D validation of Quattro/SelectMDx samples (4) covers mainly personel costs and has a significant part of "in kind" imbursement	1/07/2015	30/06/2017	58	12	Respect plans and budget.
(1) PCMM (2) CTMM (3) R&D for Prostate Cancer (4) covers mainly personell costs	1/12/2009	30/06/2015	868	835	Respect plans and budget.

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.

NOTE 25 : Subsequent events

In 2016, through the date of this document, the Company made the following normal course of business announcements:

- Published data in *The Journal of Urology* demonstrating that AssureMDx for Bladder Cancer delivers a high negative predictive value of 99.2% supporting the clinical potential of the Company's urine-based epigenetic bladder cancer test to aid urologists in the management of patients presenting with haematuria (i.e., blood in urine)

- At American Society of Clinical Onclology (ASCO) Genitourinary Cancers Symposium In San Francisco, California, USA MDxhealth revealed data demonstrating that ConfirmMDx genes can aid in the detection of clinically significant prostate cancer, as well as difficult to detect anterior cancers, showing further the product's clinical utility for patients who may benefit from early detection and treatment
- Frost & Sullivan granted MDxhealth the 2016 Global Prostate Cancer Diagnostics Technology Innovation Award
- MDxHealth Provides Preliminary Update on Results, Reporting Strong Sales Trajectory for ConfirmMDx

NOTE 26 : Disclosure under Article 114 of the Royal Decree dated January 30, 2001 implementing the Belgian Company Code

SUBSIDIARIES

The Company has two wholly-owned subsidiary, as follows:

MDXHEALTH INC.

Address	15279 Alton Parkway – Suite 100 – Irvine, CA 92618
Incorporation Date	April 14, 2003
Number of employees	119 at December 31, 2015, 96 at December 31, 2014 and 73 at December 31, 2013

MDXHEALTH B.V.

Address	Geert Grooteplein-Zuid 34, 6425 GA Nijmegen, The Netherlands
Incorporation Date	October 18, 2006
Incorporated into MDxHealth on	September 18, 2015
Number of employees	7 at December 31, 2015

REMUNERATION OF THE BOARD

The total remuneration of the Board of Directors (including the Executive Director) in 2015, 2014 and 2013 was $745,000, $898,000, and $850,000 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.

SERVICES PERFORMED BY THE AUDITOR AND PERFORMANCE OF EXCEPTIONAL ACTIVITIES OR EXECUTION OF SPECIAL INSTRUCTIONS (ARTICLE 134 BELGIAN COMPANY CODE.)

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 Company expensed €123 thousand (USD equivalent $136 thousand) in fees to the auditor in 2015. The fees are broken down as follows:

- Audit fee for statutory and consolidated financials of €65 thousand ($72 thousand)
- Audit related services (comfort letter procedures, legal missions,…) €39 thousand ($43 thousand)
- Other missions €5 thousand (USD equivalent $6 thousand) and tax consulting services €4 thousand ($4 thousand)
- Specific review of Purchase Price Allocation NovioGendix €10 thousand (USD equivalent $11 thousand)

STATUTORY AUDITOR'S REPORT

STATUTORY AUDITOR'S REPORT TO THE GENERAL SHAREHOLDERS MEETING OF THE COMPANY MDXHEALTH SA FOR THE YEAR ENDED DECEMBER 31, 2015

As required by law, we report to you on the performance of our mandate of statutory auditor. This report includes our opinion on the consolidated financial statements, as well as the required additional statements. The consolidated financial statements comprise the consolidated statement of financial position as at 31 December 2015, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended and the explanatory notes.

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 2015, prepared in accordance with the International Financial Reporting Standards as adopted by the European Union, which show a consolidated statement of financial position total of 57,742 thousand USD and a consolidated income statement showing a consolidated loss for the year of 14,473 thousand USD.

Responsibility of the board of Directors for the preparation of the consolidated financial statements

The board of Directors is responsible for the preparation of consolidated financial statements that give a true and fair view in accordance with the International Financial Reporting Standards, and for such internal control as the board of Directors determines is necessary to enable the preparation of annual accounts that are free from material misstatement, whether due to fraud or error.

Responsibility of the statutory auditor

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 (ISA's). Those standards require that we comply with the ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

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 statutory 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 statutory auditor considers the Company's internal control relevant to the preparation of 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 the board of Directors, as well as evaluating the overall presentation of the consolidated financial statements.

We have obtained from the board of Directors and company officials the explanations and information necessary for performing our audit.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Unqualified opinion

In our opinion, the consolidated financial statements of the company MDxHealth SA give a true and fair view of the group's equity and financial position as at 31 December 2015, and of its results and its cash flows for the year then ended, in accordance with the International Financial Reporting Standards as adopted by the European Union.

Report on other legal and regulatory requirements

The board of Directors is responsible for the preparation and the content of the Directors' report on the consolidated financial statements.

In the context of our mandate and in accordance with the Belgian standard which is complementary to the International Standards on Auditing (ISAs) as applicable in Belgium, our responsibility is to verify, in all material respects, compliance with certain legal and regulatory requirements. On this basis, we make the following additional statements, which do not modify the scope of our opinion on the consolidated financial statements:

- The Directors' report the consolidated financial statements includes the information required by law, is consistent with the consolidated financial statements and is free from material inconsistencies with the information that we became aware of during the performance of our mandate.

Zaventem, 26 April 2016

BDO Réviseurs d'Entreprises Soc. Civ. SCRL
Statutory auditor
Represented by Gert Claes

STATUTORY AUDITOR'S REPORT TO THE GENERAL SHAREHOLDERS MEETING OF THE COMPANY MDXHEALTH SA FOR THE YEAR ENDED DECEMBER 31, 2014

As required by law, we report to you on the performance of our mandate of statutory auditor. This report includes our opinion on the consolidated financial statements, as well as the required additional statements. The consolidated financial statements comprise the consolidated statement of financial position as at 31 December 2014, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended and the explanatory notes.

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 2014, prepared in accordance with International Financial Reporting Standards as adopted by the European Union, which show a consolidated statement of financial position total of 30,953 thousand USD and a consolidated income statement showing a consolidated loss for the year of 15,256 thousand USD.

RESPONSIBILITY OF THE BOARD OF DIRECTORS FOR THE PREPARATION OF THE CONSOLIDATED FINANCIAL STATEMENTS

The board of Directors is responsible for the preparation of 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 the board of Directors determines is necessary to enable the preparation of annual accounts that are free from material misstatement, whether due to fraud or error.

RESPONSIBILITY OF THE STATUTORY AUDITOR

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 (ISA's). Those standards require that we comply with the 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 statutory 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 statutory auditor considers the Company's internal control relevant to the preparation of 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 the board of Directors, as well as evaluating the overall presentation of the consolidated financial statements.

We have obtained from the board of Directors and company officials the explanations and information necessary for performing our audit.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

UNQUALIFIED OPINION

In our opinion, the consolidated financial statements of the company MDxHealth SA give a true and fair view of the group's equity and financial position as at 31 December 2014, and of its results and its cash flows for the year

then ended, in accordance with the International Financial Reporting Standards as adopted by the European Union.

Report on other legal and regulatory requirements

The board of Directors is responsible for the preparation and the content of the Director's report on the consolidated financial statements.

In the context of our mandate and in accordance with the Belgian standards which are complementary to the International Standards on Auditing (ISAs) as applicable in Belgium, our responsibility is to verify, in all material respects, compliance with certain legal and regulatory requirements. On this basis, we make the following additional statement, which does not modify the scope of our opinion on the consolidated financial statements:

The Director's report on the consolidated financial statements includes the information required by law, is consistent with the consolidated financial statements and is free from material inconsistencies with the information that we became aware of during the performance of our audit engagement.

Zaventem, 26 February 2015

BDO Réviseurs d'Entreprises Soc. Civ. SCRL
Statutory auditor
Represented by Bert Kegels
Registered auditor

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).

STATUTORY INCOME STATEMENT

STATUTORY INCOME STATEMENT

THOUSANDS OF €/ YEARS ENDED DECEMBER 31	*2015*	*2015 IN $ EQUIVALENT*	*2014*	*2013*
I. Operating income	**5,201**	5,827	**3,232**	**3,664**
A. Turnover	4,656	5,216	2,958	3,396
D. Other operating income	545	611	274	268
II. Operating charges	**7,116**	7,972	**4,964**	**6,097**
A. Purchase of goods and materials	154	173	352	378
B. Services and other goods	5,803	6,501	3,099	3,252
C. Remuneration, social security costs, pensions	1,091	1,222	1,349	1,966
D. Depreciation & amounts written off fixed assets	68	76	163	433
G. Other operating charges	-	-	1	68
III. Operating profit/(loss)	**(1,915)**	(2,145)	**(1,732)**	**(2,433)**
IV. Financial income	**1,127**	1,263	**652**	**364**
B. Income from current assets	1,127	1,263	652	364
C. Other	-	-	-	-
V. Financial charges	**171**	191	**10**	**791**
A. Debt charges	3	3	-	-
C. Other	168	188	10	791
VI. Current profit/(loss) before taxes	**(959)**	(1,073)	**-**	**(2,860)**
VII. Extraordinary income	**-**	-	**-**	**-**
VIII. Extraordinary charges	**-**	-	**-**	**-**
A. Extraordinary depreciations & amounts written off fixed assets	-	-	-	-
B. Extraordinary depreciation on financial assets	-	-	-	-
IX. Profit/(loss) before taxes	**(959)**	-1,073	**(1,090)**	**(2,860)**
X. Income taxes	**-**	-	**-**	**-**
XI. Profit/(loss) for the year after taxes	**(959)**	-1,073	**(1,090)**	**(2,860)**

APPROPRIATION ACCOUNT

THOUSANDS OF €/ YEARS ENDED DECEMBER 31	2015	2015 IN $ EQUIVALENT	2014	2013
A. Loss to be appropriated				
A1. Loss for the period available for appropriation	(959)	(1,073)	(1,090)	(2,860)
A2. Loss brought forward	(22,255)	(24,200)	(21,165)	(18,305)
B. Transfer from capital and reserves				
B1. From capital and share premium account	-	-	-	-
C. Transfer to equity				
D. Result to be carried forward				
D2. Loss to be carried forward	23,214	25,273	22,255	21,165

STATUTORY BALANCE SHEET

STATUTORY BALANCE SHEET AFTER APPROPRIATIONS

THOUSANDS OF €/ YEARS ENDED DECEMBER 31	2015	2015 IN $ EQUIVALENT	2014	2013
ASSETS	8,202	8,930	3,483	3,539
I. Formation expenses	-	-	-	-
II. Intangible assets	**1**	**1**	**6**	**25**
III. Tangible fixed assets	**22**	**24**	**48**	**85**
B. Plant, machinery and equipment	22	24	48	85
C. Furniture and vehicles	-	-	-	-
IV. Financial assets	**8,179**	**8,905**	**3,429**	**3,429**
A. Affiliated enterprises	8,172	8,897	3,422	3,422
A1. Investments	8,172	8,897	3,422	3,422
A2. Amounts receivable	-	-	-	-
C. Other financial assets	-	-	-	-
C1. Investments	-	-	-	-
C2. Amounts received and cash guarantee	7	8	7	7
CURRENT ASSETS	84,883	92,412	**50,302**	**34,214**
V. Amounts receivable after one year	-	-	-	-
VI. Stocks and contracts in progress	-	-	-	-
VII. Amounts receivable within one year	**56,391**	**61,393**	**34,902**	**16,418**
A. Trade debtors	56,227	61,214	34,396	16,168
B. Other amounts receivable	164	179	506	250
VIII. Investments	**28,459**	**30,983**	**15,319**	**17,705**
B. Other investments and deposits	-	8,930	1	147
IX. Cash at bank and in hand	**28,459**	-	**15,318**	**17,558**
X. Deferred charges and accrued income	**33**	**1**	**81**	**91**
TOTAL ASSETS	**93,085**	**24**	**53,785**	**37,753**

STATUTORY BALANCE SHEET AFTER APPROPRIATIONS

THOUSANDS OF €/ YEARS ENDED DECEMBER 31	*2015*	*2015 IN $ EQUIVALENT*	*2014*	*2013*
CAPITAL AND RESERVES	**79,307**	86,342	**47,629**	**36,388**
I. Capital	**36,018**	39,213	**30,054**	**27,321**
A. Issued capital	36,018	39,213	30,054	27,321
II. Share premium account	**66,503**	72,402	**39,830**	**30,232**
III. Revaluation surpluses	-	-	-	-
IV. Reserves	-	-	-	-
V. Accumulated profit/(loss)	**(23,214)**	-25,273	**(22,255)**	**(21,165)**
VI. Investment grants	-	-	-	-
VII. Provisions and postponed taxes	-	-	-	-
A. Provisions for liabilities and charges	-	-	-	-
A4. Other liabilities & charges	-	-	-	-
AMOUNTS PAYABLE	**13,778**	15,000	**6,156**	**1,365**
VIII. Debts payable after 1 year	**275**	299	-	-
A. Financial debts	275	299	-	-
A4. Credit institutions	275	299	-	-
IX. Debts payable within 1 year	**3,169**	3,451	**1,754**	**1,365**
A. Current portion of debts after one year	-	-	-	-
B. Financial debts	345	376	-	-
B1. Credit institutions	345	376	-	-
C. Trade debts	2,533	2,758	1,442	1,071
C1. Suppliers	2,533	2,758	1,442	1,071
D. Advances received on contracts in progress	-	-	-	-
E. Taxes, remuneration & social security	291	317	312	294
E1. Taxes	-	-	3	3
E2. Remuneration & social security	291	317	309	291
X. Accrued charges and deferred income	**10,334**	11,250	**4,402**	-
TOTAL LIABILITIES	**93,085**	101,342	**53,785**	**37,753**

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 L/D* OTHER	BASIS NR/R**	DEPRECIATION RATE PRINCIPAL MIN - MAX	DEPRECIATION RATE ACCESSORY COSTS MIN - MAX
Industrial, administrative or commercial buildings [a]	L	NR		
Other buildings	L	NR		
Installations and equipment [a]	L	NR	20% – 33.33%	20% - 33.33%
Vehicles [a]	L	NR	20% - 20%	20% - 20%
Office 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.

ANNEX

GLOSSARY OF KEY INDUSTRY TERMS

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 US accrediting agency for the US 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 US 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.

GLOSSARY OF KEY INDUSTRY TERMS

CMS	US Centers for Medicare & Medicaid Services
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.
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.
EPIGENETICS	Refers to heritable changes in gene expression (active versus inactive genes) that does not involve changes to the underlying DNA sequence (i.e., a change in phenotype without a change in genotype). This in turn affects how cells read the genes. Epigenetic change is a regular and natural occurrence but can also be influenced by several factors including age, the environment/lifestyle, and disease state.
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.
HIPAA	US Health Insurance Portability and Accountability Act of 1996
HITECH	US Health Information Technology for Economic and Clinical Health Act
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.

MEDICAID	Medicaid is a medical assistance program in the US established by Title XIX of the US Social Security Act. The Medicaid program is a no-cost or low-cost public health insurance program for US residents that provides needed health care services for low-income and disabled individuals.
MEDICARE	Medicare is a national social insurance program, administered by the U.S. federal government, established in 1966 under Title XVIII of the US Social Security Act. Medicare provides health insurance for US residents aged 65 and older who have worked and paid into the system. It also provides health insurance to younger people with certain disabilities and designated diseases.
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^6-methylguanine DNA-methyltransferase (MGMT) gene has been widely studied and shown to be able to predict glioblastoma cancer patient response to alkylating agents.
NPV	NPV or "Negative Predictive Value" is the probability that subjects with a negative test truly don't have the disease being tested. It is a numerical value for the proportion of individuals with a negative test result who are free of the target condition.
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.
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.
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).

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.
VERIFICATION (PRODUCT PIPELINE STEP)	A phase within the product development process to define the performance characteristics of the assay.

PRESS RELEASE (FEB. 18TH, 2016)

MDXHEALTH REPORTS FOURTH QUARTER AND FISCAL YEAR 2015 RESULTS

Based on 2015 reported cases and historical average reimbursement amounts, the total estimated value of tests performed in 2015 was $36 million. Of this amount $15.2 million was recognized as revenue, leaving uncollected outstanding unrecognized revenues of $20.8 million, consisting of $1.7 million from Medicare and $19.1 million from private payors. This uncollected amount has been excluded from the Company's 2015 revenues. While collection efforts continue on these outstanding amounts, the timing and amount of actual collections is uncertain. MDxHealth's revenue recognition policy evaluates the certainty of payment on a payor-by-payor basis, currently resulting in a mixture of accrual based revenue recognition and cash based collections depending on our evaluation of certainty of payment. MDxHealth believes this revenue recognition policy is appropriate at this time. However, the recent Medicare coverage of ConfirmMDx has already resulted in an increased number of contracts with private payors as well as managed care contracts. The Company continues to expect to transition more payors to an accrual accounting basis resulting in increased revenue recognition in 2016.

The Company's net loss for the year ended December 31, 2015, was $14.5 million, or ($0.32) a share, compared to $15.3 million loss, or ($0.40) a share, for the prior year. In Q4 2015, the Company reported a net loss of $4.1 million, or ($0.09) a share, compared to a net loss of $3.0 million, or ($0.08) a share, in the same period of 2014. The increased loss in Q4 2015 is attributable to the costs associated with the acquisition of NovioGendix in Nijmegen, The Netherlands, the continued investment in commercialization efforts in the US and our evolving revenue recognition policies for ConfirmMDx sales.

Operating Expenses

Operating expenses for the year ended December 31, 2015 increased by $5.0 million to $32.0 million from $27.0 million for the prior year. The year-over-year increase is due to R&D spending on new products and the continuing build-up of US operations to support the commercialization of the ConfirmMDx for Prostate Cancer test and preparation for new uro-oncological products. Operating expenses including Cost of Sales for Q4 2015 were $9.8 million, an increase of $2.7 million compared to $7.1 million in Q4 2014. This increase is attributable to R&D spending, continued costs related to the clinical utility study for ComfirmMDx, and additions to staff in sales, managed care, information technology and medical affairs. Q4 2015 Cost of Sales remained flat compared to same period last year despite higher volumes, due to laboratory efficiencies gained from automation.

Cash Position

The Company ended 2015 with cash and cash equivalents of $31.7 million, compared to $18.9 million on December 31, 2014. The Company raised net proceeds of $29.5 million in a private placement in June 2015. Collections from ConfirmMDx reimbursements were $12.2 million in 2015 vs. $4.5 million in 2014. Collections, which are an important variable in net cash burn, are improving, and will continue to be an important factor in strengthening the Company's cash position moving forward.

The Medicare coverage determination (LCD) has had a positive impact on private third party payor reimbursement decisions and this will continue to enhance the Company's collections going forward.

Outlook

For the 2016 fiscal year, the Company expects to see continued growth in revenue driven by the increase in sales representatives, new payor contracts, increased adoption of ConfirmMDx and introduction of the SelectMDx for Prostate Cancer test on the EU and US market. However, based on seasonality, some quarter-to-quarter fluctuation in reported case volume and revenue is expected. With increasing product offerings, test volumes and expanding coverage with payor contracts, both revenue and cash collections for 2016 are anticipated to improve. Importantly, increasing payor coverage is expected to reduce days sales outstanding (DSO) for receivables. In addition, following issuance of the Medicare coverage determination (LCD) for ConfirmMDx in November 2014, the Company continues to work collaboratively with the MolDX Program, administered by Palmetto GBA, to generate clinical study data and collect registry data under Coverage with Data Development (CDD) to support a transition to unrestricted coverage for our ConfirmMDx test.

The Company is providing the following guidance for 2016:

- Revenue growth between 30% to 50%
- Improved EBITDA compared to 2015
- Publication of SelectMDx validation study
- Launch SelectMDx on US market in H1
- Launch AssureMDx on US market in H2

2016 Reporting Calendar

- 2015 FY results: February 18, 2016
- Q1 results: May 3, 2016
- H1 results: August 18, 2016
- Q3 results: November 3, 2016

Financial Statements and Auditors' Review

The Company's statutory auditor, BDO Bedrijfsrevisoren Burg. Ven. CBVA, has confirmed that its audit procedures with respect to the Company's consolidated financial statements, prepared in accordance with the International Financial Reporting Standards as adopted in the European Union, have been substantially completed, that these procedures have not revealed any material adjustments that would have to be made to the accounting information derived from the Company's consolidated financial information that is included in this press release, and that it intends to issue an unqualified opinion.

The condensed Consolidated Statement of Comprehensive Income may be found on the Company's website at www.mdxhealth.com. The full Annual Report is expected to be made available to the public via the Company's website in April 2016.

About MDxHealth

MDxHealth is a multinational healthcare company that provides actionable molecular diagnostic information to personalize the diagnosis and treatment of cancer. The Company's tests are based on

proprietary genetic, epigenetic (methylation) and other molecular technologies and assist physicians with the diagnosis of urologic cancers, prognosis of recurrence risk, and prediction of response to a specific therapy. The Company's European headquarters are in Herstal, Belgium, with laboratory operations in Nijmegen, The Netherlands, and US headquarters and laboratory operations based in Irvine, California. For more information visit mdxhealth.com and follow us on Twitter at: twitter.com/mdxhealth.

For more information:

Dr. Jan Groen, CEO
MDxHealth
US: +1 949 812 6979
BE: +32 4 364 20 70
info@mdxhealth.com

Consilium Strategic Communications (IR & PR)
Amber Fennell, Chris Welsh & Hendrik Thys
UK: +44 20 3709 5701
mdxhealth@consilium-comms.com

This press release contains forward-looking statements and estimates with respect to the anticipated future performance of MDxHealth and the market in which it operates. Such statements and estimates are based on assumptions and assessments of known and unknown risks, uncertainties and other factors, which were deemed reasonable but may not prove to be correct. Actual events are difficult to predict, may depend upon factors that are beyond the Company's control, and may turn out to be materially different. MDxHealth expressly disclaims any obligation to update any such forward-looking statements in this release to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based unless required by law or regulation. This press release does not constitute an offer or invitation for the sale or purchase of securities or assets of MDxHealth in any jurisdiction. No securities of MDxHealth may be offered or sold within the United States without registration under the US Securities Act of 1933, as amended, or in compliance with an exemption therefrom, and in accordance with any applicable US securities laws.

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ENDNOTES

NOTE	PAGE	SOURCE
1	4-45-47	National Cancer Institute. Surveillance, Epidemiology and End Results. 2014 Prostate Cancer Statistics http://seer.cancer.gov/statfacts/html/prost.html. Ekwueme DU, Stroud LA, Chen Y. Cost analysis of screening for, diagnosing, and staging prostate cancer based on a systematic review of published studies. Prev Chronic Dis. 2007;4:A100. Mosquera J-M, Mehra R, Regan MM, et al. Prevalence of TMPRSS2-ERG fusion prostate cancer among men undergoing prostate biopsy in the United States. Clin Cancer Res. 2009;15:4706-4711.
NOTE	**PAGE**	**SOURCE**
2	46	Carroll P, Coley C, McLeod D, et al. Prostate-specific antigen best practice policy--part I: early detection and diagnosis of prostate cancer. Urology 2001; 57:217. Brawer MK, Chetner MP, Beatie J, et al. Screening for prostatic carcinoma with prostate specific antigen. J Urol 1992; 147:841. Catalona WJ, Smith DS, Ratliff TL, Basler JW. Detection of organ-confined prostate cancer is increased through prostate-specific antigen-based screening. JAMA 1993; 270:948. Crawford ED, DeAntoni EP, Etzioni R, et al. Serum prostate-specific antigen and digital rectal examination for early detection of prostate cancer in a national community-based program. The Prostate Cancer Education Council. Urology 1996; 47:863. Taneja et al.: The American Urological Association (AUA) Optimal Techniques of Prostate Biopsy and Specimen Handling. 2013. Shen et al.: Three-Dimensional Sonography With Needle Tracking - Role in Diagnosis and Treatment of Prostate Cancer. J. Ultrasound Med. 2008; Jun; 27(6): 895-905. Rabets JC et al.: Prostate cancer detection with office based saturation biopsy in a repeat biopsy population. The Journal of Urology. 2004; Jul; 172(1): 94–97. Kronz JD et al.: Predicting cancer following a diagnosis of high---grade prostatic intraepithelial neoplasia on needle biopsy: data on men with more than one follow---up biopsy. American Journal of Surgical Pathology 2001; Aug 25(8): 1079–1085. Trock BJ et al.: Evaluation of GSTP1 and APC Methylation as Indicators for Repeat Biopsy in a High-risk Cohort of Men with Negative Initial Prostate Biopsies. British Journal of Urology International 2012; July 110(1): 56-62.
NOTE	**PAGE**	**SOURCE**
3	46	Pinsky PF, Crawford ED, Kramer BS, et al. Repeat prostate biopsy in the prostate, lung, colorectal and ovarian cancer screening trial. BJU Int. 2007;4:775-779. National Cancer Institute. Surveillance, Epidemiology and End Results. 2014 Prostate Cancer Statistics http://seer.cancer.gov/statfacts/html/prost.html.
NOTE	**PAGE**	**SOURCE**
4	47-48-49	Stewart G et al.: Clinical Utility of an Epigenetic Assay to Detect Occult Prostate Cancer in Histopathologically Negative Biopsies: Results of the MATLOC Study. The Journal of Urology 2013; Mar; 189(3): 111-6. Partin A et al.: A Multicenter Validation Study Of A Tissue Methylation Assay To Predict Histopathologically Cancer-Negative Repeat Prostate Biopsies. The Journal of Urology 2014. http://dx.doi.org/10.1016/j.juro.2014.04.013, Vol. 192, 1081-1087, October 2014
NOTE	**PAGE**	**SOURCE**
5	49	Partin A et al.: A Multicenter Validation Study Of A Tissue Methylation Assay To Predict Histopathologically Cancer-Negative Repeat Prostate Biopsies. The Journal of Urology 2014. http://dx.doi.org/10.1016/j.juro.2014.04.013, Vol. 192, 1081-1087, October 2014
NOTE	**PAGE**	**SOURCE**
6	49	Van Neste et al. A tissue biopsy based epigenetic multiplex PCR assay for prostate cancer detection. BMC Urology 2012.
NOTE	**PAGE**	**SOURCE**
7	49	Van Criekinge et al; NOMCC: 215-216; 2015 AUA Prostate Cancer: Detection

and Screening V.

NOTE	PAGE	SOURCE
8	51	Wojno et al.: Reduced Rate Of Repeat Prostate Biopsies Observed In ConfirmMDx Clinical Utility Field Study, American Health and Drug Benefits 2014;7(3):129-134
NOTE	**PAGE**	**SOURCE**
9	51-52	Aubry W et al: Budget Impact Model: Epigenetic Assay Can Help Avoid Unnecessary Repeated Prostate Biopsies and Reduce Healthcare Spending. American Health Drug and Benefits 2013;Jan/Feb; 6(1): 15--24.
NOTE	**PAGE**	**SOURCE**
10	53	L. Van Neste, R.J. Hendriks, S. Dijkstra, G. Trooskens, E.B. Cornel, S.A. Jannink, H. de Jong, D. Hessels, F.P. Smit, W.J.G. Melchers, G.H. Leyten, T.M. de Reijke, H. Vergunst, P. Kil, B.C. Knipscheer, C.A. Hulsenberg-van de Kaa, P.F.A. Mulders, L.M. van Oort, W. Van Criekinge, J.A. Schalken – Detection of High-grade Prostate Cancer Using a Urinary Molecular Biomarker-Based Risk Score – April 2016
NOTE	**PAGE**	**SOURCE**
11	57	Renard et al.: Identification and Validation of the Methylated TWIST1 and NID2 Genes through Real-Time Methylation-Specific Polymerase Chain Reaction Assays for the Noninvasive Detection of Primary Bladder Cancer in Urine Samples, European Urology 58 (2010) 96–104 Millán-Rodríguez, F. et al.: Primary superficial bladder cancer risk groups according to progression, mortality and recurrence; The Journal of Urology, Volume 164, Issue 3 , 680 – 684 Globocan Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012; http://globocan.iarc.fr/Pages/fact_sheets_population.aspx National Cancer Institute. Surveillance, Epidemiology and End Results. 2014 Bladder Cancer Statistics http://seer.cancer.gov/statfacts/html/urinb.html.
NOTE	**PAGE**	**SOURCE**
12	57	J. Urol 2016 Mar; 195(3):601-7.doi:10.1016/j.juro.2015.08.085. Epub 2015 Aug. 29 Evaluation of an Epigenetic Profile for the detection of Bladder Cancer in Patients with Hematuria van Kessel KE, Van Neste L, Lurkin I, Zwarthoff EC, van Criekinge W
NOTE	**PAGE**	**SOURCE**
13	57	Sylvester Et al Predicting recurrence and progression in individual patients with stage Ta T1 bladder cancer using EORTC risk tables: a combined analysis of 2596 patients from seven EORTC trials. Eur Urol. 2006 Mar;49(3):466-5; discussion 475-7. Millán-Rodríguez, F. et al.: Primary superficial bladder cancer risk groups according to progression, mortality and recurrence; The Journal of Urology, Volume 164, Issue 3 , 680 – 684 Globocan Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012; http://globocan.iarc.fr/Pages/fact_sheets_population.aspx National Cancer Institute. Surveillance, Epidemiology and End Results. 2014 Bladder Cancer Statistics http://seer.cancer.gov/statfacts/html/urinb.html

MDxHealth SA
CAP Business Center
Rue d'Abhooz, 31
4040 Herstal
BELGIUM
T: +32 (0)4 364 20 70
F: +32 (0)4 364 20 71
VAT: BE 0479 292 400

MDxHealth Inc.
15279 Alton Parkway
Suite 100
Irvine, CA 92618
USA
T: +1 949 812 6979
Toll Free: +1 866 259 5644
F: +1 949 242 2960

MDxHealth BV
Geert Grooteplein-Zuid 34
6525 GA Nijmegen
The Netherlands
T :+31 (0) 24 327 94 94
BTW : NL.8171.13.794.B.01

Email : ir@mdxhealth.com
Website : www.mdxhealth.com
Twitter : twitter.com/mdxhealth
Facebook : www.facebook.com/MDxHealth
Linkedin : www.linkedin.com/company/mdxhealth