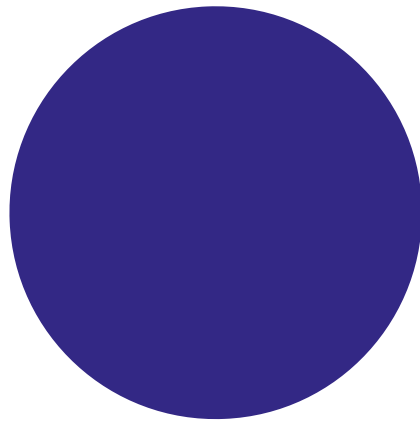




MDxHealth®

2016 ANNUAL REPORT



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2016

Annual Report

Letter to shareholders

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Dear Shareholders

Our unwavering commitment to deliver molecular diagnostic solutions that improve patient outcomes in urologic oncology continues to gain momentum. In 2016, several key milestones marked industry recognition of our contributions and further demonstrate the clinical value of our products. Notably our lead product, ConfirmMDx® for Prostate Cancer, was included in the US National Comprehensive Cancer Network (NCCN) Clinical Guidelines for Prostate Cancer Early Detection and the American Medical Association (AMA) granted a unique billing code for the test. These are significant events which have resulted in broader payor adoption.

Building upon that momentum, we successfully launched our non-invasive, liquid biopsy test, SelectMDx™ for Prostate Cancer, which rapidly attracted US

payor coverage and distribution agreements around the world. Non-invasive molecular diagnostic tests are becoming increasingly important as healthcare systems seek cost-effective tools that improve patient outcomes. This industry dynamic has fueled the adoption of our prostate cancer tests and will drive uptake of AssureMDx™ for Bladder Cancer, another liquid biopsy, urine test that will commercially launch in 2017.

Our portfolio and pipeline aim to improve patient care while lowering healthcare costs, by reducing the number of unnecessary invasive procedures and finding clinically significant cancer earlier. Growing adoption of our novel tests among the urology community, and traction with payors, led to a 57% increase in test volume and 70% revenue growth, with continued reduction in operating losses during the fiscal year.



We have delivered on last year's promise to increase product utilization, expand the portfolio and secure broader reimbursement.

Increased utilization of ConfirmMDx and expanded product offerings

In 2016, we achieved our key business objectives by increasing the utilization of our lead product, ConfirmMDx and expanding our product offerings in urologic oncology with our first liquid biopsy test, SelectMDx for Prostate Cancer. SelectMDx identifies men at risk for clinically significant prostate cancer who may benefit from an initial prostate biopsy or magnetic resonance imaging (MRI) scan.

We delivered nearly 24,000 ConfirmMDx and SelectMDx tests, a 57% increase compared to the 15,000+ tests conducted in 2015. Since the launch of our tests in mid-2012, we have delivered more than 60,000 patient test results to over 3,500 urologists .



Images from ConfirmMDx lab workflow

SelectMDx tests represented approximately 17% of the total test volume in 2016 and we anticipate the launch of our SelectMDx in vitro diagnostic (IVD) kit in Europe will continue to drive adoption within the urology community.

In the last quarter of 2016, following the publication of two clinical validation studies earlier in the year, we initiated a beta launch for our second liquid biopsy test, AssureMDx for Bladder Cancer. AssureMDx has a 99% negative predictive value and may significantly reduce unnecessary, invasive cystoscopy procedures, which are commonly used to diagnose patients and monitor for recurrence following treatment. With approximately 3 million cystoscopy procedures planned or performed in the US every year, AssureMDx addresses a potential \$500 million market, and is scheduled for full commercial launch across the US, as a laboratory developed test (LDT), in the first half of 2017.

For 2016, the continued adoption and reimbursement of ConfirmMDx, the launch of SelectMDx and successful licensing agreements delivered revenue growth of 70% compared to 2015. Total revenues of \$30 million further reduced operating losses while we sustained our investments in the business with the intention of creating long-term value to our shareholders. Through the continued support of our shareholders, we have been able to raise \$21.7 million and strengthen our financial position.

Favorable reimbursement

This year we secured 19 new commercial payor agreements and 28 payor-issued positive medical coverage policies for ConfirmMDx. Additionally, the test gained coverage under the California Medical Assistance Program (Medi-Cal), the single largest US state-run public health program with nearly 12 million enrollees.

Increasing commercial adoption and coverage by payors was driven in large part by the test's inclusion in the NCCN Guidelines and the growing number of peer-reviewed publications supporting the test. With an additional 7 clinical publications in 2016, the ConfirmMDx genes and technology have been validated in more than 50 peer-reviewed published studies, with over 5,000 patients.

The large body of evidence, inclusion in the guidelines, and widespread adoption of ConfirmMDx within the urology community, precipitated the AMA's decision to grant a unique MAAA Current Procedural Terminology (CPT) code for the test. The ConfirmMDx billing code will be effective January 2018, and is expected to further streamline our reimbursement efforts and significantly reduce collection periods.

Furthermore, since the successful commercial launch of SelectMDx in the first half of 2016, we have garnered coverage from eleven US payors and established seven distribution agreements in Europe, Asia, Latin America and Israel. The multi-center, prospective clinical validation study for SelectMDx, which was published in the leading journal *European Urology*, confirmed the test's superior performance compared to other commonly used biomarker tests and risk calculators. These results will be further validated in the ongoing 600 subject clinical study, named 4M, which will evaluate the synergy of SelectMDx and MRI, and is expected to be published this year.

We anticipate tremendous growth ahead as we continue to develop our portfolio of molecular tests for the diagnosis of urological cancers.

We are off to a very strong start in 2017 with the US Government Services Administration (GSA) contract awarded for ConfirmMDx, positive coverage policy on ConfirmMDx for Horizon Blue Cross Blue Shield of New Jersey and a non-exclusive distribution agreement with Istituto Diagnostico Varelli to offer SelectMDx throughout central and southern Italy.

We anticipate that our strategy for the year will lead to 55-75% growth on product and service income (excluding royalty and milestone payments), underpinned by improved collectability and increased payor adoption.

Our investment in our epigenetic assays and expansion into additional molecular tests for urologic oncology, combined with our focus on quality, design control and clinical validation, has been embraced by the urology community as well as payors, and recognized by the financial markets.

Our ongoing success is the result of a hardworking, talented team unified by our mission and strategy.

Due to the dedication of our team, which now numbers 160, we are fulfilling our mission to improve patient outcomes through the delivery of clinically meaningful and actionable molecular assays for urologic oncology. We sincerely thank our employees, consultants and advisors, who's continuing contributions enable our success.

On behalf of the Board of Directors of MDxHealth, we want to extend our gratitude to our shareholders, investors, collaborators and the urology community who's belief and ongoing support have enabled us to make a significant investment in our people, who in turn have ambitiously built MDxHealth into the company it is today.

Kindest Regards,
Dr. Jan Groen
Chief Executive Officer



Strategy & Business Review



2016

Key Figures

24K
patients
tested

70%
revenue
increase

\$30.9M
cash &
equivalents

\$2.4M
EBITDA
improvement

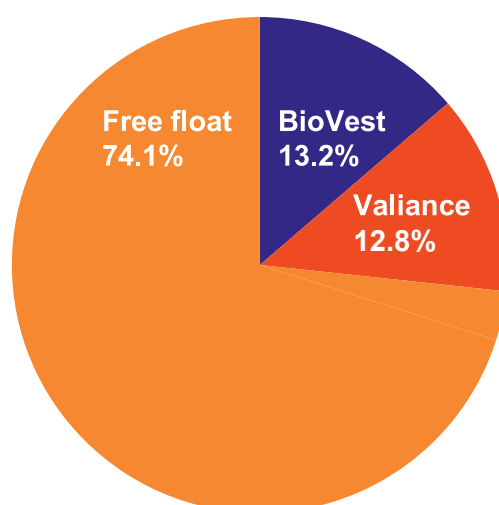
	2016	2015
Revenues	29,970	17,640
Gross profit	19,867	10,735
Gross profit margin	66%	60%
EBITDA	(11,126)	(13,501)
Cash & cash equivalents	30,871	31,680
Shareholders' equity	52,741	44,262
Total assets	67,721	57,742
Number of outstanding shares	49,845,595	45,153,633
Total number of employees	162	133

2016

Share Facts

Stock exchanges	MDXH: Euronext BR MDXDHF: OTC
Total shares outstanding	49,845,595
52 week range	€2.90 – €5.56
Market cap	€278 million
Analyst coverage:	
US	<ul style="list-style-type: none"> • Taglich Brothers • van Leeuwenhoek
Europe	<ul style="list-style-type: none"> • KBC • Degroof Petercam • Goetzpartners

Shareholders



2016

Business Highlights

Select MDx
for Prostate Cancer

US commercial LDT launch

- 3** clinical publications
- 11** US payor agreements
- 7** global distribution agreements

Confirm MDx
for Prostate Cancer

NCCN guideline inclusion & unique CPT code

- 5** clinical publications
- 19** US payor agreements
- 28** US payor issued positive medical policies

Assure MDx
for Bladder Cancer

Full launch 2017

- 2** clinical publications

Our Business





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.

MDxHealth's European headquarters are in Herstal, Belgium, with laboratory operations in Nijmegen, The Netherlands, and US headquarters and laboratory operations based in Irvine, California.

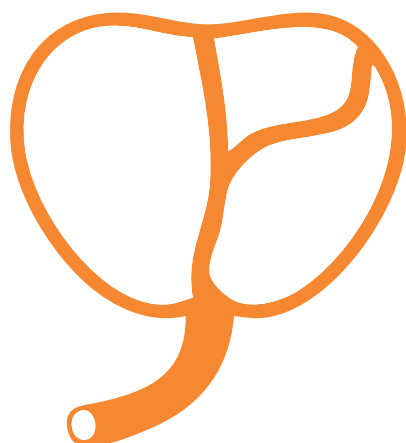
For more information visit mdxhealth.com and follow us on Twitter at: twitter.com/mdxhealth.

Our Mission

**To improve patient outcomes
by delivering molecular diagnostic
solutions for urologic cancers**

Areas of focus

Prostate Cancer



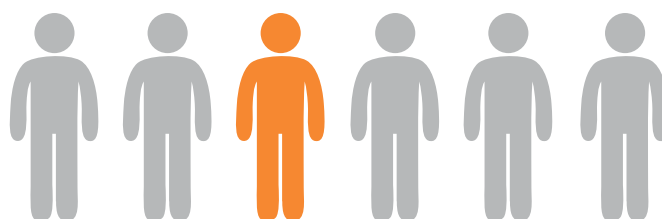
Bladder Cancer



Prostate Cancer

Unmet diagnostic needs in prostate cancer

One out of six men will be diagnosed with prostate cancer¹



Although prostate cancer is the second most common cancer diagnosed in men globally,² its accurate diagnosis and follow-up remain a challenge and come at a considerable cost to the healthcare system.^{3,4} Approximately \$6 million is spent annually on patients' first year of prostate cancer in the US alone.⁴

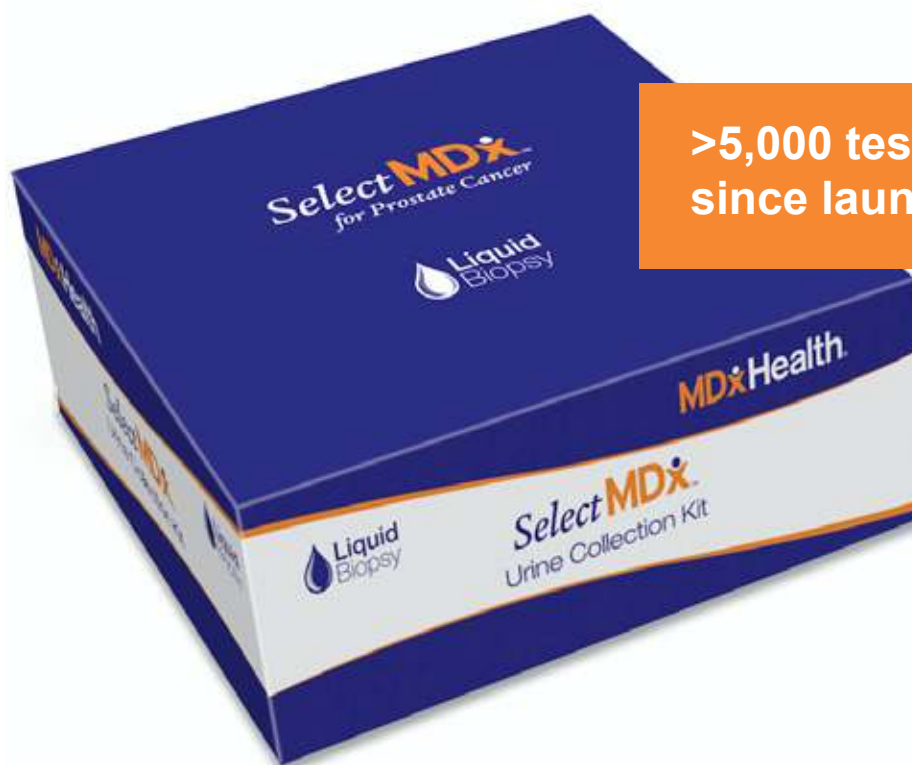
Under the current standard of care, men with an elevated (i.e., ≥ 4.0 ng/ml) or rising prostate-specific antigens (PSA) score and/or abnormal digital rectal exam (DRE) are considered at high risk for cancer and will often be referred for a prostate biopsy to determine if cancer is present.

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 absence of prostate cancer.⁶

Over 2 million prostate biopsies are performed each year in the US and Europe and less than 20% find cancer.^{6,7} Most men selected for biopsy could have avoided a painful and invasive procedure, with its associated complications and costs.^{6,8} Furthermore, 30% of biopsies miss cancer and sampling errors are an inherent and well-documented issue.^{6,9,10}

Concerns over missed cancer (i.e. false-negative biopsies) coupled with the high rate of clinically significant cancer detected upon repeat biopsy and many men refusing a second biopsy,⁶ pose a diagnostic dilemma that MDxHealth's portfolio of tests is uniquely positioned to address.

SelectMDxTM for Prostate Cancer



>5,000 tests performed
since launch

Proprietary mRNA urine-based test that identifies:

High-Risk men who may benefit from a biopsy or MRI scan

Low-Risk men who may avoid unnecessary invasive procedures or costly imaging studies



SelectMDx has a high specificity because it measures mRNA levels of two key biomarkers associated with Gleason Score ≥ 7 prostate cancer detection. SelectMDx is able to provide the likelihood of prostate cancer upon biopsy and the probability for high-grade versus low-grade disease. The test yields a 98% negative predictive value (NPV)* for clinically significant prostate cancer.¹¹

SELECTMDx
for Prostate Cancer

SAMPLE Patient Report

PATIENT	SPECIMEN	ACCOUNT
Patient Name: David Sample Date of Birth: 12/07/1952 MRN/Accession: 807581 Prostate Volume: 30cc Family History: None PSA: 0.9 ng/mL SSR: Normal	Specimen ID: 70389 Collection Date: 11/05/2015 Received Date: 11/05/2015 Report Date: 11/05/2015 Specimen Type: Urine MDx# Accession: SL-07322	Physician: Parag Mehta, MD Accession: Urology Associates Address: 14570 Allen Parkway Suite: 100 City/State/Zip: Irvine CA 92618

Patient Result: **Very Low Risk**

The SelectMDx test result for this patient indicates a very low risk for the detection of Gleason score ≥ 7 prostate cancer upon biopsy with a negative predictive value of 98%, and a negative predictive value of 99% for Gleason score ≥ 8 prostate cancer.

Test Description:

SelectMDx for Prostate Cancer is a reverse-transcription PCR (RT-PCR) assay performed on urine immediately following DRE from patients who are being considered for prostate biopsy. The test measures levels of the DLX1 and HMOX2 biomarkers to aid in patient selection for prostate biopsy. Higher levels of DLX1 and HMOX2 mRNA are associated with an increased probability for Gleason score ≥ 7 prostate cancer. A logistic regression model combining DLX1 and HMOX2 mRNA levels with established clinical risk factors, including PSA, prostate volume, DRE, family history and age, is used to estimate the likelihood of detecting GS ≥ 7 prostate cancer upon biopsy, with an area under the curve (AUC) of 0.88 (95% CI: 0.85-0.91), in addition to the likelihood of no cancer or GS ≤ 6 disease. Performance is based on the presence of all relevant data elements; if all data are not available, or 5 α -reductase inhibitors have been administered to decrease serum PSA values, results should be interpreted with caution and AUC of the test may vary.

Comments:

References:

1. Noh H, et al. Detection of High-grade Prostate Cancer Using a Urinary Microscale Biomarker-Based Risk Score. European Urology 2015; http://dx.doi.org/10.1016/j.eururo.2015.08.015.
 2. Lopez et al. Identification of a Candidate Gene Panel for the Early Diagnosis of Prostate Cancer. Clin Cancer Res 2015; Jul 1; 21(13):3583-92.
 3. Hsieh et al. The role of HMOX2 in prostate cancer development. The Prostate 2015; Dec 15; 75(25):1849-55.

MDxHealth is registered under the Clinical Laboratory Improvement Amendments (CLIA) and the College of American Pathologists as an accredited laboratory. The SelectMDx for Prostate Cancer test was developed and its performance characteristics determined by MDxHealth. It is not for diagnosis or patient management decisions about the need for a prostate biopsy or men with clinical factors suggesting an increased risk for prostate cancer that has not been validated by MDxHealth. Test results should be interpreted in conjunction with other laboratory and clinical data available to the physician for the patient.

MDxHealth is certified by ISO 15189 to ISO 9001:2008 Quality Management System. This test was performed by MDxHealth Inc., 15279 Allen Parkway, Suite 100, Irvine, CA 92618. (949) 453-0388, CAP# 0510365.

General information about SelectMDx for Prostate Cancer can be found at www.selectmdx.com. If you have any questions regarding this report, please contact MDxHealth Client Services at 800.725.5544 or selectmdx@selectmdx.com.

James Sample, Jr., MD, Laboratory Director

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SAMPLE Patient Report

PATIENT	SPECIMEN	ACCOUNT
Patient Name: David Sample Date of Birth: 12/07/1952 MRN/Accession: 807581 Prostate Volume: 30cc Family History: None PSA: 0.9 ng/mL SSR: Normal	Specimen ID: 70389 Collection Date: 11/05/2015 Received Date: 11/05/2015 Report Date: 11/05/2015 Specimen Type: Urine MDx# Accession: SL-07322	Physician: Parag Mehta, MD Accession: Urology Associates Address: 14570 Allen Parkway Suite: 100 City/State/Zip: Irvine CA 92618

Patient Result:

The SelectMDx test result for this patient indicates a 57% likelihood of detecting prostate cancer, with a 50% probability for Gleason score ≥ 7 , when performing a standard 12-core TRUS guided biopsy.

57% Likelihood of prostate cancer upon biopsy

50% Likelihood of detecting Gleason score ≥ 7

Test Description:

SelectMDx for Prostate Cancer is a reverse-transcription PCR (RT-PCR) assay performed on urine specimens collected immediately following DRE from patients who are being considered for prostate biopsy. The test measures the urinary mRNA levels of the DLX1 and HMOX2 biomarkers to aid in patient selection for prostate biopsy. Higher levels of DLX1 and HMOX2 mRNA are associated with an increased probability for Gleason score ≥ 7 prostate cancer. A logistic regression model combining DLX1 and HMOX2 mRNA levels with established clinical risk factors, including PSA, prostate volume, DRE, family history and age, is used to estimate the likelihood of detecting GS ≥ 7 prostate cancer upon biopsy, with an area under the curve (AUC) of 0.88 (95% CI: 0.85-0.91), in addition to the likelihood of no cancer or GS ≤ 6 disease. Performance is based on the presence of all relevant data elements; if all data are not available, or 5 α -reductase inhibitors (5-ARI) have been administered to decrease serum PSA values, results should be interpreted with caution and AUC of the test may vary.

Comments:

References:

1. Noh H, et al. Detection of High-grade Prostate Cancer Using a Urinary Microscale Biomarker-Based Risk Score. European Urology 2015; http://dx.doi.org/10.1016/j.eururo.2015.08.015.
 2. Lopez et al. Identification of a Candidate Gene Panel for the Early Diagnosis of Prostate Cancer. Clin Cancer Res 2015; Jul 1; 21(13):3583-92.
 3. Hsieh et al. The role of HMOX2 in prostate cancer development. The Prostate 2015; Dec 15; 75(25):1849-55.

MDxHealth is registered under the Clinical Laboratory Improvement Amendments (CLIA) and the College of American Pathologists as an accredited laboratory to perform high complexity clinical testing. The SelectMDx for Prostate Cancer test was developed and its performance characteristics determined by MDxHealth. The test is intended for use as an aid to clinicians for patient management decisions about the need for a prostate biopsy or men with clinical factors suggesting an increased risk for prostate cancer. Use outside of this intended use has not been validated by MDxHealth. Test results should be interpreted in conjunction with other laboratory and clinical data available to the physician and relevant guidelines on the decision for biopsy.

MDxHealth is certified by ISO 15189 to ISO 9001:2008 Quality Management System. This test was performed by MDxHealth Inc., 15279 Allen Parkway, Suite 100, Irvine, California 92618. (949) 453-0388, CAP# 0510365.

General information about SelectMDx for Prostate Cancer can be found at www.selectmdx.com. If you have any questions regarding this report, please contact MDxHealth Client Services at 800.725.5544 or selectmdx@selectmdx.com.

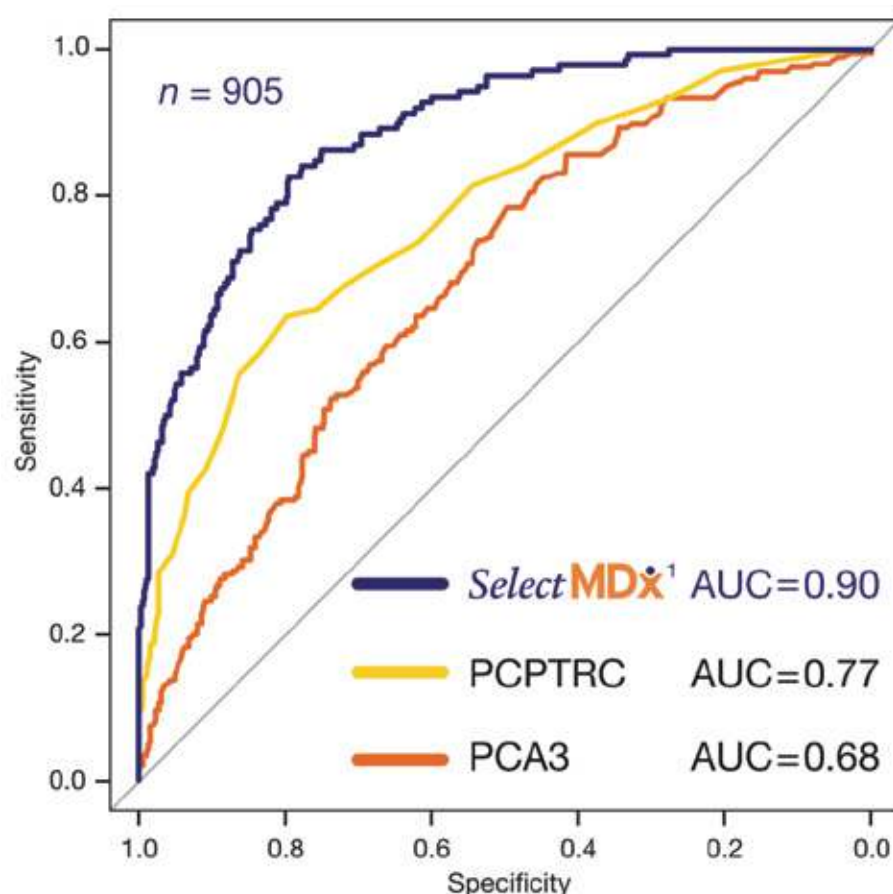
James Sample, Jr., MD, Laboratory Director

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*A high NPV is important because it is the probability that a person is truly disease-free with a negative test result

Clinical Validity

The validation study for SelectMDx confirmed superior performance compared to other commonly used biomarker tests and risk calculators¹¹



Clinical validity & utility¹¹

- 99.6 % NPV for GS \geq 8 prostate cancer
- 98 % NPV for GS \geq 7 prostate cancer
- AUC of 0.90 (95 % CI 0.85-0.95)

2016

Publications

SelectMDx has been validated in three publications this year with additional studies underway

Title	Summary	Journal
Detection of High-grade Prostate Cancer Using a Urinary Molecular Biomarker-Based Risk Score	Demonstrates SelectMDx is a powerful predictor for the detection of high-grade prostate cancer	<i>European Urology</i> <i>Van Neste L, et al</i> <i>Nov;70(5):740-748</i>
Integrating Molecular Profiling of Liquid Biopsy Samples with a Calculator Algorithm To Detect High-risk Prostate Cancer	Editorial supporting SelectMDx use in detecting prostate cancer	<i>European Urology</i> <i>Gardiner R, et al</i> <i>Nov;70(5):749-750</i>
Multicenter validation study of a urine-based molecular biomarker algorithm to predict high-grade prostate cancer	Demonstrates SelectMDx is able to effectively predict the presence of high-grade prostate cancer from urine samples collected from men with an increased PSA level	<i>European Association of Urology (EAU) Congress</i> <i>Hendriks R.J., et al</i> <i>Abstract #383</i>
Identification of High-Grade Prostate Cancer using Urine-based Molecular Biomarkers Combined with Clinical Risk Factors	SelectMDx results combined with traditional clinical risk factors was shown to be significantly better at stratifying men with aggressive and non-aggressive prostate cancer than current clinical methods	<i>American Urological Association Annual Meeting (AUA)</i> <i>Van Neste L, et al</i> <i>Abstract #MP53-04</i>

Access

SelectMDx was embraced globally after its launch as an laboratory developed test (LDT)

Following the successful US commercial launch of SelectMDx at the end of the first quarter in 2016, 11 US payor agreements were secured. In Europe, Asia, Latin America and Israel, 7 distribution agreements were established:

Cerba	France, Belgium, Luxembourg
Andros Healthcare Clinic	the Netherlands
ECZ Innovations	Poland
AMEDS/HIFU Clinic	Poland
Teva Pharmaceuticals	Israel
AceCGT Group	Hong Kong and Macao
SouthGenetics	Argentina, Bolivia, Columbia, Ecuador, Mexico, Peru, Dominican Rep., Panama, Paraguay, Uruguay, Venezuela

Confirm MDx[®] for Prostate Cancer

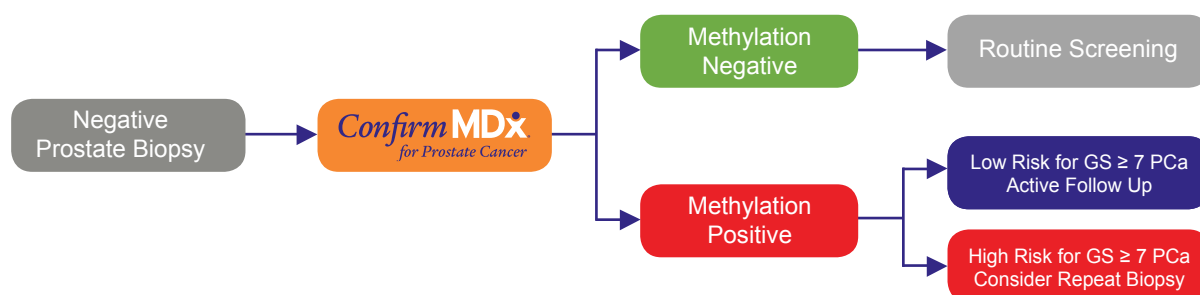


~60,000 tests
conducted since launch

Proprietary epigenetic assay performed on residual tissue from previous negative biopsy to help:

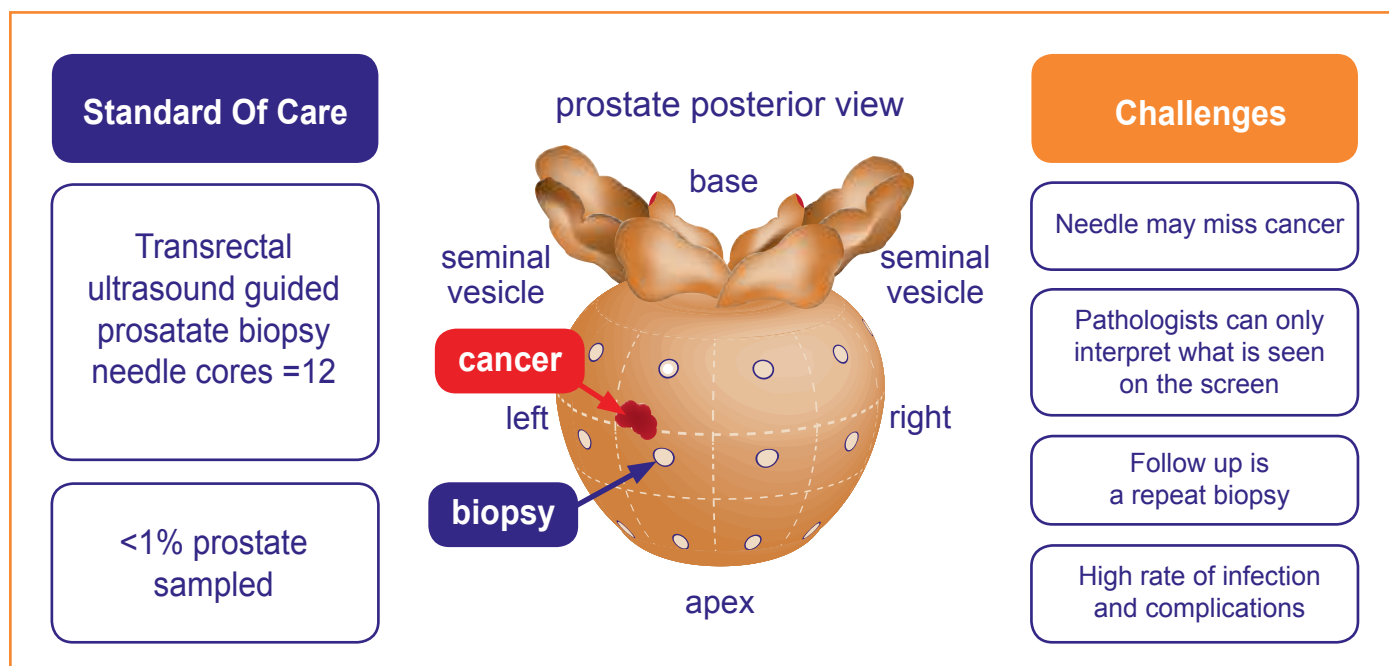
Rule Out cancer-free men from undergoing unnecessary repeat biopsies

Rule In men who may require repeat biopsies and guidance on where to biopsy

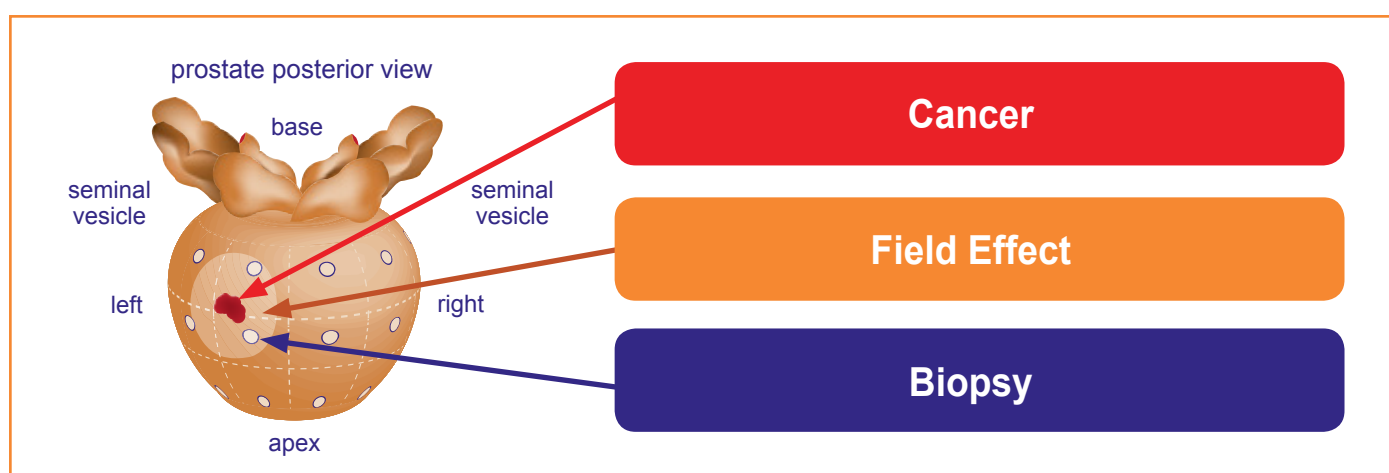


How It Works

Overview of challenges with standard of care



ConfirmMDx helps overcome biopsy shortcomings



ConfirmMDx has a high specificity because it measures the methylation of three key biomarkers and one reference marker associated with prostate cancer. The test's epigenetic field effect detects DNA methylation changes that are often indistinguishable by histopathology. ConfirmMDx is able to provide the likelihood and location of prostate cancer upon repeat biopsy with a 96% negative predictive value (NPV).^{12,13}

SAMPLE Patient Report

ConfirmMDx for Prostate Cancer

PATIENT	SPECIMEN	ACCOUNT
Patient Name: Stephen James Date of Birth: 10/15/1945 MRN/Patient: MRN 123 PATH: Negative PSA: 5 ng/mL DRE: Normal	Specimen: 1776 Collection Date: 11/10/2015 Received Date: 11/17/2015 Report Date: 11/24/2015 Specimen Type: Prostate FFPE tissue slides MDxH Accession: PR-123456	Physician: Mike Test, MD Account: Urology Partners of California Address: 15279 Alton Parkway Suite 100 City/State/Zip: Irvine CA 92618

Patient Result: DNA Methylation Negative

The negative result for this patient indicates a low likelihood of detecting prostate cancer upon repeat biopsy.

Result Description:

Clinical validation study results indicate a negative predictive value (NPV) of 96% for high-grade disease (Gleason score ≥ 7) and a 90% NPV for all grades of prostate cancer. Cancer association with DNA methylation of ConfirmMDx gene markers has been reported on ~4,500 patients.^{1,24}

DNA Methylation Status Table				Distribution of Methylation Diagram	
Biopsy Site	GSTP1 Methylation	APC Methylation	RASSF1 Methylation		
Left Lateral Base:	Negative	Negative	Negative		
Left Lateral Mid:	Negative	Negative	Negative		
Left Lateral Apex:	Negative	Negative	Negative		
Left Base:	Negative	Negative	Negative		
Left Mid:	Negative	Negative	Negative		
Left Apex:	Negative	Negative	Negative		
Left Transition Zone:	Negative	Negative	Negative		
Right Base:	Negative	Negative	Negative		
Right Mid:	Negative	Negative	Negative		
Right Apex:	Negative	Negative	Negative		
Right Lateral Base:	Negative	Negative	Negative		
Right Lateral Mid:	Negative	Negative	Negative		
Right Lateral Apex:	Negative	Negative	Negative		
Right Transition Zone:	Negative	Negative	Negative		

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SAMPLE Patient Report

ConfirmMDx for Prostate Cancer

PATIENT	SPECIMEN	ACCOUNT
Patient Name: 14 - 07 RASS Pos Date of Birth: 10/15/1945 MRN/Patient: MRN 123 PATH: HG-PN PSA: 3.5 ng/mL DRE: Normal	Specimen: S641305 Collection Date: 11/10/2015 Received Date: 11/17/2015 Report Date: 11/24/2015 Specimen Type: Prostate FFPE tissue slides MDxH Accession: PR-123456	Physician: Mike Test, MD Account: Urology Partners of California Address: 15279 Alton Parkway Suite 100 City/State/Zip: Irvine CA 92618

Patient Result: DNA Methylation Positive

The DNA methylation positive test result for this patient indicates a 88% likelihood of detecting prostate cancer, with a 38% probability for low-grade disease (GS ≤ 6) versus a 50% probability of high-grade disease (GS ≥ 7), on repeat biopsy.

Likelihood of prostate cancer on repeat biopsy

0% 38% 50% 88% 100%

Likelihood of low grade prostate cancer **Likelihood of high grade prostate cancer**

The ConfirmMDx test result indicating the likelihood of low and high-grade prostate cancer being detected on repeat biopsy is calculated by using a logistic regression model, incorporating DNA methylation intensity with clinical risk factors, including PSA, DRE, age, and histopathology of the previous biopsy, yielding an area under the curve (AUC) of 0.762 (95% CI: 0.679-0.844). Performance is based on the presence of all relevant data elements and AUC may vary if all data are not available. Cancer association with DNA methylation of these gene markers has been reported on ~4,500 patients.^{1,23}

DNA Methylation Status Table				Distribution of DNA Methylation Diagram	
Biopsy Site	GSTP1 Methylation	APC Methylation	RASSF1 Methylation		
Left Lateral Base:	Positive	Positive	Positive		
Left Lateral Mid:	Negative	Negative	Negative		
Left Lateral Apex:	Negative	Negative	Negative		
Left Base:	Positive	Positive	Positive		
Left Mid:	Negative	Negative	Negative		
Left Apex:	Negative	Negative	Negative		
Left Transition Zone:	Negative	Negative	Negative		
Right Base:	Negative	Negative	Negative		
Right Mid:	Negative	Negative	Negative		
Right Apex:	Negative	Negative	Negative		
Right Lateral Base:	Negative	Negative	Negative		
Right Lateral Mid:	Negative	Negative	Negative		
Right Lateral Apex:	Negative	Negative	Negative		
Right Transition Zone:	Negative	Negative	Negative		

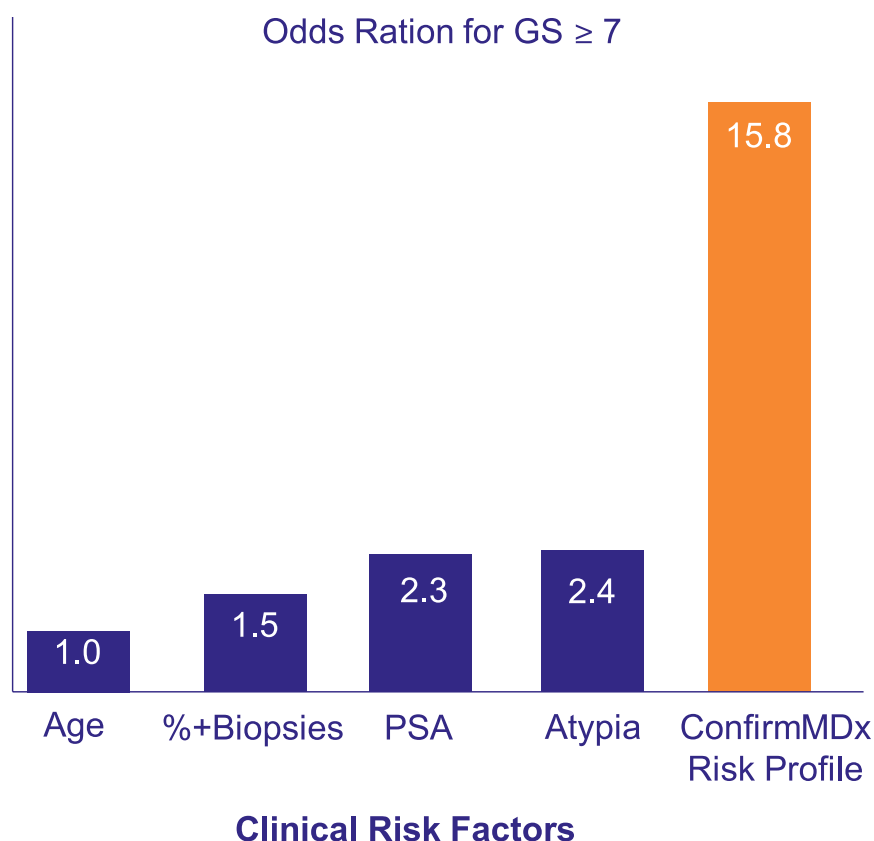
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Clinical Validity

The validation study for ConfirmMDx confirms superior performance compared to other commonly used biomarker tests and risk calculator^{12,13}

The Most Significant Independent Predictor for Prostate Cancer on Repeat Biopsy

Odds Ratio for GS \geq 7



Clinical validity & utility¹²⁻¹³

- 96% NPV for GS \geq 7 prostate cancer
- 90% NPV for all prostate cancer
- Included in the 2016 NCCN guidelines

2016

Publications

ConfirmMDx has been validated in over 50 studies with additional utility studies underway

Title	Summary	Journal
Risk score predicts high-grade prostate cancer in DNA-methylation positive, histopathologically negative biopsies.	Epigenetic risk score can specifically detect high-grade prostate cancers	<i>The Prostate</i> Van Neste L, et al Sep;76(12):1078-87
Clinical evaluation of an epigenetic assay to predict missed cancer in prostate biopsy specimens	ConfirmMDx reduced unnecessary repeat prostate biopsies & identified men at risk of harboring occult high- grade prostate cancer	<i>Trans Am Clin Climatol Assoc.</i> Partin A, et al 127: 313–327
Ability of an epigenetic assay to identify anterior prostate tumors based on a negative 12-core biopsy	ConfirmMDx detected an epigenetic field effect associated with the presence of anterior-predominant tumors that was missed in a previous negative biopsy	<i>American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU)</i> Morgan T, et al Abstract #131
Combined DNA-methylation intensity and clinical risk score to stratify patients for high-grade disease	ConfirmMDx stratifies patients with high-grade disease	<i>American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU)</i> Van Neste L, et al Abstract #51
Clinical Utility of an Epigenetic Assay to Reduce Unnecessary Repeat Prostate Biopsies	Demonstrated ConfirmMDx results helped stratify patients to reduce unnecessary biopsies	<i>American Urological Association Annual Meeting (AUA)</i> Hafron J, et al Abstract #MP39-08

Access

ConfirmMDx reimbursement significantly increased in 2016 following inclusion in the US National Comprehensive Cancer Network (NCCN) Guidelines

MDxHealth started 2016 with existing Medicare coverage and 2 positive commercial medical policies. Additional published data, placement in the NCCN Guidelines, and further investment in Managed Care contributed to 19 new commercial payor contracts and 26 additional positive commercial medical policies, including:

Health Care Services Corporation (HCSC) which includes Blue Cross and Blue Shield plans for Illinois , Montana, New Mexico, Oklahoma, Texas	15 million members
Cigna	~13 million members
Independence Blue Cross serves 25 states & Washington D.C.	8.5 million members
Highmark Blue Cross Blue Shield of Pennsylvania, Delaware and West Virginia	5.2 million members
Horizon Blue Cross Blue Shield of New Jersey	3 million members
Blue Cross Blue Shield of Alabama	3 million members
GEHA	1.5 million members

In 2016, the AMA awarded a unique Category I MAAA CPT code for ConfirmMDx, effective January 2018, which is expected to streamline reimbursement efforts and significantly reduce collection periods

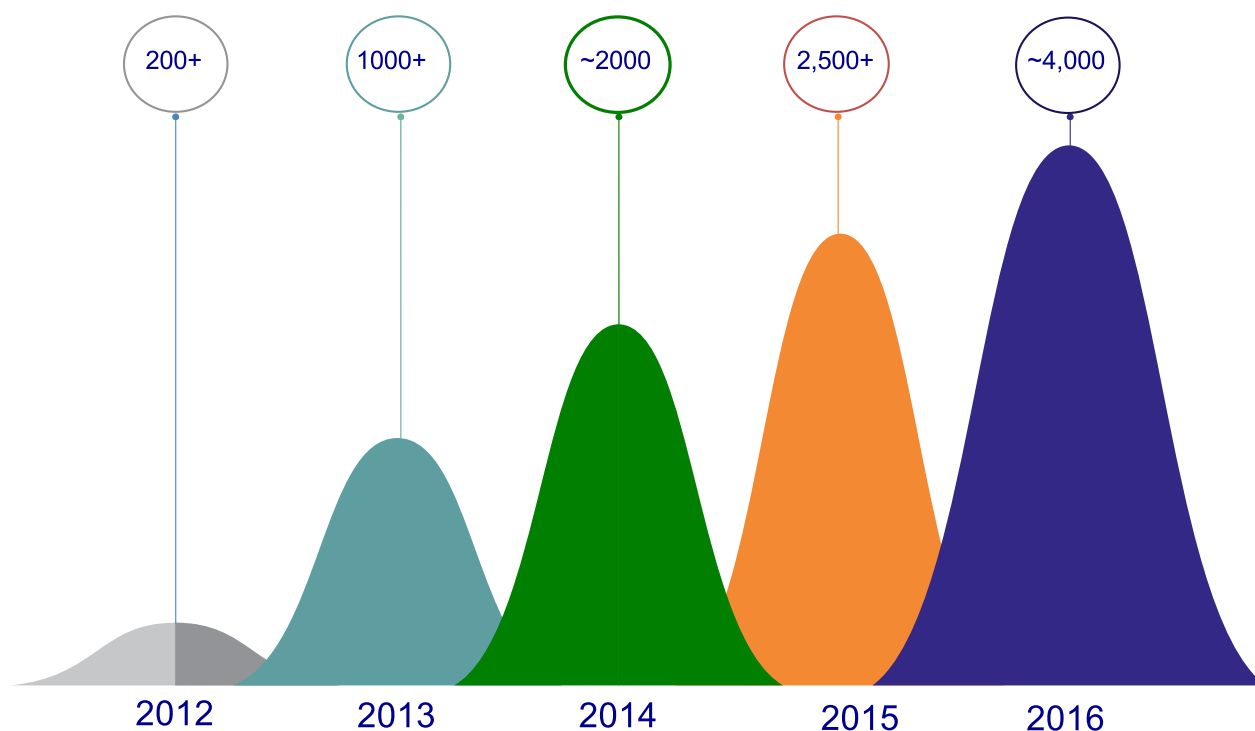
Market Opportunity

MDxHealth had a growing number of urologists order ConfirmMDx with more opportunity ahead

11,000
Urologists

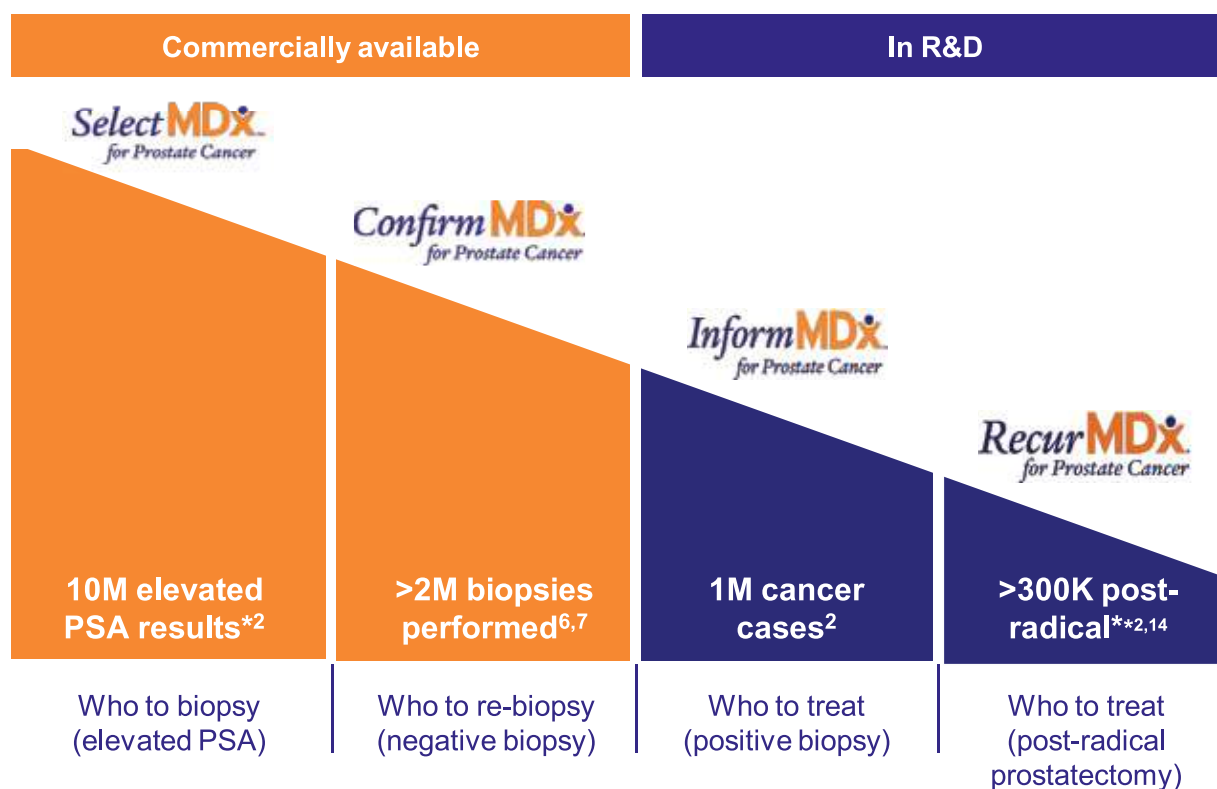
8,500
Office-based urologists

Cumulative unique ordering urologists since launch



Portfolio Vision

MDxHealth's diagnostics become the standard of care in prostate cancer



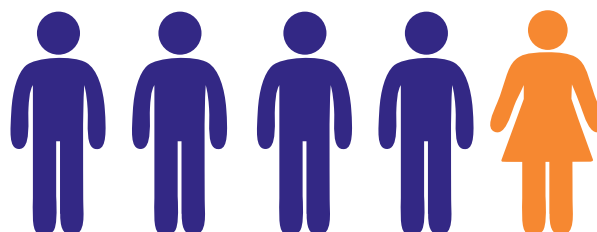
**Company's estimation based on the reference*

*** 30% calculation based on references*

Bladder Cancer

Unmet diagnostic needs in bladder cancer

Men are four times more likely to get bladder cancer than women¹⁵



Bladder cancer is the ninth most common cancer globally and its accurate diagnosis and follow-up remain a challenge, making it the most expensive cancer to treat.¹⁵⁻¹⁷

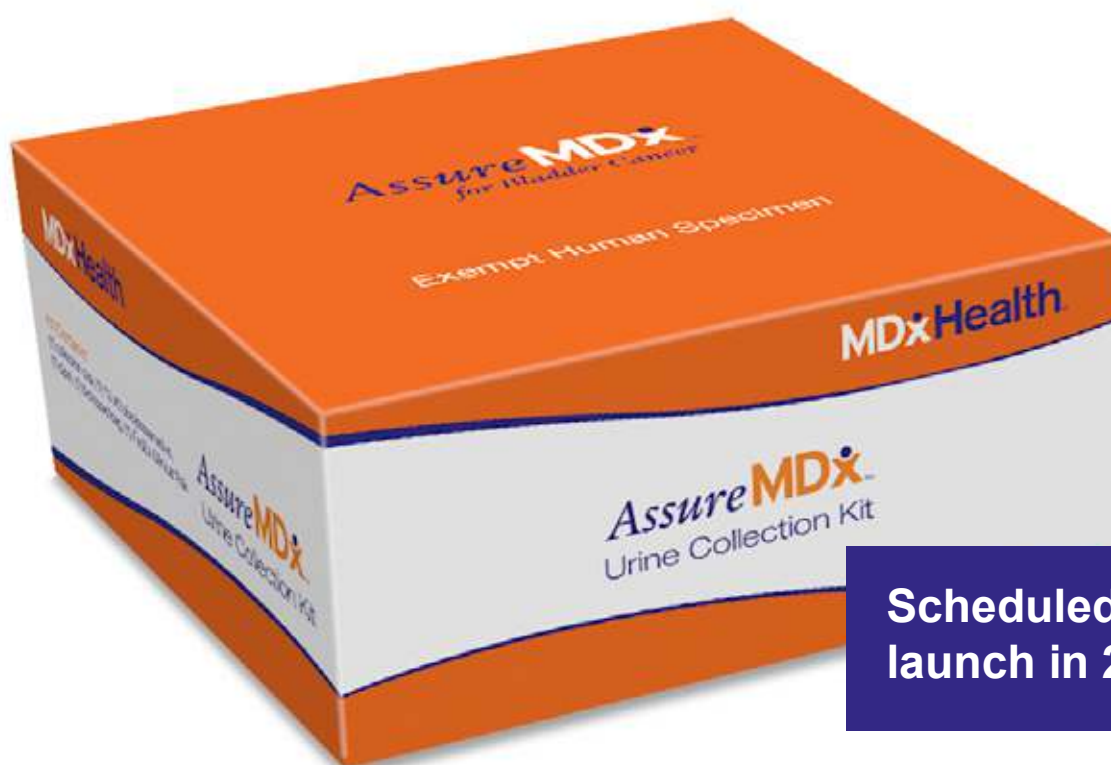
Hematuria (presence of blood in urine) is the first sign of bladder cancer and it has been estimated that there are approximately 10.8 million hematuria visits to urologists per year in the US alone.¹⁸ Urologists conduct cytopathology from a bladder wash or urine sample; however these methods only have 20-50% sensitivity for low grade tumors so patients generally undergo a cystoscopy.^{19,20}

In the US, approximately 3 million cystoscopies are planned or conducted annually.¹⁸ 230,000 cystoscopies are performed in patients with a near-zero risk of bladder cancer.¹⁸ Only about 28% of patients undergoing a cystoscopy will be diagnosed with cancer and 20,000 bladder cancer cases are missed annually among moderate- and high-risk hematuria patients.^{18,21}

It is estimated that 70% of patients in the US treated for early stage bladder cancer will experience a recurrence and lifelong surveillance with cystoscopy is recommended.¹⁹ However, cystoscopy is unideal for monitoring because it is too invasive of a procedure to ask a patient to undergo repeatedly. A highly sensitive and non-invasive diagnostic test is needed to monitor early tumors and recurrence for the 400,000 patients under surveillance in the US.*^{19,,22}

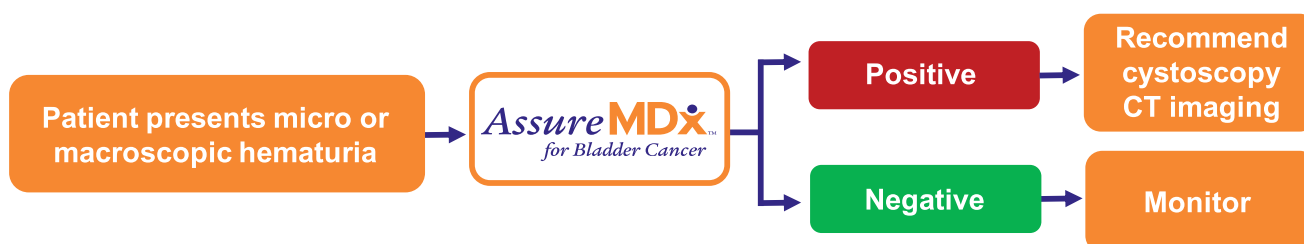
** Calculation based on 70% of NIH bladder cancer incidence*

AssureMDx™ for Bladder Cancer



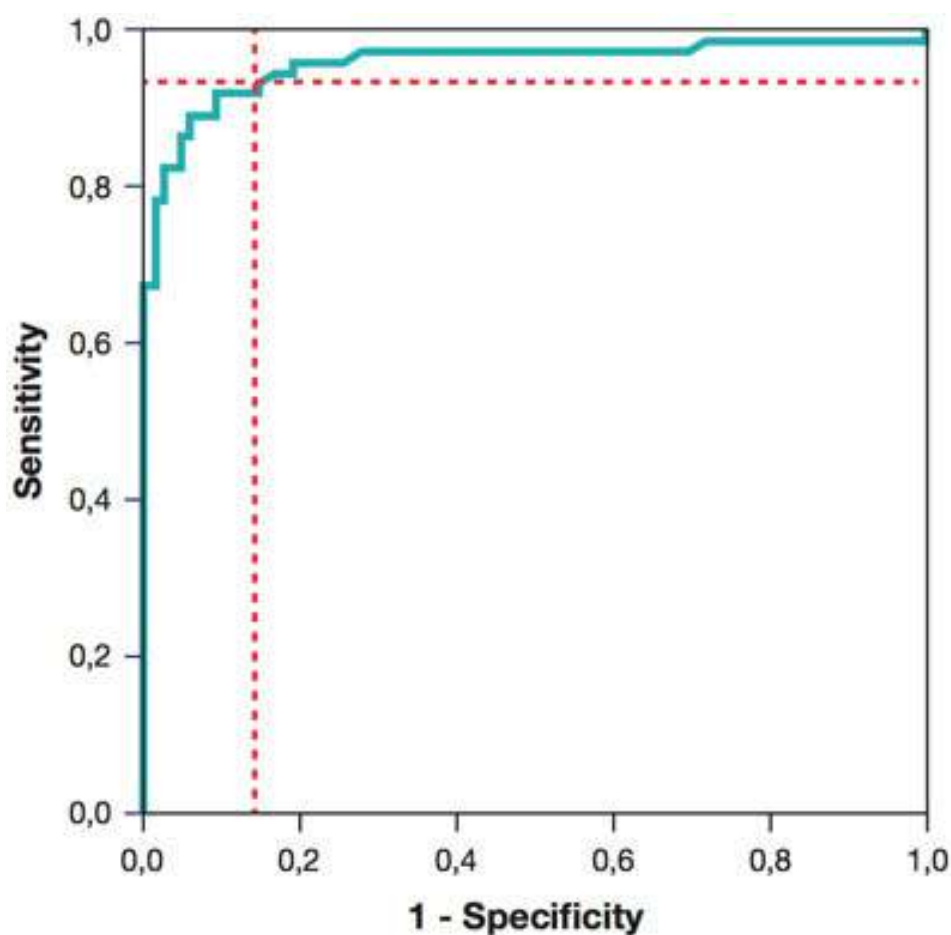
**Scheduled to
launch in 2017**

A non-invasive urine test that combines epigenetic and mutation biomarkers to predict the presence of bladder cancer in patients presenting with micro or macroscopic hematuria



Clinical Validity

The validation study for AssureMDx demonstrated the test's ability to predict bladder cancer



Clinical validity & utility²³

- 99% NPV for bladder cancer
- 93% sensitivity
- 86% specificity

2016

Publications

AssureMDx had one publication in 2016 and one acceptance for a 2017 publication

Title	Summary	Journal
<u>Validation of a DNA Methylation-Mutation Urine Assay to Select Patients with Hematuria for Cystoscopy</u>	Molecular urine test is highly accurate & may allow better selection of patients for more invasive procedures	<i>Journal of Urology</i> van Kessel KE, et al Mar;197(3 Pt 1):590-595
<u>Evaluation of an Epigenetic Profile for the Detection of Bladder Cancer in Patients with Hematuria</u>	Epigenetic and mutational biomarkers in urine can detect bladder cancer	<i>Journal of Urology</i> van Kessel KE, et al Mar;195(3):601-7

Business Model

MDxHealth provides service testing in the US and Europe with the ambition of providing in vitro diagnostic kits globally to hospitals and laboratories



In the US, MDxHealth provides CLIA* service testing of laboratory developed tests (LDTs), ConfirmMDx and SelectMDx, are sold directly to physicians through a sales force of 33 representatives. The Company plans to double the salesforce within five years. AssureMDx will be sold similarly following its launch in 2017.

The Company's sales strategy is to increase adoption in the US by educating community-based, large group practices and academic urologists on the clinical and economic benefits of the tests in the portfolio through studies and relationships with key opinion leaders and institutions.

**Clinical Laboratory Improvement Amendments*



In Europe and beyond, MDxHealth provides SelectMDx service testing sold directly to hospitals, commercial labs and private clinics through direct sales representatives in Benelux, Germany and Italy supported by European global distributors and lab partners. By mid-2017, SelectMDx will be launched as a CE-marked IVD kit for testing to be conducted within hospitals and laboratories.

Quality Policy

MDxHealth is committed to develop and provide the highest quality clinical laboratory services

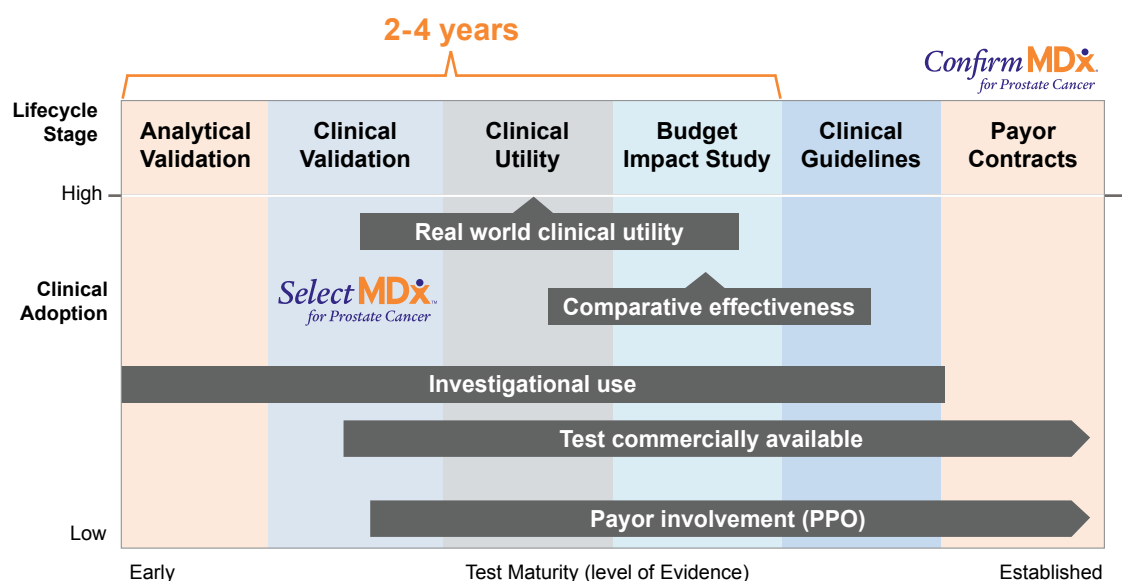
In the US, MDxHealth performs testing services at its 13,444 sqft, College of American Pathology (CAP)-accredited and Clinical Laboratory Improvement Amendments of 1988 (CLIA) and ISO 9001:2008 certified, molecular laboratory facility located at its US headquarters in Irvine, California. In Europe, testing is offered through its state-of-the-art 1,735 sqft ISO 13485:2016 certified diagnostic facilities in Nijmegen, The Netherlands.

We comply with all applicable regulatory requirements, continuously monitor and maintain the effectiveness of the quality management system



Reimbursement

MDxHealth has experience navigating the reimbursement roadmap in the US



Testing revenues are derived from several different sources depending on the billing and contractual arrangements, and applicable laws:

- 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;
- 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.

2017 Strategy



Increased utilization of products globally



Continue product offering expansion:

AssureMDx commercial launch

SelectMDx CE-marked IVD kit



Continue demonstrating portfolio clinical utility, including:

SelectMDx prospective clinical study publication

Health economic data publication

Outlook



55-75% growth on product & service income excl. royalties/ milestones



Improved collectability & reduced working capital requirements



Continued reduction in operating losses



Increased private US payor adoption & favourable reimbursement rates

Commercial Collaborations



Limited non-transferrable non-exclusive licensing agreements to use MDxHealth's patented specific PCR (MSP) technology in Oncnostics's GynTect® IVD test to detect cervical precancerous lesions/ cancer and Qiagen's QIASure to differentiate patients' risk of developing cervical cancer



Exclusive licensing agreement of biomarkers for Cologuard test for colorectal cancer



MDxHealth's commercial product in the NCCN guidelines, PredictMDx for Glioblastoma, is available through non-exclusive distribution agreements



Intellectual Property

Our portfolio and partnership strategies are rooted in intellectual property

38
Patent
families



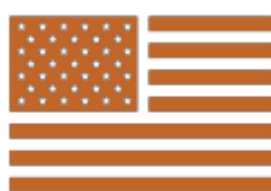
ROW

23

Issued patents

15

Pending patents



US

25

Issued patents

20

Pending patents

2016

Financial Review

2016

Financial Review

The review of the Company's financial condition and results of operations pertains to the Company's consolidated financial statements 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 Part IV of the present report.

Results of Operations for the Year Ended December 31, 2016 compared to Year Ended December 31, 2015.

Revenues

Total revenues for the year ended December 31, 2016 amounted to \$30 million, an increase of 70% compared to total revenues of \$17.6 million a year earlier. Product and service income constituted \$25 million of the 2016 total revenues figure. Nearly 24,000 patients were tested worldwide across all MDxHealth products in 2016, with SelectMDx representing approximately 17% of the total.

The strong growth in the US contributed \$24.4 million or 82% of total revenue. The strong growth of ConfirmMDx sales was driven by wide market adoption and continued expansion of reimbursement coverage. In 2016, the test was included in the US National Comprehensive Cancer Network (NCCN) Clinical Guidelines, which led to 19 new payor agreements and 28 payor issued positive medical policies.

Non-US revenues included initial sales of SelectMDx, milestone fees and royalties from license deals, and came in at \$5.5 million, up 133% or \$2.4 million compared to 2015. Royalties and milestone fees predominantly resulted from the license agreement with Exact Sciences Corporation for stool-based screening of colorectal cancer. In 2016, non-US revenues included two Exact Sciences' milestone fees for a total of \$1.75 million after its Cologuard test attained cumulative net sales of \$50 million and net sales of \$50 million in a single year.

The Company only recognizes revenue prior to actual collection when there is reasonable evidence that the tests which are delivered and billed will effectively be reimbursed. Product and Services income amounted to \$25 million in 2016, compared to \$15.8 million in 2015. A total net amount of \$49.3 million was billed for tests delivered in 2016, but a significant portion of these billed amounts are recognized only when the payment is collected. These unrecognized transactions will most likely impact revenues in future months as they either are collected or the payment pattern for given third-party payors warrants accrual accounting treatment for these transactions per the Company's revenue recognition policy. Revenue recognition is expected to gradually improve as the Company concludes firm agreements for reimbursement with a growing number of payors.

Cost of goods and services sold

The cost of goods includes royalties that MDxHealth must pay to third parties and the costs associated with providing testing services to third parties. Cost of goods sold for 2016 came in at \$10.1 million, compared to \$6.9 million in 2015. Increased revenues resulted in a gross profit of \$19.9 million, while a sustained focus on operational efficiencies yielded an improvement of the gross profit margin from 60.9% in 2015 to 66.3% in 2016.

Research and development expenses

The Company continued to validate the clinical utility of its expanded offering through clinical trials and publications. Research and development expenses amounted to \$1,977 thousand in 2016 compared to \$3,257 thousand in 2015. The decrease by 39% directly resulted from capitalizing development expenses associated with the Company's tests. In aggregate, and including capitalized expenses, R&D expenditure amounted to \$4,411 thousand or 17.7% of products and services income, compared to 20.7% in 2015.

<i>Thousands of \$/ Years ended December 31</i>	2016	2015
Personnel costs	1,594	935
Lab consumables	912	358
External research and development collaborators	966	1,591
Depreciation & amortization	715	220
Other expenses	224	506
Subtotal	4,411	3,610
Capitalization of internally developed products	-2,434	-353
Total	1,977	3,257

Selling, general and administrative expenses

In 2016, selling, general and administrative expenses amounted to \$31 million compared to \$22.4 million in 2015, an increase of 38.4%. The year-on-year increase is attributable to the acquisition of NovioGendix (renamed to MDxHealth BV), which was only included for one quarter in 2015. Furthermore, MDxHealth invested in the build-out of the organisation to support the global commercial launch of SelectMDx. MDxHealth is pursuing a direct sales strategy for SelectMDx in Benelux, Germany and Italy, supported by European and global distributors and commercial lab partners. The Company appointed a global commercial team to cover business development and direct sales. The details of administrative and selling expenses is as follows:

<i>Thousands of \$/ Years ended December 31</i>	2016	2015
Personnel costs	18,823	12,865
Depreciation	1,007	502
Professional fees	3,936	1,994
Marketing expenses	2,122	1,885
Travel expenses	1,886	1,469
Offices and facilities expenses	1,412	974
Royalties to third parties	641	1,379

Other expenses	918	675
Patent expenses	1,546	615
Capitalization of internally developed products	(1,338)	
Total	30,953	22,358

Financial results

The increase of the net financial loss from \$0.09 million in 2015 to \$0.44 million in 2016 largely resulted from \$0.3 million of unrealized foreign exchange translation losses arising on the revaluation of the contingent liability arising from the acquisition of NovioGendix.

Net loss

EBITDA for the year improved by \$2.4 million as the loss was reduced from \$13.5 million in 2015 to \$11.1 million. This improvement was partly offset by increased amortization charges, bringing the Company's net loss for 2016 to \$13.2 million, a \$1.3 million improvement over 2015. The increased amortization resulted from scheduled amortization of intangible assets associated with the acquisition of NovioGendix in 2015.

Liquidity, working capital, and capital resources for the years ended December 31, 2016 and 2015

Year ended December 31, 2016

Cash and cash equivalents stood at \$30.8 million at the end of 2016 after having successfully raised \$21.7 million (€20.4 million) in a private placement of 4,526,962 new shares at €4.50 (\$4.99) per share. The number of outstanding shares at December 31 was 49,845,595.

Increased private payor adoption and a sustained focus on reimbursement has helped to improve working capital throughout 2016. Cash used by operations amounted to \$16.6 million, compared to \$14.4 million in 2015, and included cash collections of \$19.7 million, a 61% increase year-on-year. The award of a unique current procedural terminology (CPT) code by the American Medical Association (AMA), which will become effective January 1, 2018, is expected to significantly shorten collection periods from Medicare and private payors.

Year ended December 31, 2015

MDxHealth closed the year 2015 with \$31.7 million of cash and cash equivalents 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, due to the acquisition of NovioGendix in The Netherlands and the acquisition of tangible assets for \$1.6 million. The net proceeds from the capital increases in 2015 was \$34.8 million. Excluding the capital increase, the Company used \$22 million of cash over the year.

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Corporate Governance



Part II:

Corporate Governance

This section summarizes the main rules and principles of MDxHealth's Corporate Governance Charter. The complete Corporate Governance Charter is available on the MDxHealth website, at <http://www.mdxhealth.com/shareholder-information>.

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 provision 7.7 of 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 this provision of the 2009 Code is not appropriate and adapted to take into account the realities of companies in the life sciences industry that are in a development and growth phase, such as MDxHealth. Notably, the ability to remunerate independent and other Non-Executive Directors with warrants allows to limit the portion of remuneration in cash that MDxHealth would otherwise need to pay to attract or retain renowned experts with the most relevant skills, knowledge and expertise. 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 in the next section.

Board of Directors

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 2 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 obligation is January 1, 2019 for companies that meet on a consolidated basis at least two of the following criteria: (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 criteria. The Company is using its best efforts to ensure that the Board of Directors will meet the one-third gender diversity requirement by January 1, 2018. The Board of Directors intends to propose at the upcoming annual general shareholders' meeting of the Company to be held on May 26, 2017 a resolution whereby 1 additional female would be appointed as new Director of the Company, which (if adopted) would increase to ratio to 29% female Directors against 71% male Directors).

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 9 times throughout 2016. All Directors were present or represented at these 9 meetings, except for Valiance Advisors LLP, represented by its permanent representative, Mr. Jan Pensaert, which was not represented at one meeting.

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, Shaffar LLC, with Mr. Mark Shaffar as permanent representative, is the chairman of the Board of Directors. Mr. Shaffar assumed the role of Board chair in 2016 following the resignation of Greenlands Consulting LLC, with Mr. Edward L. Erickson as permanent representative, from the Board in June 2016.

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, 2016	Position	Term Start	Term End ⁽¹⁾	Professional Address
Shaffar LLC, represented by Mr. Mark Shaffar	61	Chairman, Non-Executive Independent Director	2016	2020	CAP Business Center Rue d'Abhooz, 31 4040 Herstal, Belgium
Dr. Jan Groen	57	Executive Director	2010	2017	CAP Business Center, Rue d'Abhooz, 31 4040 Herstal, Belgium
Gengest BVBA, represented by Mr. Rudi Mariën	71	Non-Executive Director	2011	2017	Karel van de Woestijnestraat 1-3, 9000 Gent, Belgium
Hasseltberg BVBA, represented by Mrs. Ruth Devenyns	51	Non-Executive Independent Director	2011	2020	Kardinaal Sterckxlaan 47 - 1860 Meise, Belgium
Valiance Advisors LLP, represented by Mr. Jan Pensaert	45	Non-Executive Director	2014	2018	Lilly House 13 Hanover Square London W1S 1HN United Kingdom
Lab Dx L.L.C., represented by Mr Walter Narajowski	63	Non-Executive Independent Director	2015	2020	CAP Business Center, Rue d'Abhooz, 31 4040 Herstal, Belgium

Notes:

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. Mark R. Shaffar has been a consultant and advisor at Shaffar LLC since May 2014 and he also holds a mandate as an independent director of Biocartis Group NV since June 2015. He has nearly 40 years of experience in the biotechnology sector, having held numerous positions at Abbott Laboratories, including divisional vice-president of acquisition and licensing for twelve years, director of technology acquisition and licensing for seven years, and manager of licensing and acquisitions for five years. Mr. Mark Shaffar holds a master of management with a major in management policy, finance from the Northwestern University Kellogg Graduate School of Management and a bachelor of science in biochemistry from the University of Wisconsin-Madison.



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 Ogeda SA. 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:
- 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, Pharmeduroboost 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 2016: Hasseltberg BVBA, represented by Mrs Ruth Devenyns (chair), Valiance Advisors LLP, represented by Mr. Jan Pensaert, and LabDx L.L.C., represented by Mr. Walter Narajowski, who replaced Greenlands Consulting LLC, represented by Mr. Ed Erickson, following his resignation from the Audit Committee and the Board in June 2016. 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 Ogeda, and her previous roles in venture capital and investment banking.

The audit committee is a collegial body, and deliberates and makes decisions as such. The audit committee met 2 times in 2016. 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 in 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 in 2016: Lab Dx L.L.C., represented by Mr. Walter Narajowski (chair), Gengest BVBA, represented by Mr. Rudi Mariën, and Shaffar LLC, represented by Mr. Mark Shaffar, who replaced Greenlands Consulting LLC, represented by Mr. Ed Erickson, following his resignation from the audit committee and the Board in June 2016.

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

The nomination and remuneration committee met 3 times in 2016. 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:

1. assessing how the Board of Directors and its committees operate,
2. checking that the important issues are suitably prepared and discussed,
3. checking the Board's and committees' current composition against the desired composition,
4. 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
5. 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.

Executive Management



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 at the date of this report are illustrated below:



Dr Jan Groen
CEO



Joe Sollee
EVP, General Counsel &
Chief Compliance Officer



Chris Thibodeau
EVP & U.S. Chief
Operations Officer



Jean-Marc Roelandt
EVP & Chief
Financial Officer

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, 2016	Position	Permanent Address
Dr. Jan Groen	57	Chief Executive Officer (CEO)	CAP Business Center Rue d'Abhooz, 31 4040 Herstal, Belgium
Marcofin BVBA, represented by Jean-Marc Roelandt	51	Executive Vice President & Chief Financial Officer	CAP Business Center Rue d'Abhooz, 31 4040 Herstal, Belgium
Joseph Sollee	52	Executive Vice President, General Counsel & Chief Compli- ance Officer	15279 Alton Pkwy, Ste 100 Irvine, CA 92618, USA
Christopher Thibodeau	46	Executive Vice President & Chief Operations Officer	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. Jean-Marc Roelandt, as representative of Marcofin BVBA, Executive Vice President & Chief Financial Officer

Mr. Roelandt, the representative of Marcofin BVBA, joined MDxHealth in January 2017 and brings over 20 years of financial leadership experience in a range of multinational industries. Mr. Roelandt was born in 1965 in Ghent, Belgium and holds a master’s degree in Applied Economic Sciences from the University of Ghent, Belgium. He started his professional career as audit manager at Ernst & Young and qualified as a Certified Public Accountant (Instituut van de Bedrijfsrevisoren) in 1996, after which he held various senior positions in several publicly listed Belgian companies. He was Chief Financial Officer of Ubizen NV from April 1999 until he joined BHF Kleinwort Benson (previously known as RHJ International) in January of 2005. At BHF Kleinwort Benson Group, he served as Chief Financial Officer and Managing Director for more than 11 years. In addition to his responsibilities as a member of BHF Kleinwort Benson Group’s executive management, he was also appointed Executive Director and Chief Financial Officer of Kleinwort Benson Bank in London in July 2015. He held those positions until the public take-over of BHF Kleinwort Benson Group in 2016.

Mr. Joseph Sollee, Executive Vice President, General Counsel & Chief Compliance Officer

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 20 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 in investment banking 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 certified into the legal bars of New York, Washington D.C. and North Carolina.

Mr. Christopher Thibodeau, Executive Vice President & U.S. Chief Operations 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 U.S. Chief Operations Officer, he is responsible for MDxHealth’s U.S.-based 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.

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Statutory Auditor

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 shareholders' meeting to be held in 2018. However, BDO has been the statutory auditor since January 10, 2003, and following the implementation into Belgian law of the European audit reform, and the mandatory rotation requirements, the Company launched a tender to appoint a new statutory auditor at the upcoming annual shareholders' meeting to be held on May 26, 2017. Subject to certain requirements, the new law allows audit firms to be re-appointed for a maximum term of 18 years, and it is anticipated that BDO will be recommended by the Board of Directors for a term of 3 years ending immediately after the closing of the annual shareholders' meeting to be held in 2020. 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 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 €114 thousand (USD equivalent \$125 thousand) in fees to the auditor in 2016. The fees are broken down as follows:

- Audit fee for statutory and consolidated financials of €65 thousand (\$72 thousand)
- Audit related services (legal missions) €4 thousand (\$4 thousand)
- Tax consulting services €44 thousand (\$48 thousand)
- Other missions: €1 thousand (\$1 thousand)

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Remuneration Report



Remuneration report

The following report has been prepared by the nomination and remuneration committee and approved by the Board of Directors of MDxHealth on April 20, 2017. 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 2016 to develop a remuneration policy

During 2016, 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 2016. The increase in annual warrants grants was first approved at the annual general shareholders' meeting held in May 2014.

Procedure adopted 2016 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 remuneration policy in 2016

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 2016.

- 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 \$38,591¹) for the Chair of the Board of Directors;
- €30,000 (\$33,078¹) for the Chair of the Audit Committee;
- €28,000 (\$30,873¹) for the Chair of the Nomination and Remuneration Committee; and
- €25,000 (\$27,565¹) 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 2016, 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.

- 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

¹ Exchange rate 1 € = 1.1026 \$ (historical rate 2016)

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 2016, 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 2016.

Expected changes with respect to accounting year 2017 and the following accounting year

No significant change to the remuneration policy of Directors and Executive managers is envisaged for 2017 or the following accounting year.

The bonuses of the management team members for 2017 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 2016 compensation of the Non-Executive Directors in function at the date of this document:

Name ¹	Position ²	Pro-rata of annual retainer fee (€K)	Other services (€K)	Total ³ (€K)
Mr. Shaffar	NED – Board Chair, member NRC (as from May 2016)	20	0	20
Mr. Erickson	NED – Board Chair, member AC & NRC (until June 2016)	15	0	15
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, member AC	28	0	28
TOTAL for Non-Executive Board members		93	0	93

Notes:

¹: Mr. Mark Shaffar serves on the Board as a permanent representative of Shaffar, 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. Mrs. Devenyns serves on the Board as a permanent representative of Hasseltberg BVBA. Mr. Walter Narajowski serves on the Board as a permanent representative of LabDx, L.L.C. Mr. Edward Erickson served on the Board until June 2016 as a permanent representative of Greenlands 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 2016, the composition of the Board of Directors changed.

During the course of 2016, 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 2016, 2015, and 2014 was €668,000 (\$732,000), €671,000 (\$745,000), and €634,000 (\$842,000) 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 wilful misconduct. Therefore the Company has taken out Directors' liability insurance. The insurance policy was renewed in 2016. 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 2016 were composed as follows :

	EURO (€)	\$ EQUIVALENT
Fixed gross remuneration ¹ :	403,992	445,442
Bonuses paid and awarded ² (gross) :	113,959	125,650
Pension benefits:	14,988	16,525
Other benefits ³ :	40,325	44,462
TOTAL	573,264	632,079

Notes:

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

²: Excludes value of 400,000 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 2016, 2015 and 2014 were €573,000, €583,000 and €546,000, respectively (in USD equivalent \$632,000, \$648,000, and \$726,000 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 122,000 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.

At the Board meeting of February 21, 2017, the non-conflicted members of the Board of Directors agreed to the following bonus for the performance of Dr. Jan Groen in 2016:

- €113,959 cash bonus
- 50,000 new warrants (employee stock options) formally granted on February 21, 2017 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 2017 amounts to €121.500.

During the course of 2016, the Company has not deviated from its remuneration policy for the Executive Director.

Remuneration earned by other Executive Managers

The 2016 combined remuneration package of the other executive management team members (excluding the CEO) - i.e. Christopher Thibodeau, Joseph Sollee, Miriam Reyes, Philip Ginsburg and Francis Ota - including employer taxes, was €1,500,377.

	Euro (€)	\$ equivalent
Fixed gross remuneration ¹ :	1,220,242	1,345,440
Bonuses paid and awarded ² (gross) :	196,078	216,196
Pension benefits:	42,396	46,746
Other benefits ³ :	41,661	45,936
Total	1,500,377	1,654,318

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 2016, 2015, and 2014 was €2,073,642 €1,849,261 and €1,259,920, respectively (USD equivalent \$2,286,399, \$2,051,940 and \$1,673,650 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 February 21, 2017, cash bonuses were awarded to certain executive management team members for their performance in 2016 as follows (amounts exclude employer taxes):

• CEO	€113,959 (\$125,650)
• Other Executive Management	€196,078 (\$216,197)

The primary performance objectives for the bonuses of the above management team members in 2016 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 2016, 90,000 warrants were exercised; Christopher Thibodeau exercised 65,000 warrants, Joseph Sollee exercised 25,000 warrants.

During the course of 2016, 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;
- Acting under the direction of Board, the Company engaged Marcofin BVBA, with Mr. Jean-Marc Roelandt serving as its permanent representative, to provide financial management services and assistance for the daily operations of the Company's activities, effective as of January 16, 2017, under the terms of a Management Services Agreement.

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.

2016 Share-based compensation of Directors and Executive Managers

During the course of 2016, the following share-based compensation was awarded 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 2 other current members of the Executive management team received a total of 100,000 new warrants

In reference to the 10,000 new warrants received by each Non-Executive Director in 2016, each Non-Executive Director received:

- 10,000 new warrants at the annual general shareholders meeting of May 29, 2016, with the following characteristics:
 - Exercise price of €4.16 (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 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

An addition 150,000 warrants were granted to executive management in 2017, based on a decision of the Board of Directors on February 21, 2017, with the following characteristics:

- Exercise price of €5.35 (one stock option (warrant) gives right to buy one share)
- Straight-line vesting over 4 years for all beneficiaries
- Exercise Period: the warrants are not exercisable until after the third anniversary the date of their grant
- Duration of warrants: 10 years

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

Done on April 20, 2017

On behalf of the Board of Directors

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Principle Risks & Uncertainties



Part III: Principle Risks & Uncertainties

MDxHealth operates in a rapidly changing environment that involves a number of risks and uncertainties, some of which are beyond its control. This discussion highlights some of the principal risks and uncertainties, which may affect MDxHealth's business, financial condition and results of operation. The Company cannot be certain that it will successfully address these risks. Additional risks and uncertainties not presently known, which management currently deems immaterial or which are like those faced by other companies in the Company's industry or business in general, may also impair its business operations.

Strategic and commercial risks

The molecular diagnostics industry is highly competitive and characterized by rapid technological changes

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.

The market for assessing men at risk for prostate cancer is large. As a result, this market has attracted competitors, some of which possess 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. 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. These competitors could have technological, financial, reputational, and market access advantages over MDxHealth.

The commercial success of MDxHealth will depend on the market acceptance and adoption of its tests

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 the Company's sales efforts that it educates enough patients, clinicians and administrators about molecular diagnostics testing, in general, as well as about its tests, and demonstrate their clinical benefits. It is likely that clinicians may not adopt, and third-party payors may not cover or adequately reimburse for, the Company's tests unless they determine, based on published peer-reviewed journal articles and the experience of other clinicians, that they 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, MDxHealth cannot predict whether it will have sufficient data, or whether the data it has will be presented to the satisfaction of any payors seeking such data, in the process of determining coverage for its diagnostic tests.

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

If MDxHealth's tests or the technology underlying its current or future tests do not receive sufficient favorable exposure in peer-reviewed publications, the rate of clinician adoption of its tests and positive reimbursement coverage decisions for its tests could be negatively affected. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for diagnostic tests, and the Company's inability to control when, if ever, its results are published may delay or limit its ability to derive sufficient revenue from any product that is the subject of a study.

MDxHealth's financial results are largely dependent on sales of one test, and it will need to generate sufficient revenues from this and other future solutions to grow its business.

Revenues in 2016 were still largely dependent on the sales of the Company's ConfirmMDx test for Prostate Cancer. Revenues from sales of ConfirmMDx accounted for approximately 80% of total revenues and is expected to decrease further over the next several years, based on anticipated sales of the SelectMDx test for Prostate Cancer and AssureMDx, a test for bladder cancer monitoring, scheduled for commercial launch in the US in 2017. However, there can be no assurance that SelectMDx and AssureMDx will be successfully commercialized. If the Company is unable to increase sales of ConfirmMDx or successfully develop and commercialize other solutions or enhancements, its revenues and its ability to achieve profitability would be impaired, and the market price of its shares could decline.

MDxHealth faces uncertainties over the reimbursement of its tests by third party payors

Successful commercialization of the Company's tests 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 the Company's immediate objectives and long-term commercial goals. The Company does not recognize revenue for test results delivered without a contract for reimbursement or without a history of consistent

payment. 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.

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 MDxHealth provides.

Outside of the US, various coverage, pricing and reimbursement approvals are required. The Company expects that it will take several years to establish broad coverage and reimbursement for its tests with payors in countries outside of the US where it commercializes its solutions, and its 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 MDxHealth may have difficulty satisfying. Reimbursement levels outside of the US may vary considerably from the reimbursement amounts the Company receives in the US. In addition, because MDxHealth plans in many circumstances to rely on distributors to obtain reimbursement for its tests, to the extent it does not have direct reimbursement arrangements with payors, the Company may not be able to retain reimbursement coverage in certain countries with a particular payor if its agreement with a distributor is terminated or expires or a distributor fails to pay for other reasons.

Operational risks

If MDxHealth is unable to protect its intellectual property effectively, it may be unable to prevent third parties from using its intellectual property

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

MDxHealth is dependent on licenses and collaborations with third parties

The Company licenses technology from third parties necessary to develop and commercialize its products. Termination of any of these licenses could prevent the Company from producing or selling some or all of its tests, and a failure of the licensors to abide by the terms of the licenses or to prevent infringement by third parties could harm the Company's business and negatively impact its market position.

MDxHealth is also engaged in several collaborations and licenses with commercial partners, such as leading pathology laboratories with large urology client bases. Failure to maintain these partnerships could adversely affect revenues and profitability.

MDxHealth faces an inherent risk of product liability claims

The marketing, sale and use of MDxHealth's tests could lead to product or professional liability claims against it if someone were to allege that its tests failed to perform as they were designed, or if someone were to misinterpret test results or improperly rely on them for clinical decisions. Although MDxHealth maintains product and professional liability insurance which is deemed to be appropriate and adequate, it may not fully protect the Company 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. Furthermore, any product liability lawsuit could harm its reputation, which could impact its results of operations.

Failure to attract or retain key personnel or to secure the support of key scientific collaborators could materially adversely impact MDxHealth's business

Competition for desirable personnel is intense, and there can be no assurance that MDxHealth will be able to attract and retain the necessary staff. The failure to maintain management or to attract sales personnel as the Company moves towards the commercialization of its tests could materially adversely affect the business, financial condition and results of operations.

MDxHealth has established relationships with leading key opinion leaders and scientists at important research and academic institutions that it believes are key to establishing tests using its technologies as a standard of care for cancer assessment and diagnosis. If its collaborators determine that cancer testing using its 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, the Company would encounter significant difficulty establishing tests using its technologies as a standard of care for prostate cancer diagnosis, which would limit its revenue growth and profitability.

MDxHealth laboratory facilities may become inoperable

MDxHealth currently perform all its testing in its laboratory facilities located in Irvine, California and Nijmegen, The Netherlands. The Company does not have redundant laboratory facilities in the US or in Europe. Its laboratory facilities could become inoperable due to circumstances beyond its control, which could adversely affect its business and operations. The facilities, the equipment MDxHealth uses to perform its tests and services and its 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 MDxHealth to perform its tests for some period.

The facilities may also be rendered inoperable because of regulatory sanction. In the US, MDxHealth is subject to federal and state laws and regulations regarding the operation of clinical laboratories. The US Federal Clinical Laboratory Improvement Amendments (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.

MDxHealth relies on a limited number of suppliers for manufacture and supply of its laboratory instruments and materials

Many of the consumable supplies and reagents used as raw materials in the Company's testing process are procured from a limited number of suppliers, some of which are sole-source. In addition, it relies on a limited number of suppliers, or in some cases a single supplier, for certain equipment with which it performs testing services. Because the actual production or manufacture of such critical equipment and materials cannot be ensured, MDxHealth may be subject to significant delays caused by interruption in production or manufacturing, which could adversely affect its business, results of operations and financial condition.

Failure in MDxHealth's information technology, telephony or other systems could significantly disrupt business operations

Information technology and telephony systems are used extensively in virtually all aspects of the business, including laboratory testing, sales, billing, customer service, logistics and management of medical data. The Company's information technology, telephony and other systems, are vulnerable to damage and failure, computer viruses, natural disasters and physical or electronic break-ins. Despite the precautionary measures MDxHealth has taken to prevent breakdowns in its information technology and telephony systems, sustained or repeated system failures that interrupt its ability to process test orders, deliver test results or perform tests in a timely manner or that cause it to lose patient information could adversely affect its business, results of operations and financial condition.

Security breaches or loss of data may harm MDxHealth's reputation, expose it to liability and adversely affect its business

MDxHealth faces four primary risks relative to protecting sensitive and critical personally identifiable information, intellectual property or other proprietary business information about its customers, payors, recipients and collaboration partners, including test results: loss of access risk, inappropriate disclosure or access risk, inappropriate modification risk, and the risk of being unable to identify and audit controls over the first three risks.

The secure processing, storage, maintenance and transmission of this critical information is vital to the Company's operations and business strategy, and it devotes significant resources to protecting such information. Although measures to protect sensitive information from unauthorized access or disclosure are taken, MDxHealth's information technology and infrastructure, and that of its 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.

Security breaches, the loss or misappropriation of data, privacy violations or the failure to implement satisfactory remedial measures could disrupt operations and lead to loss of reputation, regulatory penalties and other material financial losses and adversely affect MDxHealth's business, prospects, results of operations and financial condition.

Regulatory risks

Failure to comply with governmental payor regulations could result in MDxHealth being excluded from participation in Medicare, Medicaid or other governmental payor programs, which would adversely affect MDxHealth's business

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, returning funds already paid, civil monetary penalties, criminal penalties and/or limitations on the operational function of its laboratories. If MDxHealth were unable to receive reimbursement under a governmental payor program, a material portion of its revenue would decline, which could adversely affect results of operations and financial condition.

MDxHealth conducts business in a heavily regulated industry, and changes in regulations or violations of regulations may, directly or indirectly, adversely affect its results of operations and financial condition and harm its business

MDxHealth's business operations and activities are subject to a range of healthcare laws and regulations (at the local, national and federal levels). The clinical laboratory testing industry is highly regulated, and there can be no assurance that the regulatory environment in which the Company operates will not change significantly and adversely to it in the future. In addition, the commercialization of any of its tests as kits will subject the Company to additional healthcare laws and regulations governing diagnostics products.

While MDxHealth believes that it is currently in material compliance with applicable laws and regulations, a determination that it has violated these laws, or the public announcement that it is being investigated for possible violations of these laws, would adversely affect its business, prospects, results of operations and financial condition.

If its operations or products are found to be in violation of any applicable laws and regulations, MDxHealth may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of its operations, the exclusion from participation in governmental healthcare programs and imprisonment, any of which could adversely affect its business and results of operations. In addition, a significant change in any of these laws may require the Company to change its business model to maintain compliance with these laws, which could reduce revenue or increase costs and adversely affect its business, prospects, results of operations and financial condition.

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

MDxHealth is 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 several transfers and transfer price determinations between its parent company and its subsidiaries or other affiliates. The Company's effective tax rates could be adversely affected by changes in tax laws, treaties and regulations, both internationally and domestically. An increase of the effective tax rates could have an adverse effect on its business, financial position, results of operations and cash flows.

Financial risks

MDxHealth has a history of losses, and expects to incur net losses for the next several years

MDxHealth has incurred substantial net losses since its inception, and there can be no assurance that it will achieve profitability. Even if the Company achieves significant revenues, it may not become profitable, and even if it achieves profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain consistently profitable could adversely affect the market price of MDxHealth's common stock and could significantly impair its ability to raise capital, expand its business or continue to pursue its growth strategy.

MDxHealth might require substantial additional funding to respond to business challenges or take advantage of new business opportunities, which may not be available on acceptable terms, or at all

At the end of 2016, cash and cash equivalents totalled \$30.8 million. Based on its assessment of operational and industry factors, the 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 2018. Although the Company believes that it has sufficient capital to fund its operations for at least the next twelve months, capital outlays and operating expenditures are expected to increase over the next several years as infrastructure, commercial operations and research and development activities expand. MDxHealth may require additional equity or debt funding from time to time to respond to business challenges or take advantage of new business opportunities, which may not be available at acceptable terms, or at all.

If additional funds are raised through the sale of equity, convertible debt or other equity-linked securities, stockholders' ownership will be diluted. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of common stock. If additional funds are raised by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of common stock, and the terms of the debt securities issued could impose significant restrictions on the Company's operations.

If adequate funds are not available, MDxHealth may have to scale back its operations or limit its research and development activities, which may cause the Company to grow at a slower pace, or not at all, and the business could be adversely affected.

MDxHealth may engage in acquisitions that could disrupt its business, cause dilution to its stockholders and reduce its financial resources

In addition to the acquisition of NovioGendix, a privately held company based in Nijmegen (The Netherlands), in September 2015, MDxHealth may enter into other transactions in the future to acquire other businesses, products or technologies. Any acquisitions may not strengthen the Company's competitive position, and these transactions may be viewed negatively by customers or investors.

The Company could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification it may obtain from the seller. In addition, MDxHealth may not be able to successfully integrate the acquired personnel, technologies and operations into its existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management from day-to-day responsibilities, increase expenses and reduce cash available for operations and other uses. MDxHealth cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on its operating results.

MDxHealth is exposed to fluctuations in currency exchange rates

MDxHealth's results of operations may be particularly affected by volatility in currency exchange rates and its ability to effectively manage currency transaction risks. In general, the Company conducts its business, earn revenue and incur costs in the local currency of the countries in which it operates. During the year ended December 31, 2016, approximately 99% of revenue was generated, and approximately 94% of total costs were incurred in, US dollars. As MDxHealth continues to expand internationally, its exposure to currency risks will increase. Historically, foreign currency exposure has not been managed in a manner that would eliminate the effects of changes in foreign exchange rates.

Further financial risks are described in note 16 to the Consolidated Financial Statements

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Part IV: Financial Statements



Part IV:

Financial Statements

Consolidated financial statements

The following consolidated accounts are prepared 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 non-consolidated 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 22, 2017. 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 26, 2017.

Consolidated statement of comprehensive income

Thousands of \$ except per share amounts / Years ended December 31	Notes	2016	2015
Product and service income	4	24,924	15,752
Royalties	4	4,943	1,715
Government grant income	4	103	173
Revenues		29,970	17,640
Cost of goods & services sold	4	10,103	6,905
Gross profit		19,867	10,735
Research and development expenses	5	1,977	3,257
Selling, general and administrative expenses	5	30,953	22,358
Other operating income		220	498

Other operating expenses		3	-
Total operating charges		32,713	25,117
Operating Loss (EBIT)		-12,846	-14,382
Financial income	7	36	13
Financial expenses	7	477	104
Loss before taxes		-13,287	-14,473
Income taxes		-113	-
Net Loss for the year from continuing operations		-13,174	-14,473
Loss for the year from discontinued operations		-	-
Loss for the year		-13,174	-14,473
Other comprehensive income		-	-
Items that will be reclassified to profit or loss			
Exchange differences arising on translation of foreign operations		36	-289
Total comprehensive loss for the year (net of tax)		-13,138	-14,762
Basic earnings per share (EPS) \$			
Using weighted average number of shares	9	-0.29	-0.35
Using end of period number of shares	9	-0.26	-0.32

Consolidated statement of financial position

Assets

Thousands of \$/ Years ended December 31	Notes	2016	2015
Goodwill	10.1	1,145	1,145
Intangible assets	10.2	12,829	10,030
Property, plant and equipment	11	2,259	1,888
Grants receivable (> 1 year)		0	33
Non-current assets		16,233	13,096
Inventories	12	1,479	1,427
Grants receivable (< 1 year)		60	180
Trade receivables	13	18,498	10,978
Prepaid expenses and other current assets	13	580	381
Cash and cash equivalents	14	30,871	31,680
Current assets		51,488	44,646
TOTAL ASSETS		67,721	57,742

Liabilities & Shareholders' Equity

Thousands of \$/ Years ended December 31	Notes	2016	2015
Share capital	16	45,853	42,791
Issuance premium	16	101,105	83,118
Accumulated profit/(loss)		-85,626	-71,153
Result of the year		-13,174	-14,473
Share-based compensation	22	5,269	4,701
Translation reserves		-686	-722
Total equity		52,741	44,262
Deferred tax liabilities		729	842
Grants payable (> 1 year)		-	15
Long-term liabilities	3	1,550	1,390
Loans and borrowings	17/18	108	408
Non-current liabilities		2,387	2,655
Loans and borrowings	18/19	430	440
Trade payables	20	7,546	6,610
Grants payable (< 1 year)		-	104
Other current liabilities	20	3,535	2,801
Short-term liabilities	3	1,082	870
Current liabilities		12,593	10,825
TOTAL EQUITY AND LIABILITIES		67,721	57,742

Consolidated statement of cash flow

Thousands of \$/ Years ended December 31	Notes	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES			
Operating Profit/(Loss)		-12,846	-14,382
Depreciation, amortization and impairment results	10/11	1,720	881
Share-based compensation	22	568	437
(Gain)/Loss on disposal of fixed assets		-	-
Interests paid	7	-12	-5
Income taxes		113	
Change in inventories	12	-52	-567
(Increase)/decrease in accounts receivable ⁽¹⁾	13	-7,566	-3,111
Increase/(decrease) in account payable ⁽²⁾	19	1,490	2,353
Total adjustments		-3,739	-12
Net cash provided by/(used in) operating activities		-16,585	-14,394
CASH FLOWS FROM INVESTING ACTIVITIES			
Acquisition of subsidiary, net of cash acquired		-	-5,389
Proceed from sale of fixed assets		-	-
Interest received	7	5	13
Other financial profit/(loss)	7	-434	-99
Purchase of property, plant and equipment	11	-1,111	-1,577
Purchase of intangible assets	10	-3,774	-524
Net cash provided by/(used in) investing activities		-5,316	-7,576
CASH FLOWS FROM FINANCING ACTIVITIES			
Payments on long-term obligations			-617
Proceeds from long-term obligations		152	1,036
Payments on loans and borrowings		-72	-188
Proceeds from issuance of shares (net of issue costs)	16	21,015	34,811
Net cash provided by/(used in) financing activities		21,095	35,042
Net increase/(decrease) in cash and cash equivalents		-806	13,072
Cash and cash equivalents at beginning of year		31,680	18,897
Effect on Exchange rate changes		-3	-289
Cash and cash equivalents at end of period	15	30,871	31,680

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	16	16		22		
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
Balance at January 1, 2016	45,153,633	125,909	- 85,626	4,701	- 722	44,262
Net loss			-13,174			-13,174
Other comprehensive income					36	36
Total comprehensive income			-13,174	-	36	-13,138
Issuance of shares	4,691,962	21,972				21,972
Deduction of SPO costs		-923				-923
Share-based compensation				568		568
Balance at December 31, 2016	49,845,595	146,958	-98,800	5,269	-686	52,741

Notes

Notes to consolidated financial statements

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NOTE 1: General information [Back to Notes list](#)

MDxHealth SA is a limited liability company incorporated in Belgium.

MDxHealth is a molecular diagnostics company that develops and commercializes advanced epigenetic and other molecular tests for cancer assessment and the personalized treatment of patients. Applying its patented DNA methylation platform and proprietary biomarkers, the Company helps address a large and growing unmet medical need for better cancer diagnosis and treatment information. The Company develops and commercializes advanced molecular diagnostic products for personalized cancer treatment 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 response to therapy. MDxHealth's products and pipeline cover major cancer areas such as prostate, bladder, kidney, cervical and brain cancer.

MDxHealth's products are developed based on a patented DNA methylation platform integrating 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 offers its products in North America through a CLIA certified, ISO 9001 certified and CAP accredited service laboratory. Since September 2015, following the acquisition of NovioGendix, MDxHealth also operates in The Netherlands, offering its SelectMDx test in Europe through its laboratory in Nijmegen.

The MDxHealth group is headquartered in Belgium. The parent company, MDxHealth SA, has its registered and corporate office 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 changed 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 disburses 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 on Accounting policies for further explanations.

NOTE 2: Summary of Significant Accounting policies [Back to Notes list](#)**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), and as adopted by the European Union up to December 31, 2016.

The principal accounting policies applied in the preparation of the 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.

Going Concern

Despite the consecutive losses reported since the Company's inception, the financial statements have been established assuming the Company is a going concern. The Board of Directors believes that the losses are inherent to the current stage of the Company's business life cycle as a biotech company, and not representative of the Company's potential to become profitable. For the past several years, the Company has consistently increased revenues and reduced operating losses and 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.

New Standards, Interpretations and Amendments

New Standards, Interpretations and Amendments adopted by the Group

During the current financial year, the Group has adopted all the new and revised Standards and Interpretations issued by the International Accounting Standards Board (IASB) and the International Financial Reporting Interpretations Committee (IFRIC) of the IASB, that are relevant to its operations and effective for the accounting year starting on January 1, 2016. The Group has not applied any new IFRS requirements that are not yet effective as per December 31, 2016.

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 2010-2012 Cycle (issued by the IASB in December 2013)
- Annual Improvements to IFRSs 2012-2014 Cycle (issued by the IASB in September 2014)
- IFRS 10 Consolidated Financial Statements – Amendments regarding the application of the consolidation exception (December 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 19 Employee Benefits — Amendments relating to Defined Benefit Plans: Employee Contributions (November 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, 2016.

- IFRS 15 Revenue from Contracts with Customers
- IFRS 9 Financial Instruments — Classification and Measurement

IFRS 15, Revenue from Contracts with Customers: IFRS 15 was issued which establishes a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. IFRS 15 will supersede the current revenue recognition guidance including IAS 18 Revenues, IAS 11 Construction contracts and the related interpretations when it becomes effective.

The core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Specifically, the standard introduces a 5-step approach to revenue recognition:

- Step 1: Identify the contract(s) with a customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation

Under IFRS 15, an entity recognized revenue when a performance obligation is satisfied, i.e. when 'control' of the goods or services underlying the particular performance obligation is transferred to the customer.

The directors of the Group anticipate that the application of IFRS 15 may have a material impact on the amounts reported and disclosures made in the Group's consolidated financial statements. However, it is not practicable to provide a reasonable estimate of the effect of IFRS 15 until the Group has completed its detailed review.

IFRS 9, Financial Instruments: addresses the classification, measurement and de-recognition of financial assets and financial liabilities, introduces new rules for hedge accounting and requires a new impairment model for financial assets. The Group does not expect a significant impact from the new measurement, classification and de-recognition rules on the Group's financial assets and liabilities.

The Group elected not to early adopt the following new Standards, Interpretations and Amendments, which have been issued but not yet endorsed by the European Union as per December 31, 2016.

- Annual Improvements to IFRSs 2014-2016 Cycle
- IFRS 2 Share-based Payment — Amendments to clarify the classification and measurement of share-based payment transactions
- IFRS 16 Leases
- IAS 7 Cash flow statement — Amendments as result of the Disclosure initiative
- IAS 12 Income taxes — Amendments regarding the recognition of deferred tax assets for unrealized losses

It is not expected that the initial application of the above-mentioned IFRS standards, interpretations and amendments will have a significant impact on the consolidated financial statements.

Basis of consolidation

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

In 2003, MDxHealth SA (Belgium) incorporated MDxHealth Inc. (US) as a wholly-owned subsidiary. MDxHealth SA acquired 100% of the shares of NovioGendix on September 18, 2015, which was renamed MDxHealth BV. The subsidiaries are included following the full consolidation method. All intra-group transactions, balances, income and expenses are eliminated upon consolidation.

Foreign currency translation

Functional and presentation currency

The Company's functional and presentation currency is the US dollar based on the continuing development of the commercial activities in the US market.

Transactions in currencies other than US dollar are recognized 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 when applying the Company's accounting policies, which affect the reported amounts of assets and liabilities, the disclosure of 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 continuously evaluated based on historical experience and other factors, including expectations of future events, which are believed to be reasonable under the circumstances. In the future, actual experience may differ from these estimates and assumptions. The areas involving more judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements, are disclosed in the following notes:

Note 3: Business Combination, in respect of valuation of assets and liabilities at acquisition date; [Back to Notes list](#)

Note 4: Revenue Recognition, in respect of detailed criteria for the recognition of revenue; [Back to Notes list](#)

Note 8: Income tax, in respect of recoverability of tax loss carry forward; [Back to Notes list](#)

Note 10-1: Goodwill, in respect of allocation to cash generating unit and of valuation of and recoverability of goodwill; [Back to Notes list](#)

Note 10-2: Intangible Assets, in respect of allocation to cash generating unit and of valuation of in-process research and development and capitalization of development costs; [Back to Notes list](#)

Note 22: Share based compensation, in respect of valuation of equity instruments issued. [Back to Notes list](#)

Revenue recognition

Substantially all 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 (a) after test results are delivered and billed, (b) when the fee is fixed or determinable and (c) the collection of the fee is reasonably assured. MDxHealth uses certain criteria to assess compliance with these conditions, including:

- There is persuasive evidence that an agreement exists;
- Percentage claims collected versus percentage claims billed is at least 50%, and
- The trend of percentage collected versus billed is not declining over the months;

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, when no contractual arrangement exists, based on an analysis of each individual payor's payment patterns and history for each product or service. 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 maintained.

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.

Since the first sales of the ConfirmMDx for Prostate Cancer test in mid-2012, the Company's revenue recognition policy has limited the amount of revenue recognized. As the volume of reimbursement transactions from payors has grown, the basis to establish reasonable estimates of payment patterns by payor or claim categories has gradually improved. In 2016, a net amount of \$49.3 million was billed for tests performed, of which approximately 60% was recognized as revenue (2015: 59%). The balance is only recognized when and to the extent a payment is collected, leaving a significant portion of invoiced amounts unrecognized. The deferral of part of the revenue is expected to gradually decrease as the Company continues to conclude firm agreements for reimbursement with a growing number of payors. At the end of 2014, a Local Coverage Determination (LCD) for Medicare reimbursement of ConfirmMDx for Prostate Cancer was issued by Palmetto GBA, an 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.

As a result of the Company's revenue recognition policy, total revenue in any given year includes amounts related to tests performed in previous years as (a) deferred unrecognized amounts are collected, (b) recognized amounts are collected for different amounts than initially accrued for and (c) balances outstanding for more than 2 years are written off.

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 all earning criteria relative to the milestone have been achieved.

Royalties are 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.

Segment Information

The Company does not distinguish different segments, neither business nor geographical segments since most 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 supported all the Company's commercial endeavours. In 2016, the Company earned 99.7% of its revenue from its clinical laboratory testing services and out-licensing of intellectual property. The remaining 0.3% came from a R&D grant in Belgium and in The Netherlands. In 2016, the clinical laboratory testing in the US CLIA laboratory represented 82% of the Company's revenue (2015: 86%), while the out-licensing of intellectual property revenue and grant income in Europe represented 17% (2015: 14%).

At the end of 2016, 78% of the non-current assets (other than financial instruments, deferred tax assets, postemployment benefit assets, rights arising under insurance contracts and intangible assets derived from Business Combination – see note 3) were located in the US (2015: 98%) and the remaining 22% in Europe (2015: 2%).

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 acquisition method 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

Goodwill is measured as the excess of the sum of the consideration transferred (including the fair value of the contingent consideration), the amount of any noncontrolling interests in the acquiree, and the fair value of the acquirer's previously held equity interest in the acquiree (if any) over the net of the acquisition date amounts of the identifiable assets acquired and the liabilities assumed.

Any contingent consideration to be transferred by the acquirer will be recognized at fair value at the acquisition date. A contingent consideration classified as an asset or liability that is a financial instrument is measured at fair value with the changes in fair value recognized in the statement of profit or loss.

Acquisition-related costs are expensed as incurred and included in selling, general and administrative expenses.

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 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

Goodwill

Goodwill represents the difference between the fair value of the consideration paid for an acquisition and the fair value of the Group's share of the net identifiable assets of the acquired company at the date of the acquisition. Where intangible assets are identified in the acquired company, such as brands ongoing contracts or customer lists, these are valued to form part of the net identifiable assets.

Goodwill arising from business combinations is not amortized but is subject to an annual impairment test, according to IAS 36 "Impairment of Assets". Any impairment adjustments are reflected as an expense in the income statement. Impairment of goodwill is not reversed.

Goodwill arising from business combinations is allocated to cash generating units, which are expected to receive future economic benefits from synergies that are most likely to arise from the acquisition. These cash generating units form the basis of any future assessment of impairment of the carrying value of the acquired goodwill.

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 determined using appropriate valuation techniques.

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
- Developed 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/or "General and administrative expenses".

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

Internally generated intangible assets (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 product
- Sale of the product will generate future economic benefits, and;
- Expenditures on the project can be measured reliably.

Internally generated intangible assets are carried at their cost less any accumulated amortization and any accumulated impairment losses. Amortization over the asset's useful life shall begin when the asset is available for use.

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 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.

The 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. Amortization shall begin when the asset is available for use, i.e. when it is in the location and condition necessary for it to operate in the manner intended by management. Amortization 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 amortization 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 amortization 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 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.

Government Grants

A government 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-term highly liquid investments and bank overdrafts. Bank overdrafts, if any, are included in borrowings included 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 does not hold or issue derivative instruments for trading purposes.

Financial Assets

Financial assets are assessed for indicators of impairment at each reporting period. Financial assets are impaired where there is objective evidence that because 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 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 grants stock options in accordance with several share-based compensation plans in consideration for services performed by personnel, directors and business associates. The cost of the services rendered is measured at the fair value of the granted options and recognized as an expense in the income statement. The corresponding credit is recorded directly into equity.

The estimate of the number of options which will ultimately vest is revised at each reporting date. The change in estimate is recorded as an 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 options are exercised.

NOTE 3: Business Combination [Back to Notes list](#)

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 subject to meeting certain milestones, up to an additional \$3.3 (or €3.0 million) in cash, 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 € 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.

During 2015 the following consideration (net of cash acquired) were paid in relation to business combination:

Thousands of \$	2015
Acquisition price paid in shares	5,041
Acquisition price paid in cash (net of cash acquired)	240
Total consideration paid	5,281
<u>Recognized values:</u>	

Thousands of \$ Recognized values	2015
Goodwill	1,145
Intangible assets	7,800
Property plant and equipment	16
Trade and other receivables	153
Cash and cash equivalents	40
Deferred tax liabilities	-842
Trade payables	-12
Other current liabilities	-769
Short-term liabilities	-820
Total purchase price	5,321
Less cash acquired	-40
Cash out flow on acquisitions net of cash acquired	5,281

NOTE 4: Product and Service Income and Cost of goods sold [Back to Notes list](#)

Product and Service Income

Thousands of \$/ Years ended December 31	Notes	2016	2015
Product and service income		24,924	15,752
Royalties		4,943	1,715
Government grant income	24	103	173
Total		29,970	17,640

Total revenues in 2016 and 2015 were \$29,970 thousand and \$17,640 thousand respectively. The commercial revenues other than direct sales for ConfirmMDx for Prostate Cancer were primarily generated from royalties and milestone fees, services provided to pharmaceutical companies, and initial sales of SelectMDx.

Cost of goods & services sold

Thousands of \$/ Years ended December 31	2016	2015
Cost of goods & services sold	10,103	6,905
Total	10,103	6,905

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 \$4,689 thousand.

NOTE 5: Operating result [Back to Notes list](#)

Research and development expenditures

Thousands of \$/ Years ended December 31	Notes	2016	2015
Personnel costs	6	836	935
Lab consumables		238	358
External research and development collaborator fees		31	1,238
Depreciation and amortization		649	220
Other expenses		224	506
Total		1,977	3,257

Research and development expenses, before capitalization, have increased because of the acquisition of NovioGen in 2015. Development expenses amounting to \$2,434 thousand associated with the improvement of ConfirmMDx and the development of SelectMDx and AssureMDx were capitalized and included in intangible assets.

Selling, general and administrative expenses

Thousands of \$/ Years ended December 31	Notes	2016	2015
Personnel costs	6	18,390	12,865
Depreciation		1,007	502
Professional fees		3,031	1,994
Marketing expenses		2,122	1,885
Travel expenses		1,886	1,469
Offices & facilities expenses		918	974
Royalties to third parties		1,546	1,379
Other expenses		1,412	675
Patent expenses		641	615
Total		30,953	22,358

SG&A expenses mainly represent general management costs, consulting, selling and marketing costs. The year-on-year increase is attributable to the acquisition of NovioGendix, which was only included for one quarter in 2015. Furthermore, the Company invested in the build-out of the organisation to support the global commercial launch of SelectMDx. The Company is pursuing a direct sales strategy for SelectMDx in Benelux, Germany and Italy, supported by European and global distributors and commercial lab partners. The Company appointed a global commercial team to cover business development and direct sales. The capitalized SG&A expenses relate to the internal development of an improved Laboratory Information Management System.

NOTE 6: Personnel costs [Back to Notes list](#)

Thousands of \$/ Years ended December 31	2016	2015
The number of employees at the end of the year was:		
Management (headcount)	3	6
Laboratory staff (headcount)	17	14
SG&A staff (headcount)	142	113
Total	162	133
Their aggregate remuneration comprised:		
Wages and salaries	16,060	10,714
Social security costs	1,220	823
Pension costs	548	377
Health insurance expenses	1,377	822
Share-based compensation	568	444
Other costs	644	620
Total	20,417	13,800

The personnel numbers in the table reflect year-end numbers.

NOTE 7: Finance income / (expenses) [Back to Notes list](#)

Thousands of \$/ Years ended December 31	2016	2015
Interest on bank deposits	6	13
Foreign exchange gain/(loss)	-5	-5
Other financial gain/(loss)	-442	-99
Net financial results	-441	-91

The financial results largely related to the revaluation of the contingent liability associated with the acquisition of NovioGendix in 2015, for a total of \$372 thousand.

NOTE 8: Taxes [Back to Notes list](#)

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	2016	2015
Loss for the year	-13,174	-14,473
Income tax expense	-	-
Loss before income tax	-13,174	-14,473
Tax using the MdxHealth's domestic tax rate of 33,99%	-4,478	-4,919
Effect of unused tax losses not recognized as deferred tax assets (*)	4,478	4,919
Total tax expense	-	-

No income taxes were payable in view of the losses incurred by the group. On December 31, 2016 the Group had a net tax loss carried forward amounting to \$161,828 thousand (2015: \$170,128 thousand), implying a potential deferred tax asset of \$55,005 thousand (respectively \$57,826 thousand million in 2015). The tax losses related to MDxHealth SA in Belgium are available for carry forward indefinitely.

The Company has a notional interest deduction to offset future taxable profits amounting to \$976 thousand in 2016 and \$2,613 thousand in 2015, of which \$1,636 thousand expired during 2016. The notional interest deduction of 2016 will expire in 2017 for an amount of \$685 thousand and in 2018 for an amount of \$291 thousand.

Tax credits amounted to \$381 thousand in 2016 and \$397 thousand in 2015.

It is uncertain if the Company will have taxable profits in the near future to allow all or part of the deferred tax asset to be utilized and as a result, no deferred tax asset was recognized in 2016.

Deferred tax liabilities	In the consolidated statement of financial position		In the consolidated income statement	
Thousands of \$/ Years ended December 31	2016	2015	2016	2015
Developed Technology	373	486	113	-
In-process research and development	356	356	-	-
Total	729	842	113	-

Following the acquisition of NovioGendix, the Company recognized a deferred tax liability of \$1,900 thousand resulting from 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 \$1,108 thousand.

(*) 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 [Back to Notes list](#)

The 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	2016	2015
Result for the purpose of basic loss per share, being net loss	-13,174	-14,473
	46,075,366	41,275,611
<i>Weighted average number of shares for the purpose of basic loss per share (assuming stock split in all periods)</i>		
Basic loss per share (in \$)	-0.29	-0.35

At December 31, 2016, 2015, the Company has dilutive potential shares in the form of warrants. The Company is reporting a net loss, given that the warrants have an anti-dilutive effect rather than a dilutive effect

NOTE 10.1: Goodwill [Back to Notes list](#)

The goodwill resulted from the allocation of the purchase price paid for the acquisition of NovioGendix in September 2015 and amounted to 1,145 in 2016 and 2015. The Company being the sole CGU, the annual impairment test was performed based on the recoverable amount of the entire Group. The Group's recoverable amount was determined using the publicly quoted market price of the Company's outstanding shares at December 31, 2016, and was found to be in excess of its carrying value, including the goodwill.

NOTE 10.2: Intangible assets [Back to Notes list](#)

Thousands of \$	Intellectual and property rights & Software licenses	Development assets	Developed 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
Thousands of \$	Intellectual and property rights & Software licenses	Development assets	Developed Technology	In-Process R&D from	TOTAL
Gross value					
At January 1, 2016	3,721	2,355	4,500	3,300	13,876
Additions– externally acquired	807				807
Additions– internally developed		2,968			2,968
Additions– acquired through business combination					
Disposals					
Impairment					
Currency translation adjustments		-1			-1
Gross value at December 31, 2016	4,528	5,322	4,500	3,300	17,650

Accumulated amortization					
At January 1, 2016	-3,565	-118	-163	-	-3,846
Additions	-58	-471	-450		-979
Disposals					
Impairment					
Currency translation adjustments	6				6
Accumulated amortization at December 31, 2016	-3,619	-589	-613	-	-4,821
Net value at December 31, 2016	909	4,733	3,887	3,300	12,829

Development expenses amounting to \$2,968 thousand associated with the improvement of ConfirmMDx and the development of SelectMDx and AssureMDx were capitalized and included in intangible assets.

NOTE 10.3 Indefinite lifetime assets [Back to Notes list](#)

The Group has the following significant amounts with indefinite lifetime:

Thousands of \$/ Years ended December 31	2016	2015
Goodwill	1,145	1,145
In Process R&D	3,300	3,300
Total	4,445	4,445

For purposes of annual impairment testing, the recoverable amounts of these assets are based on the value-in-use based on cash flow projected for a 10-year period. The most important criteria in the calculation of value in use are expected growth rates, capital investment levels and discount rates. The pre-tax discount rate, used to discount projected cash flows reflect management's assessment of risks related to the cash generating unit and is estimated at 40 percent. Management's assessment of the value-in-use of the assets materially exceeds their carrying value, therefore the outcomes are not sensitive to management's significant assumptions.

NOTE 11: Property, plant and equipment [Back to Notes list](#)

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

Thousands of \$	Laboratory equipment	Furniture	IT equipment	Leasehold improvements	Leasing	TOTAL
Gross value						
At January 1, 2016	4,206	143	319	300	285	5,253
Additions	776	50	151	95	39	1,111
Disposals	-4		-5			-9
Impairment						
Gross value at December 31, 2016	4,978	193	465	395	324	6,355
Accumulated amortization						
At January 1, 2016	- 2,693	- 136	- 227	- 269	- 40	- 3,365
Additions	-511	-9	-80	-34	-105	-739
Disposals	1		5			8
Impairment						
Accumulated amortization at December 31, 2016	-3,201	-145	-302	-303	-145	-4,096
Net value at December 31, 2016	1,777	48	163	92	179	2,259

NOTE 12: Inventories [Back to Notes list](#)

Thousands of \$/ Years ended December 31	2016	2015
Raw materials and consumables	1,479	1,427
Total Inventories	1,479	1,427

Inventories are recognized at the lower of cost or net realizable value.

NOTE 13: Trade and other receivables [Back to Notes list](#)**Trade receivables**

Thousands of \$/ Years ended December 31	2016	2015
Trade accounts receivable	18,498	10,978
Total trade accounts receivable	18,498	10,978

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

In 2016, the trade accounts receivable balances were mainly composed of services for ConfirmMDx for Prostate Cancer for \$14,653 thousand. The average Days Sales Outstanding stood at 204 days in 2016 compared to 229 days in 2015. The remaining balances related to, milestone fees and royalties.

Prepaid expenses and other current assets

Thousands of \$/ Years ended December 31	2016	2015
Prepayments	484	214
Deposits	45	79
Recoverable VAT	37	48
Other	14	40
Total prepaid expenses and other current assets	580	381

The Company considers that the carrying amount of other receivables approximates their fair value.

NOTE 14: Cash and cash equivalents [Back to Notes list](#)

Thousands of \$/ Years ended December 31	2016	2015
Cash at bank and in hand	30,871	31,680
Total cash and cash equivalents	30,871	31,680

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 \$365 thousand representing a guarantee with respect to the loan granted by ING (see Note 18 for more information on bank loans). The group holds no other restricted cash.

NOTE 15: Financial Risk Management [Back to Notes list](#)**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 2016, the Company operated with more than 800 different customers, systematically reducing credit risk compared to prior periods.

In the US healthcare system, and particularly within the molecular diagnostic CLIA laboratory industry, where there are 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.

In addition to reimbursement risk associated with commercial third party payors, credit risk may also arise from 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. Credit risk exists for those patients who cannot meet their co-payment or deductible portions.

Customer's compliance with agreed credit terms is regularly and closely monitored. Trade accounts receivable amounted to \$18,494 thousand at December 31, 2016 and no allowance for doubtful debt was recorded.

Receivables related to research grants from the Dutch government (\$60 thousand at December 31, 2016) 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 \$30,871 thousand 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 and 2016. In reference to note 18, the Group has contracted bank loans for a total of \$869 thousand 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 to report the exposure to variations in interest rates of +2% and -2%. Consequently, the Group is exposed to additional interests' charges of \$8 thousand if LIBOR increases by 2%, and to a reduction of \$3 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, 2016 in EURO are composed of cash on hand of €19,835 thousand.

In accordance with IFRS 7, the Company performed 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 €5,600 thousand (€600 thousand revenue and €6,100 thousand costs), resulting in a potential loss of €625 thousand in case of an increase of the USD/Euro exchange rate by 10%, and a potential gain of €508 thousand in case of a 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 five loan agreements with banks and two financial leases at December 31, 2016 (see note 18) and 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 16: Share capital and reserves [Back to Notes list](#)

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	2016	2015
Common shares	49,845,595	45,153,633
Total outstanding shares	49,845,595	45,153,633

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

Years ended December 31	Thousands of \$/		Thousands of €/	
	2016	2015	2016	2015
Share Capital as per statutory accounts	51,383	47,399	39,761	36,019
IPO Costs & Capital Increase costs	-5,530	-4,608	-4,550	-3,682
Share capital under IFRS	45,853	42,791	35,211	32,337
Issuance premium	101,105	83,118	83,411	66,503
Share capital and issuance premium	146,958	125,909	118,622	98,980

The share capital and issuance premium increased in 2016 because of the private placement with institutional investors of 4,526,962 new shares on November 7, 2016 issued at €4.50 per share, and two other capital increases related to warrants exercise.

The 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 non-consolidated statutory accounts prepared in accordance with Belgian-GAAP, the net assets of a limited liability company (société anonyme) have fallen below 50% of a company's 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 17: Loans and Borrowings [Back to Notes list](#)

		Outstanding at December 31			
		Interest rate	Maturity	2016	2015
\$ 303,000.00	bank loan	LIBOR + 1.20%	30/04/2017	76	227
\$ 75,000.00	bank loan	LIBOR + 1.20%	30/11/2017	38	75
\$ 220,000.00	bank loan	LIBOR + 1.20%	30/11/2017	110	220
\$ 152,800.00	bank loan	LIBOR + 1.20%	30/11/2017	76	153
\$ 118,000.00	bank loan	LIBOR + 1.20%	31/08/2018	103	153

\$ 285,964.61	obligations under finance lease finance lease (third parties)	3.50%	30/07/2018	106	173
\$ 36,026.64	obligations under finance lease finance lease (third parties)	3.50%	01/03/2019	29	-
				538	848

All bank loans, for a total of \$869 thousand and have been used to finance the acquisition of laboratory equipment of the US facilities in Irvine. They have a maturity of 2-years, with a 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 by a cash pledge. More information on interest rate risk and a sensitivity analysis is presented in Note 16 Financial Risks Management – interest risk.

The Company has one finance lease obligation with Cisco Systems Capital Corporation. The lease has a term of 3 years and includes an option to purchase 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, 2016 is \$135 thousand and the associated interest expense for 2016 amounted to \$5 thousand.

NOTE 18: Operating lease obligations [Back to Notes list](#)

Thousands of \$/ Years ended December 31	2016	2015
Outstanding commitments for future minimum rent payments, which fall due as follows:		
Within one year	561	464
In the second to fifth year	1,113	1,087
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 19: Trade and other payables [Back to Notes list](#)

Trade accounts payable

Thousands of \$/ Years ended December 31	2016	2015
Trade accounts payable	6,046	5,152
Accruals for invoices to be received	1,500	1,458
Total trade accounts payable	7,546	6,610

Other current liabilities

Thousands of \$/ Years ended December 31	2016	2015
Payroll	3,490	2,800
Other accruals	45	1
Total other current liabilities	3,535	2,801

The trade accounts payable and other current liabilities balances have predominantly increased as a direct result of increasing activity of its CLIA lab facility in Irvine, California.

NOTE 20: Retirement benefit schemes [Back to Notes list](#)

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

A total cost of \$548 thousand in 2016 (2015: \$377 thousand) 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 must 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 recognized 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 21: Financial instruments and fair value [Back to Notes list](#)

The table shows the Group's significant financial assets and liabilities. All financial assets and liabilities are carried at amortized cost with the exception of the contingent considerations in relation to acquisitions reported at fair value through profit and loss.

All financial assets and liabilities are considered to have carrying amounts that do not materially differ from their fair value.

Assets	2016	2015	Hierarchy
Receivables	18.498	10.978	
Cash and cash equivalents	30.871	31.680	
Total financial assets	49,369	42,658	
Liabilities			
Financial liabilities at fair value:			
Contingent consideration payable	2.632	2.260	Level 3
Subtotal financial liabilities at fair value	2,632	2,260	
At amortized cost:			
Loans and borrowings	538	848	
Trade payables	7.546	6.610	
Other liabilities	3.535	2.801	
Subtotal financial liabilities at amortized cost	11.619	10.259	
Total financial liabilities	14.251	12.519	

Recognized fair value measurements - Valuation technique and principal inputs

- The carrying value of the financial instruments has been determined on the basis of the following methods and assumptions:
- The carrying value of the cash and cash equivalents, the trade receivables, the trade payables and the other liabilities approximate their fair value due to their short term character;
- Loans and borrowings are evaluated based on their interest rates and maturity date. Their fair value approximates their carrying value.
- The contingent liabilities are evaluated at their fair value calculated on the present value of future earn out based on the defined milestones.

Fair value hierarchy

The Company uses the following hierarchy for determining and disclosing the fair value of financial instruments by valuation technique:

- Level 1 : quoted prices in active markets for identical assets and liabilities;
- Level 2 : other techniques for which all inputs which have a significant effect on the recorded fair value are observable, either directly or indirectly; and
- Level 3 : techniques which use inputs that have a significant effect on the recorded fair value that are not based on observable market data. No financial assets or financial liabilities have been reclassified between the valuation categories during the year.

No financial assets or financial liabilities have been reclassified between the valuation categories during the year.

The fair value of the contingent consideration payable is based on an estimated outcome of the conditional purchase price/contingent payments arising from contractual obligations. It is initially recognized as part of the purchase price and subsequent changes in fair value are recorded through profit and loss. The discount rate used in 2016 was 9.3%.

NOTE 22: Share based payments [Back to Notes list](#)

This section provides an overview of the outstanding warrants as of December 31, 2016. 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) 579,927 warrants were terminated or lapsed, (ii) 473,310 warrants were exercised, (iii) 1,444,063 warrants were granted but not yet exercised, and (iv) 713,500 warrants were not yet granted by the Company. For the year 2016, 286,564 warrants were terminated or lapsed, 165,000 warrants were exercised and 32,400 warrants were vested. As a result, as at December 31, 2016, there are 1,444,063 warrants outstanding, entitling their holders to subscribe to 1,444,063 shares of the Company.

Number of potential shares from outstanding warrants	
At January 1, 2016	1,507,627
Number of warrants cancelled/forfeited during the year	- 294,064
Number of warrants exercised during the year	- 165,000
Number of warrants granted during the year	388,000
At December 31, 2016	1,436,563

The warrants are granted to employees (mainly), consultants or directors of the Company and its subsidiaries. Each warrant entitles its holders to subscribe to one new 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. 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 instalments of 25% per year, the first tranche of 25% vesting on the first anniversary date of the date of grant and the following tranches 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 2015	361,000	4.33	361,000	4.33
Outstanding 31 December 2015	1,378,475	3.85	1,507,627	3.52
Granted in 2016	388,000	3.69	388,000	3.69
Outstanding 31 December 2016	1,436,563	3.63	1,436,563	3.63
Exercisable at 31 December 2016	922,252	3.43	922,252	3.42

The following table provides an overview of the outstanding potential shares from warrants per personnel category at December 31, 2016:

Category	Number of potential shares from outstanding warrants
Executive Director	197,813
Non-Executive Directors	184,000
Management team (excluding the Executive Director)	465,265
Other employees, consultants, and former service providers	593,125
Total outstanding at December 31, 2016	1,436,563

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 comprehensive income is given below as is the cumulated amount per the consolidated statement of financial position:

Thousands of \$/ Years ended December 31	2016	2015
Share-based compensation	568	443
Cumulated Share-based compensation	5,269	4,701

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 €3.63 (\$ conversion 3.83 at December 31, 2016). The weighted average remaining contractual life of all outstanding warrants at the end of 2016 is 6.23 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.
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
1-Feb-16	-	10,000	€4.13	-	51.18%	0.85%	67.99	49.97
4-Feb-16	50,000	134,000	€3.78	-	52.49%	0.72%	67.89	49.87
2-Apr-16	-	52,000	€3.62	-	53.40%	0.58%	65.33	53.33
29-May-16	30,000	40,000	€4.13	-	51.85%	0.54%	64.11	52.11
1-Jan-16	-	4,000	€3.79	-	51.12%	1.06%	69.01	50.99
1-Jun-16	-	2,000	€3.43	-	53.73%	0.49%	64.01	52.01
1-Aug-16	-	4,000	€3.62	-	53.51%	0.16%	62.01	50.01
21-Oct-16	-	20,000	€4.44	-	54.19%	0.28%	59.34	47.34
22-Jan-16	-	20,000	€3.83	-	52.81%	0.86%	68.32	56.32
1-Dec-16	-	22,000	€4.65	-	54.16%	0.75%	57.99	39.98

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 [Back to Notes list](#)

Transactions between MDxHealth SA, MDxHealth Inc. and MDxHealth B.V. which are related parties, have been eliminated on 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 2016, the services charged by the parent company to the subsidiary amounted to \$4,800 thousand.

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

During the year ended December 31, 2016, the executive management team included six members:

1. Chief Executive Director, Dr. Jan Groen
2. Executive Vice President of Corporate Development & General Counsel, Mr. Joseph Sollee
3. Executive Vice President and Chief Commercial Officer, Mr. Christopher Thibodeau
4. Executive Vice President of Finance, Mr. Francis Ota
5. Senior Vice President of Laboratory Operations, Ms. Miriam Reyes
6. Chief Medical Officer, Dr. Philip Ginsburg

Their combined remuneration package, including employer taxes, amounted to the following:

Thousands of \$ except per personnel, warrants & share amounts Years ended December 31	2016	2015
Number of management members and Executive Directors	6	6
Short-term employee benefits	2,133	1,895
Post-employment benefits	63	58
Other employment costs	90	99
Total benefits	2,286	2,052
IFRS share-based compensation expense	191	217
Outstanding receivables from persons	-	-
Outstanding payables to persons	-	-
Shares owned	226,277	23,277
Number of warrants offered	160,000	210,000
Cumulative outstanding warrants	682,813	715,313
Exercisable warrants	442,814	434,689
Exercised warrants	90,000	222,187

In 2016, in aggregate for the six members of the executive management team, 90,000 warrants were exercised and 160,000 new warrants were granted and accepted (for an annualized IFRS cost of \$191 thousand).

In 2015, as an aggregate for the group comprised by the 6 executive managers, 222,187 warrants were exercised and 210,000 new warrants were granted and accepted (for an annualized IFRS cost of \$217 thousand).

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, totalling less than \$1 thousand in 2016.

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 2016 and 2015, respectively \$130 thousand and \$97 thousand were paid as fees and expense reimbursement to independent members of the Board of Directors.

A total of 60,000 warrants were granted to Non-Executive Directors in 2016. A total of 12,000 warrants were exercised in 2016.

NOTE 24: Significant agreements, commitments and contingencies [Back to Notes list](#)

Fair value of Earn Out

On September 18, 2015, MDxHealth 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, additional cash consideration of €250 thousand was paid. On top of the acquisition price, MDxHealth is committed to pay future milestone fees. The fair value of this earn out as of December 31, 2016 is estimated at \$2,632 thousand over the period 2017-2019.

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 typically 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), Radboud University (The Netherlands) 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. In regards to the Company's developed tests, the Company has entered into a range of marketing and sales arrangements with commercial entities. These important relationships provide the Company with additional resources and infrastructure to expand the geographic reach and awareness of the Company's solutions, primarily in relation to the ConfirmMDx and SelectMDx tests. MDxHealth's marketing partners include Cerba Healthcare (Belgium), Teva Pharmaceuticals (Israel), SouthGenetics (South and Central America), ECZ Innowacje (Poland) and, in the US, Miraca Life Sciences, Bostwick Laboratories and Li Path.

In regards to intellectual property that MDxHealth has developed or improved, MDxHealth has sublicensed certain of its non-core epigenetic technologies to commercial partners, several of whom have launched products that generate royalties and other fees. These sublicenses include:

- an exclusive sublicense agreement to 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 DNA methylation biomarker in stool-based detection of colorectal cancer, in exchange for certain milestone fees, deferred license fees and 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.
- an exclusive sublicense to Laboratory Corporation of America (LabCorp) for 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.
- non-exclusive sublicense agreements for the Company's patented methylation specific PCR (MSP) technology for diagnostic applications, in exchange for certain license fees and running royalties, to several partners including oncnostics GmbH, Qiagen GmbH and Takara Bio.

Litigation

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

NOTE 25: Subsequent events [Back to Notes list](#)

In 2017, through the date of this document, the Company made the following normal course of business announcements:

- Horizon Blue Cross Blue Shield (Horizon BCBS) of New Jersey has issued a positive medical policy for the ConfirmMDx for Prostate Cancer test. This is the fourth Blue Cross Blue Shield Association licensee to establish positive coverage policy and adds to the growing list of payers covering ConfirmMDx for Prostate Cancer. Horizon BCBS is New Jersey's oldest and largest health insurer, with more than 3.8 million members.
- MDxHealth has signed a distribution agreement to make its SelectMDx for Prostate Cancer test available to Istituto Diagnostico Varelli's urology clients throughout central-south Italy. Under the terms of the agreement, Istituto Diagnostico Varelli will serve as a non-exclusive distributor in Italy encompassing five of the country's 20 regions; Lazio, Apulia, Campania, Calabria and Basilicata. Liquid biopsy samples will be sent to MDxHealth's state-of-the-art clinical diagnostic laboratory in Nijmegen, The Netherlands for analysis. Istituto Diagnostico Varelli will reimburse MDxHealth for all testing services performed.
- MDxHealth has been awarded a US Government Federal Supply Schedule Contract for medical laboratory testing services for ConfirmMDx for Prostate Cancer. The ConfirmMDx test is now available to federal, state, and local government buyers in the US through Medical Laboratory Testing and Analysis Services Schedule 621 II, Contract V797D-70066.
- SelectMDx for Prostate Cancer was chosen as pre-biopsy diagnostic tool in the groundbreaking US Prostate Cancer Risk Clinic at the University of Michigan.
- MDxHealth signed a distribution agreement to make its SelectMDx for Prostate Cancer test available to Lab21 Clinical Laboratory's urology clients in the United Kingdom. Under the terms of the agreement, Lab21 will serve as a non-exclusive distributor for SelectMDx in the United Kingdom.

NOTE 26: Disclosure under Article 114 of the Royal Decree dated January 30, 2001 implementing the Belgian Company Code [Back to Notes list](#)**Subsidiaries**

The Company has the following two wholly-owned direct subsidiaries:

MDxHealth Inc.

Address	15279 Alton Parkway – Suite 100 – Irvine, CA 92618
Incorporation Date	April 14, 2003
Number of employees	151 at December 31, 2016, 119 at December 31, 2015, and 96 at December 31, 2014

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	8 at December 31, 2016 and 7 at December 31, 2015

Remuneration of the Board

The total remuneration of the Board of Directors (including the Executive Director) in 2016 and 2015 was \$732,000, and \$745,000 respectively (excluding VAT, stock-based compensation and reimbursement of expenses). 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 €114 thousand (USD equivalent \$125 thousand) in fees to the auditor in 2016. The fees are broken down as follows:

- Audit fee for statutory and consolidated financials of €65 thousand (\$72 thousand)
- Audit related services (legal missions) €4 thousand (\$4 thousand)
- Tax consulting services €44 thousand (\$48 thousand)
- Other missions: €1 thousand (\$1 thousand)

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Auditor's opinion

Auditor's opinion

Statutory auditor's report to the general meeting of the company MDxHealth SA for the year ended December 31, 2016

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 statement. The consolidated financial statements comprise the consolidated statement of financial position as at December 31, 2016, 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 December 31, 2016, 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 67.721 thousand USD and a consolidated income statement showing a consolidated loss for the year of 13.174 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 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) as adopted in Belgium. 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 December 31, 2016, 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 statement, 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, April 25, 2017

BDO Réviseurs d'Entreprises Soc. Civ. SCRL
Statutory auditor
Represented by Gert Claes

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Condensed non-consolidated financial statements



Condensed non-consolidated financial statements

The statutory financial statements to be filed with the Belgian National Bank are prepared in accordance with 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 and does 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 investor section of MDxHealth's website (www.mdxhealth.com).

Statutory Income Statement

Thousands of €/ Years ended December 31	2016	2016 in \$ equivalent	2015
I. Operating income	9,351	10,311	5,201
A. Turnover	9,050	9,979	4,656
D. Other operating income	301	332	545
II. Operating charges	6,945	7,658	7,116
A. Purchase of goods and materials	221	244	154
B. Services and other goods	5,619	6,196	5,803
C. Remuneration, social security costs, pensions	1,086	1,197	1,091
D. Depreciation & amounts written off fixed assets	19	21	68
G. Other operating charges	-	-	-
III. Operating profit/(loss)	2,406	2,653	(1,915)
IV. Financial income	1,496	1,649	1,127
B. Income from current assets	1,319	1,454	1,127
C. Other	177	197	-
V. Financial charges	158	174	171
A. Debt charges	-	-	3
C. Other	158	174	168
VI. Current profit/(loss) before taxes	3,744	4,128	(959)
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	3,744	4,128	(959)
X. Income taxes	-	-	-
XI. Profit/(loss) for the year after taxes	3,744	4,128	(959)

Appropriation account

Thousands of €/ Years ended December 31	2016	2016 in \$ equivalent	2015
A. Loss/gain to be appropriated			
A1. Loss/Gain for the period available for appropriation	3,744	4,128	(959)
A2. Loss brought forward	(23,214)	(24,651)	(22,255)
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	19,470	20,523	23,214

STATUTORY BALANCE SHEET

Statutory balance sheet after appropriations

Thousands of €/ Years ended December 31	2016	2016 in \$ equivalent	2015
ASSETS	8,197	8,642	8,202
I. Formation expenses	-	-	-
II. Intangible assets	-	-	1
III. Tangible fixed assets	19	20	22
B. Plant, machinery and equipment	19	20	22
C. Furniture and vehicles	-	-	-
IV. Financial assets	8,179	8,621	8,179
A. Affiliated enterprises	8,172	8,614	8,172
A1. Investments	8,172	8,614	8,172
A2. Amounts receivable	-	-	-
C. Other financial assets	-	-	-
C1. Investments	-	-	-
C2. Amounts received and cash guarantee	7	7	7
CURRENT ASSETS	111,633	117,672	84,883
V. Amounts receivable after one year	-	-	-
VI. Stocks and contracts in progress	-	-	-

VII. Amounts receivable within one year	83,428	87,941	56,391
A. Trade debtors	83,327	87,835	56,227
B. Other amounts receivable	101	106	164
VIII. Investments	28,139	29,661	28,459
B. Other investments and deposits	-	-	-
IX. Cash at bank and in hand	28,139	29,661	28,459
X. Deferred charges and accrued income	66	70	33
TOTAL ASSETS	119,831	126,313	93,085


Statutory balance sheet after appropriations

Thousands of €/ Years ended December 31	2016	2016 in \$ equivalent	2015
CAPITAL AND RESERVES	103,702	109,313	79,307
I. Capital	39,761	41,912	36,018
A. Issued capital	39,761	41,912	36,018
II. Share premium account	83,411	87,924	66,503
III. Revaluation surpluses	-	-	-
IV. Reserves	-	-	-
V. Accumulated profit/(loss)	(19,470)	(20,523)	(23,214)
VI. Investment grants	-	-	-
VII. Provisions and postponed taxes	-	-	-
A. Provisions for liabilities and charges	-	-	-
A4. Other liabilities & charges	-	-	-
AMOUNTS PAYABLE	16,129	17,000	13,778
VIII. Debts payable after 1 year	42	44	275
A. Financial debts	42	44	275
A4. Credit institutions	42	44	275
IX. Debts payable within 1 year	3,045	3,209	3,169
A. Current portion of debts after one year	-	-	-
B. Financial debts	340	358	345
B1. Credit institutions	340	358	345
C. Trade debts	2,421	2,552	2,533
C1. Suppliers	2,421	2,552	2,533
D. Advances received on contracts in progress	-	-	-
E. Taxes, remuneration & social security	284	299	291
E1. Taxes	-	-	-
E2. Remuneration & social security	284	299	291
X. Accrued charges and deferred income	13,042	13,747	10,334
TOTAL LIABILITIES	119,831	126,313	93,085

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Part V: Additional information



Part V: Additional information

Shareholder information

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 2016, the issued capital of MDxHealth amounted to € 39,761,328.75 represented by 49,845,595 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 (EUR)	Issue price per share post stock-split (EUR)	Capital increase (EUR)	Share capital after transaction (EUR)	Share Issuance Premium after transaction (EUR)	Aggregate # of shares after capital increase
Incorporation								
Jan. 10, 2003	Incorporation	202,975	0.30	0.06	61,500.00	61,500.00	0	202,975
Phase I Financing Round December 20, 2002 (Preferred A Shares)								
Feb. 7, 2003	Capital increase in cash	197,025	20.00	4.00	3,940,500.00	4,002,000.00	0	400,000
Jun. 30, 2003	Capital increase in cash	33,333	20.00	4.00	666,660.00	4,668,660.00	0	433,333
Sep. 30, 2003	Capital increase in cash	218,139	22.31	4.46	4,866,681.09	9,535,341.09	0	651,472
Jun. 20, 2004	Capital increase in cash	195,504	23.87	4.77	4,666,680.48	14,202,021.57	0	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⁾	9,000,000.00	23,202,021.57	0	1,221,976
Mar. 31, 2006	Capital increase in cash	193,548	31.00	6.20	5,999,988.00	29,202,009.57	0	1,415,524

Stock Split								
May 23, 2006	Stock split 5/1	/	/	/	/	/	0	7,077,620
Initial Public Offering and Exercise of Over-Allotment Warrants								
Jun. 30, 2006	Capital increase in cash	2,933,334	7.50	7.50	22,000,005.00	51,202,014.57	0	10,010,954
Jun. 30, 2006	Capital decrease	/	/	/	-10,217,809.00	40,984,205.57	0	10,010,954
Jun. 30, 2006	Capital increase through exercise of warrants	440,000	7.50	7.50	1,817,200.00	42,801,405.57	1,482,800.00	10,450,954
Exercise of Warrants								
Apr. 18, 2007	Capital increase through exercise of warrants	182,560	4.70	4.70	747,666.16	43,549,071.73	1,593,731.31	10,633,514
Private Placement								
Oct. 19, 2007	Capital increase in cash	1,063,351	10.00	10.00	4,354,954.02	47,904,025.75	7,872,287.29	11,696,865
Exercise of Warrants								
Oct. 25, 2007	Capital increase through exercise of warrants	50,837	4.73	4.73	208,202.93	48,112,228.68	7,904,487.77	11,747,702
Exercise of Warrants								
Apr. 24, 2008	Capital increase through exercise of warrants	61,120	4.59	4.59	250,316.96	48,362,545.64	7,934,871.81	11,808,822
Nov. 5, 2008	Capital increase through exercise of warrants	19,375	4.73	4.73	79,350.31	48,441,895.95	7,947,140.25	11,828,197
Private Placement								
Dec. 18, 2008	Capital increase in cash	1,332,877	6.29	6.29	5,458,797.75	53,900,693.70	10,872,138.83	13,161,074
Exercise of Warrants								
Apr. 17, 2009	Capital increase through exercise of warrants	24,540	4.49	4.49	100,503.57	54,001,197.27	10,881,808.74	13,185,614
Reduction of Share Capital								
Jun. 21, 2010	Share Capital reduction	/	/	/	/	10,517,661.90	10,881,808.74	13,185,614
Private Placement								
Apr. 8, 2011	Capital increase in cash	5,436,713	1.50	1.50	4,336,865.96	14,854,527.86	14,700,012.24	18,622,327
Private Placement								
Jul. 4, 2012	Capital increase in cash	6,891,113	1.45	1.45	5,497,040.84	20,351,568.70	19,202,971.61	25,513,440
Private Placement								
Jun. 25, 2013	Capital increase in cash	8,737,863	2.05	2.05	6,970,193.32	27,321,762.02	30,232,776.07	34,251,303
Private Placement								
Nov. 7, 2014	Capital increase in cash	3,425,000	3.60	3.60	2,732,122.50	30,053,884.52	39,830,653.57	37,676,303

Exercise of Warrants								
Apr. 30, 2015	Capital increase through exercise of warrants	172,187	2.01	2.01	137,353.57	30,191,238.09	40,039,189.53	37,848,490
Private Placement								
Jun. 26, 2015	Capital increase in cash	6,150,000	4.50	4.50	4,905,855.00	35,097,093.09	62,808,334.53	43,998,490
Private Placement								
Sep. 18, 2015	Capital increase in cash	1,086,956	4.14	4.14	867,064.80	35,964,157.89	66,441,267.57	45,085,446
Exercise of Warrants								
Nov. 27, 2015	Capital increase through exercise of warrants	68,187	1.70	1.70	54,392.77	36,018,550.66	66,502,756.44	45,153,633
Exercise of Warrants								
May 9, 2016	Capital increase through exercise of warrants	116,000	1.70	1.70	92,533.20	36,111,083.86	66,607,143.24	45,269,633
Private Placement								
Nov. 7, 2016	Capital increase in cash	4,526,962	4.50	4.50	3,611,157.59	39,722,241.45	83,367,314.65	49,796,595
Exercise of Warrants								
Nov. 10, 2016	Capital increase through exercise of warrants	49,000	1.69	1.69	39,087.30	39,761,328.75	83,410,887.35	49,845,595
Per statutory accounts						39,761,328.75	83,410,887.35	49,845,595
Per IFRS consolidated accounts						35,211,280.80	83,410,887.35	49,845,595

Authorized capital

By virtue of the resolution of the extraordinary general shareholders' meeting held on June 20, 2016, the Board of directors was expressly authorized to increase the share capital in one or more transactions by a total value of thirty-six million, one hundred and eleven thousand, eighty-three euros and eighty-six cents (€36,111,083.86) (the "Authorized Capital Amount").

The Board of Directors may 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 2021 which shall resolve on the annual accounts relating to the financial year ending on December 31, 2020. 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 20, 2016, the Board of directors was also 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 for 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 Companies Code. The Board of directors may exercise this power for a period of up to 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, 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:

- The board of directors has used its powers under the authorised capital provided for in article 6.1. on November 7, 2016 by issuing 4.526.962 new shares for a total of three million six hundred, eleven thousand, one hundred fifty-seven euro and fifty-nine cents (€ 3,611,157.59).

As a result, the available amount for a share capital increase under the authorized capital is equal to thirty-two million, four hundred ninety-nine thousand, nine hundred twenty-six euro and twenty-seven cents (€ 32,499,926.27).

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 based on 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, 2016, 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; (iii) a clear description of the formalities to be fulfilled by the shareholders in order to be entitled to participate to the general meeting and to exercise their voting right, including the period within which the shareholders should indicate to the Company their intention to participate to the meeting; (iv) a description of the procedure to vote by proxy (or at distance to the extent permitted by the articles of association); (v) details with regard to the right of shareholders to amend items of the agenda, require additional items/proposed resolutions to be put on the agenda, and ask questions; (vi) the timeframe

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

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

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

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

Formalities to attend the general meeting:

All holders of shares, warrants or bonds (if any) issued by the Company can attend shareholders' meetings. Only shareholders, however, can vote at shareholders' meetings. To attend the general shareholders' meeting, holders of securities issued by the Company should consider 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, 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 Companies 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, 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 2016, the issued capital of MDxHealth SA amounted to €39,761,328.75 represented by 49,845,595 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 take-over 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 immediately and at the latest four Euronext business 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.

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Glossary

Assay	A term for a single experiment or a diagnostic test incorporating the required markers to analyze a clinical specimen.
Biopsy	A procedure where a tumor tissue sample is removed from the body for laboratory examination to determine whether cancer or some other disease is present. A biopsy can be performed using a needle to extract a small number 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.
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 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.
CMS	US Centers for Medicare & Medicaid Services
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.
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.
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 specific 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 for whom 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.

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