

Providing accurate and clinically actionable urologic solutions to inform patient diagnosis and treatment



About

**Mdxhealth** is a commercial-stage precision diagnostics company that provides actionable molecular diagnostic information to personalize the diagnosis and treatment of prostate cancer and other urologic diseases. The Company’s tests are based on proprietary genetic, epigenetic and other complex molecular technologies.

**Mdxhealth** provides highly accurate and clinically actionable urologic solutions to inform patient diagnosis and treatment while improving healthcare economics for payers and providers.

The Company’s US headquarters and laboratory operations are in Irvine, California. The European headquarters are located in Herstal, Belgium, with laboratory operations in Nijmegen, The Netherlands. MDxHealth is listed on the NASDAQ and Euronext Brussels stock exchange under the ticker symbol MDXH.

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Dear Shareholders,

2022 was a transformative year for mdxhealth. We came into the year with one product, our Confirm mdx test, generating virtually all of the company’s revenue. We exit 2022 with an expanded menu of 4 tests, all generating or poised to generate revenue in 2023. This progress reflects our commitment to be a growth company capable of sustainable revenue and profit growth.

When I joined mdxhealth in 2019, it was clear that the company had in place well developed and validated clinical and scientific validation of our core technologies, as well as a world class laboratory capable of scale and growth. What was required though was a complete restructuring of our operating discipline and commercial execution. Over the last 3 years, we have now in place a best-in-class sales team and disciplined approach to operating expense management and have set a clear path to profitability.

It is important to note the following developments for mdxhealth in 2022, all of which underscore and reflect the commitment we made to focus and execution, and which together will serve as the basis for our success and growth going forward:

- Our initial menu of Confirm mdx and Select mdx continued to be adopted by our urology customer base in 2022, while recovering from the impact of the pandemic over the past 3 years, with prostate cancer screenings estimated to be down 50 percent. Our reported volumes underscore our performance in driving sustainable adoption in spite of this market dynamics which we see reversing over the next number of quarters.
- At the beginning of the year, we launched our Resolve mdx test for urinary tract infections (UTI) comprised of a broad panel of organisms and drug resistance and susceptibility markers. This unique solution allows for rapid clinically actionable diagnostics for the approximately two million cases that present with UTI symptoms annually to our target urology customer base. This initiative is driven by the unique and focused sales channel we have into urology. Our strategy here was validated, with almost \$5 million in revenue for 2022.
- We completed a truly transformative acquisition of the Oncotype Genomic Prostate Score (GPS) test (formerly Oncotype DX GPS) from Exact Sciences. This acquisition

served to both expand and solidify our sales channel expanding to 70 representatives in the field and over 50 direct reps, which we believe is a channel that can continue to deliver on additional strategic growth initiatives as we go forward. This acquisition also provides mdxhealth with the most comprehensive menu in prostate cancer with all of our prostate cancer tests included in the National Comprehensive Cancer Network (NCCN) Guidelines.

- We secured support for our growth initiatives from our February 2023 equity offering which allowed for strengthening of our balance sheet as well as expansion of our investor base with high quality institutional investors in the U.S.
- We expanded our laboratory capabilities with the acquisition of our mdxhealth Plano Texas facility. This strategic initiative expands our capabilities and supports our UTI and additional potential growth opportunities.

We believe that each of these developments, and all of them collectively, solidify our position as the clear leader in prostate cancer precision diagnostics with a well established and focused sales channel into urology in the U.S. In addition, all of our efforts in 2022 position mdxhealth to deliver sustainable revenue growth, linear growth in our gross margin, disciplined and controlled operating expenses and a clear path to profitability. Finally, as I emphasized last year, the one aspect of our business that has not changed is our people. They have all risen to the growth and excellence challenge and are committed to delivering on our growth promise and positive path forward.

I would like to close by thanking our shareholders and employees for your continued support and restating our unwavering commitment to operating discipline and delivering value to all our stakeholders including patients, customers, employees and shareholders.

Respectfully,

Belgium, 24 April, 2023

**Michael K. McGarrity**  
*Chief Executive Officer*

# Business Review



## Key Figures 2022

	~47K Patients tested Growth compared to FY 2021 +45%	\$37.1M total revenue 2021: \$22.2M	\$37.9M Operating Loss 2021: \$26.8M	\$-29.3M Adjusted EBITDA <sup>(1)</sup> 2021: \$-23.8M	\$15.5M Cash and cash equivalents
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Thousands of \$ (except per share amounts) For the years ended December 31	2022	2021
Services	36,965	21,937
Licenses	25	250
Royalties and other revenues	64	52
<b>Revenues</b>	<b>37,054</b>	<b>22,239</b>
Cost of goods & services sold	(17,835)	(11,675)
<b>Gross profit</b>	<b>19,219</b>	<b>10,564</b>
Research and development expenses	(7,557)	(6,673)
Selling and marketing expenses	(26,582)	(17,744)
General and administrative expenses	(23,539)	(14,149)
Other operating income, net	559	1,161
<b>Operating Loss</b>	<b>(37,900)</b>	<b>(26,841)</b>
Financial expenses, net	(6,144)	(2,161)
<b>Loss before income tax</b>	<b>(44,044)</b>	<b>(29,002)</b>
Income tax	0	0
<b>Loss for the year</b>	<b>(44,044)</b>	<b>(29,002)</b>
<b>Earnings per share attributable to parent (EPS)</b>		
Basic and Diluted, \$	(0.28)	(0.24)

<sup>(1)</sup> EBITDA: Earnings Before Interest, Taxes, Depreciation and Amortization and one-time transaction expenses related to GPS acquisition

# Share Facts 2022

Stock exchange	NASDAQ: MDXH Euronext (Brussels): MDXH	
Total shares outstanding	162,880,936	
52 week range	€ 0.60 - € 0.90	
Market cap (as of Dec 31, 2022)	€ 97.4 million	
Analyst coverage	Firm	Analyst
	William Blair	Andrew Brackmann
	BTIG	Mark Massaro
	Piper Sandler	Jason Bednar
	Oppenheimer	François Brisebois
	KBC Securities	Thomas Vranken

# Business highlights 2022

## 2022 Business Review

2022 was a transformational year for mdxhealth as we executed the acquisition of the Genomic Prostate Score (GPS) test (formerly Oncotype DX GPS) from Exact Sciences, thereby solidifying our leadership in the precision diagnostics urology market and providing the most comprehensive menu of advanced molecular tests for urology in prostate cancer.

In addition, the introduction of our novel Urinary Tract Infection (UTI) testing services in 2021 began to bear fruit in 2022 with the contribution of approximately \$5 million to our topline revenues. As part of our rebranding in 2022, our UTI test was named Resolve mdx for Urinary Tract Infection.

## Highlights for the year ended December 31, 2022

- Acquired Genomic Prostate Score (GPS) test (formerly Oncotype DX GPS) from Exact Sciences in August 2022, solidifying leadership in the precision diagnostics urology market and providing the most comprehensive menu of advanced molecular tests for urology in prostate cancer
- The November 2022 released NCCN for Prostate Cancer Guideline (Version 1.2023) expands the indication for use of the GPS test to include high-risk patients with localized prostate cancer. This expanded criteria to address high-risk patients provides additional validation for the clinical utility of GPS in making prostate cancer treatment decisions and enables mdxhealth to more fully serve its targeted patient population
- 2022 full year revenues increased by 67% to \$37.1 million versus \$22.2 million for 2021; excluding GPS, 2022 revenue increased 25% to \$27.7 million versus 2021. 2022 revenues were comprised of \$21.8 million from Confirm mdx, \$9.3 million from GPS, \$4.9 million from Resolve mdx, with the remaining revenues from Select mdx and other.

## MDxHealth Business Overview

We are a commercial-stage precision diagnostics company committed to providing non-invasive, clinically actionable and cost-effective urologic solutions to improve patient care. Our novel genomic testing solutions combine advanced clinical modeling with genomic data to provide each patient with a personalized risk profile, which provides more accurate and actionable information than traditional clinical risk factors used by clinicians. Our Select mdx and Confirm mdx tests address men at risk for undetected prostate cancer, providing physicians with a clear clinical pathway to accurately identify clinically significant prostate cancer while reducing the use of invasive procedures that are prone to complications. Our Genomic Prostate Score (GPS) test addresses men newly diagnosed with localized prostate cancer, providing physicians with a clear clinical pathway to make the most informed treatment decision for their individual disease. Our team’s collective decades of experience in precision diagnostics and our portfolio of novel biomarkers for diagnostic, prognostic and predictive molecular assays supports our active pipeline of new testing solutions for urologic diseases.

Prostate cancer is presently the most common, and second deadliest, form of cancer in men. The broad adoption of prostate-specific antigen (PSA) screening in the 1980s created a paradigm shift in men’s health, reducing the incidence of metastatic prostate cancers by more than 50%. However, widespread PSA testing also significantly increased the pool of symptomatic men, resulting in overdiagnosis, overtreatment, serious complications, and potential anxiety — triggering a retreat from standardized PSA screening — culminating with the U.S. Preventative Services Task Force’s (“USPSTF’s”) decision to recommend against all PSA testing and prostate cancer screening in 2012. Following recommendations from clinicians and patient advocates together with building evidence of an uptick in metastatic prostate cancer incidence, the USPSTF softened its position in 2017, upgrading PSA screening for middle aged men. However, the USPSTF’s reversal left unresolved the clinical dilemma posed by the estimated pool of over ten million men living with an elevated PSA in the

United States. Approximately 25 million PSA tests are performed each year, and over 15% of these reveal heightened PSA levels — leading to an estimated pool of over three million undiagnosed men informed each year of their heightened risk for prostate cancer based on elevated PSA test results and/or negative biopsy results. Other than repeated invasive needle biopsy procedures, these symptomatic men and their clinicians have limited tools to manage their cancer risk.

Our Select mdx and Confirm mdx testing solutions directly address this unmet clinical need. Since the commercial launch of Confirm mdx in 2012 and Select mdx in 2016, we have performed over 200,000 tests ordered by more than 1,000 urologists in the United States. Select mdx for Prostate Cancer (a urine test for men being considered for their first prostate biopsy) and Confirm mdx for prostate cancer (an epigenetic test for men post-prostate biopsy), are designed to (i) improve the earlier detection of clinically significant prostate cancer in at-risk men and (ii) reduce the unnecessary costs and patient anxiety associated with the diagnosis and treatment of the disease. Both tests have been included in the National Comprehensive Cancer Network (NCCN) Guidelines for the Early Prostate Cancer Detection. Both tests have also successfully completed formal technical assessment review for Medicare reimbursement and have received a positive final local coverage determination.

While our existing prostate cancer tests, Select mdx and Confirm mdx, improve the decision for biopsy in at-risk patients, our recently acquired Genomic Prostate Score (GPS) test moves us further into the cancer management pathway, providing solutions for patients newly diagnosed with localized prostate cancer to make the most informed treatment decision for their individual disease. Our acquisition of the GPS (formerly Oncotype DX GPS) prostate cancer business in August 2022 from Genomic Health, Inc., a subsidiary of Exact Sciences Corporation (“Exact Sciences”), has accelerated our plans to build on our leadership in the urologic diagnostic space.

Currently, most newly diagnosed cases of prostate cancer remain indolent – slow growing and non-lethal. Patients diagnosed with indolent prostate cancer may be appropriately managed with observation or Active Surveillance (AS), while those with aggressive cancers may benefit from immediate treatment. Practice-management agencies worldwide have implemented guidelines stressing the importance of discerning favorable from unfavorable disease features to guide personalized management for patients diagnosed with low- and high-risk prostate cancer, including among others NCCN, the American Urology Association (AUA)/American Society for Radiation Oncology (ASTRO)/Society of Urologic Oncology (SUO), the American Society of Clinical Oncology (ASCO), the National Institute for Health and Care Excellence (NICE), and the European Association of Urology (EAU). The use of Active Surveillance has increased in recent years, with approximately half of patients newly diagnosed with localized prostate cancer choosing to avoid immediate intervention or similar treatment.

GPS is a tissue-based, multi-gene test that has been clinically validated to predict aggressive cancer at the time of diagnosis, helping to identify those men who need immediate surgery or radiation therapy versus those who can confidently choose Active Surveillance. Since its commercial launch in 2013, over 100,000 GPS tests have been performed, ordered by more than 3,000 urologists in the United States. GPS is able to provide a more precise and accurate assessment of disease progression, which helps more men avoid the lifelong complications associated with aggressive treatments. In 2015, the GPS test successfully completed a formal technical assessment review for Medicare reimbursement and received a positive final local coverage determination.

Building from the foundation of our complementary marketed products, we are committed to sustained growth, with our core management principles defined by a commitment to focus, commercial execution and operating discipline throughout our organization. While MDxHealth is domiciled and listed as a public company in Belgium, our primary commercial focus is the United States, where over 95% of our tests are performed and revenues are generated. Our leadership change in 2019 and coincident organizational and operational discipline implemented throughout the MDxHealth group of companies has further focused our commitment to U.S.-sourced growth, with our entire executive management team and over 90% of staff based in or reporting to our U.S. headquarters and laboratories.

We have established a systematic approach to commercializing our precision diagnostic solutions in our target markets in the United States, focusing on active engagement, education and market development directed toward health care professionals and their patients. Our commercial team is focused on prioritizing large and high-volume community urology centers, and on building long-standing relationships with key physicians and practice groups who have strong connections to the population of men who may be eligible for our solutions. Our ultimate goal is to support physicians using our tests through all aspects of the patient’s journey, starting from initial diagnosis through to advanced prostate cancer management. We also seek to build on our long-term partnerships with key opinion leaders (“KOLs”) and patient associations that are oriented towards the needs of our patients and customers. Our sales and marketing organization is focused on building physician awareness of the clinical and economic benefits provided by our tests through education of urologists and their clinical staff as well as pathology and laboratory staff, targeted KOL development and training, and development of tools for our customers to interact with patients and consumers (doctor-to-consumer education).

## Our Product Portfolio

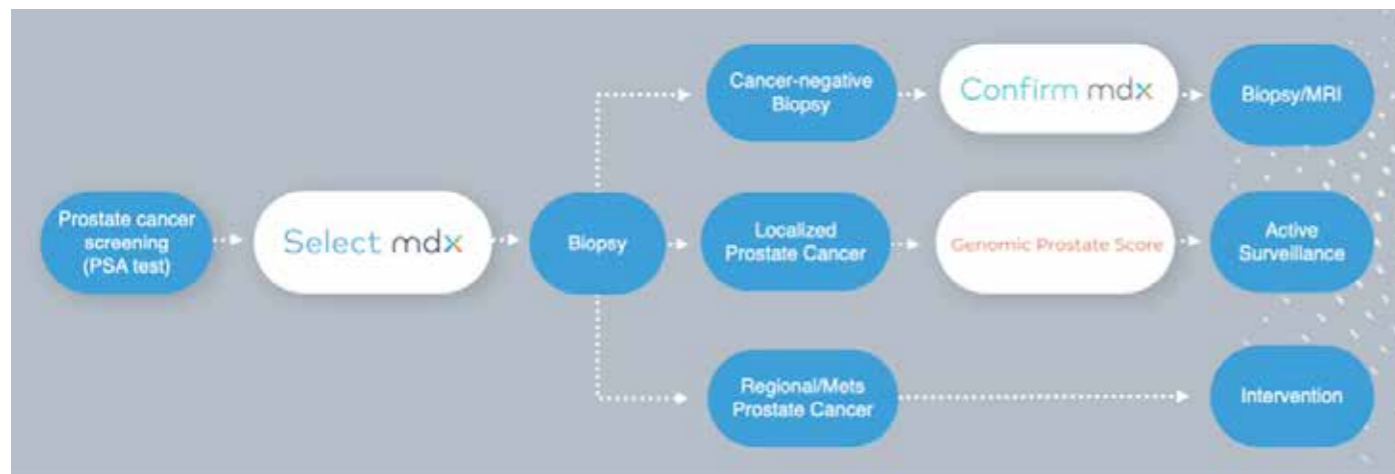
Our core commercial tests address a substantial unmet clinical need in the prostate cancer diagnostic and treatment pathway. According to the American Cancer Society, prostate cancer is the most common, and second deadliest, form of cancer in males in the United States. Prior to the emergence of precision diagnostic solutions, existing diagnostic tests were critically flawed, with high false negatives and false positives, leading to costly and invasive diagnostic protocols and attendant complications.

To screen at-risk men for prostate cancer, approximately 25 million PSA tests are performed each year, and over 15% of those reveal heightened levels of PSA. An elevated PSA level can be caused by many different sources, the majority of which are not cancer. Current clinical guidelines suggest that men with an elevated PSA should be considered for a prostate biopsy, so that a pathologist can visually inspect the sampled tissue to identify any sign of malignancy. However, 60% of biopsies are negative, not revealing any cancer, and as many as a third of these negative biopsies are false negatives, providing limited comfort to patients and their physicians that cancer was not missed. The relatively modest sensitivity and specificity of these current standard-of-care tests and procedures has led to increased patient anxiety, potentially unnecessary, invasive and costly interventions, and increased complications and hospitalizations.

Our Select mdx test — which is a noninvasive urine test with 95% Negative Predictive Value (NPV) for clinically significant prostate cancer — can be used to help physicians determine whether a costly, painful and complication-prone needle-core biopsy is advisable when a patient presents with an elevated PSA level or an abnormal digital rectal exam (DRE). For those men who proceed to a biopsy procedure, our Confirm mdx test — which measures biomarker signals in the biopsied tissue provides additional information to physicians and increases the accuracy of the biopsy, with a 96% NPV for clinically significant disease.

Upon an initial diagnosis of localized prostate cancer, our GPS test – which measures the expression of a panel of genes in prostate cancer tissue to predict the aggressiveness of the disease – can help distinguish between aggressive and indolent prostate cancer, which informs treatment decisions and helps to identify patients who may avoid unnecessary interventions.

To further supplement our prostate cancer menu, we have developed a novel, advanced urinary tract infection (UTI) test that delivers patient-specific antimicrobial treatment options within 24-48 hours (standard urine cultures can take up to 5 to 7 days). Developed especially for patients with recurrent, persistent, and complicated UTIs, Resolve mdx combines precise pathogen identification and resistance gene detection with a proprietary susceptibility methodology that identifies personalized oral antibiotic options for fast resolution and improved patient outcomes.



## Our Competitive Strengths

We believe we have the following competitive strengths which underpin our commercial execution success and will position us for sustainable growth:

- Targeted Menu Improving Prostate Cancer Diagnosis and Treatment.** We offer a menu of tests that provide clinically actionable results for men at-risk for, as well as men newly diagnosed with, prostate cancer. Collectively, Select mdx, Confirm mdx and GPS provide urologists with a clear clinical pathway to accurately identify and appropriately treat prostate cancer while minimizing the use of aggressive procedures and treatments, improving health outcomes and significantly lowering costs to the healthcare system.
- Strong Commercial Focus and Presence.** We aim to increase adoption of our commercial tests by leveraging our direct sales force in the United States to continue to market and sell to our urology-focused network. We have significant experience in building effective commercial teams consisting of sales reps, strategic account managers, and clinical liaisons led by a management team with a track record of success. In addition, our payor and reimbursement, revenue cycle management and client services groups provide expert support for our field sales team as well as our patients and customer base. We believe we can leverage these groups to explore additional opportunities for growth based on this commercial channel. Outside the United States we will continue to evaluate distribution partners to drive adoption in markets where our menu is best suited.
- Commercial Channel Advantage.** Building from the launch of our first commercial test in 2012, we have established mdxhealth as an industry leader in precision diagnostics for prostate cancer detection and treatment. We intend to take advantage of our established urology and pathology relationships to support menu expansion and additional growth opportunities as appropriate and within our focus.
- Compelling Reimbursement Strategy.** Adoption of our Confirm mdx, Select mdx and Genomic Prostate Score tests has been supported by Medicare local coverage determinations (LCDs) issued via the Palmetto GBA-administered MoIDX Program, their inclusion in NCCN and other US and internationally recognized clinical-practice guidelines, as well as consistent expansion of coverage by commercial payors. Our Resolve mdx UTI test is currently reimbursed by Medicare and most private insurance payors, based on nationally recognized Current Procedural Terminology (CPT) codes.

- Robust and Reliable Technology.** We possess a proprietary know-how and intellectual property (“IP”) portfolio capable of advancing our precision diagnostics pathway as well as high quality laboratory operations, including our CAP accredited, CLIA certified and New York State Department of Health (“NYSDOH”) approved molecular laboratory facilities. We also have an extensive library of biomarkers which can be applied in additional urology and men’s health diagnostics.
- Proven Leadership with Industry Expertise.** Our management team members have proven track records of execution and value creation across medical devices, diagnostics and biotech. We believe we have built a culture of performance, responsibility and accountability — from research and development, to sales and marketing, and operations and management, we are committed to building value for all of our stakeholders, including patients, customers, employees and shareholders.

## Our Strategy

Our ultimate goal with our core testing solutions is to take an at-risk patient from prostate cancer screening all the way through the diagnostic and therapeutic pathway of prostate cancer. As such, we are focused on continuing to drive adoption of our Select mdx, Confirm mdx, and GPS tests and expand our product offerings. The key elements of our strategy include:

- Physician and Patient Education.** One important component of our efforts to successfully penetrate the urology market and promote clinical adoption of our Select mdx, Confirm mdx, GPS and Resolve mdx tests is to drive awareness of these tests. We educate physicians and patients through a variety of channels including by supporting clinical studies for the publication of peer reviewed journals and abstracts at key scientific conferences, forging relationships with the leading medical and scientific opinion leaders in urology, developing strategic partnerships with leading pathology laboratories with large urology client bases and via public relations and advertising campaigns.
- Expand Test Menu.** We intend to build on our leadership in the prostate cancer diagnostic space by expanding our existing menu of tests. We are currently developing a candidate test, Monitor mdx, for the prostate cancer diagnostic and treatment pathway. Monitor mdx is intended to function as a non-invasive solution that risk stratifies patients for continued Active Surveillance versus intervention, while also improving patient compliance with Active Surveillance protocols.
- Expand Reimbursement.** An important component of our commercial strategy is to expand reimbursement for our tests. Our Select mdx, Confirm mdx and GPS tests have been covered by a Medicare MoIDX LCD since 2023, 2014 and 2015, respectively. Our managed care team continues to pursue adoption of positive coverage and reimbursement policies and contracts by other payors. We believe the clinical utility and actionability of our tests, combined with our experience and knowledge of the complex coverage and reimbursement landscape in the United States, will enable us to expand coverage and reimbursement among the commercial payor market. We continue to build upon our successful strategy, supported by governmental and commercial coverage policies, as a foundation to secure additional contracts from major payors.

Market Opportunity

Among U.S. males, prostate cancer is the most diagnosed cancer and the second leading cause of cancer death. According to the American Cancer Society, in 2021, over 260,000 men are expected to be diagnosed with prostate cancer in the United States, with more than 34,000 dying from the disease.

There are currently significant challenges with diagnosing and treating prostate cancer in the United States. Approximately 25 million PSA tests are performed each year, and over 15% of those reveal heightened levels of PSA. Current clinical guidelines suggest that men with an elevated PSA should be considered for a prostate biopsy, However, approximately 60% of biopsies are negative, not revealing any cancer, and as many as a third of these negative biopsies are false negatives, providing limited comfort to patients and their physicians that cancer was not missed. For those men whose biopsies are positive, the majority will harbor indolent cancer, but traditional methods are unable to accurately identify which of these men might safely avoid invasive and costly interventions. In addition, for patients diagnosed with localized prostate cancer who are on Active Surveillance, management of their disease relies on the measurement of prostate-specific antigen (PSA) levels and digital rectal examination (DRE), which can be unreliable and lead to overdiagnosis and overtreatment.

The relatively modest sensitivity, specificity and prognostic ability of current standard-of-care tests and procedures has led to increased patient anxiety, potentially unnecessary, invasive and costly interventions, and increased complications and hospitalizations. Our suite of commercial products addresses these issues, presenting a substantial market opportunity. The Company has calculated approximate addressable market opportunities for our menu of tests, based on the estimated:

- 3 million men screened for prostate cancer annually
- 500,000 men who undergo prostate biopsies annually
- 268,000 men diagnosed prostate cancers annually
- 2 million UTI cases managed by urologists annually

Our menu addresses a \$4.8B U.S. market opportunity

Comprehensive Urology Menu



\* Resolve mdx test in development.(all figures based on management estimates)

Commercial Products

Select mdx for Prostate Cancer Urine Test

The current standard for prostate cancer screening is the PSA blood test. Unfortunately, the PSA is not specific to clinically significant prostate cancer — it is more of an indicator of prostate health. There are many factors such as benign prostatic hyperplasia (“BPH”), inflammation, prostatitis and a naturally occurring enlarged prostate that can cause an elevated PSA. In men with an elevated PSA level between 3-10 ng/mL, only 25-40% of biopsies reveal cancer — and the majority of these identified cancers are indolent. Also, following a prostate biopsy procedure, around 18% of men suffer complications (blood in urine) and around 3% are hospitalized for infection (sepsis). Select mdx helps physicians determine if a patient is at higher or lower risk for prostate cancer and which men can safely avoid biopsy.

Select mdx is a non-invasive urine test that measures the expression of two mRNA cancer-related biomarkers (HOXC6 and DLX1) combined with an advanced clinical model incorporating traditional risk factors. The test provides a personalized risk profile that helps the physician determine whether:

- The patient may benefit from a biopsy and early prostate cancer detection; or
- The patient can avoid a biopsy and return to routine screening.

Men identified by the test as having a high likelihood of clinically significant cancer can, upon biopsy, be diagnosed and treated sooner, while men identified at very low risk may avoid biopsy.

The following chart depicts the functioning of the Select mdx test:



Guidelines Inclusion

Select mdx has been included in the NCCN Prostate Cancer Early Detection guidelines since 2020. NCCN is a non-profit alliance of the 31 leading cancer centers in the United States. Select mdx has also been included in the European Association of Urology (EAU) Prostate Cancer guidelines since 2018.

Clinical Validation Studies

The use of Select mdx as a predictive test to identify men at low risk for aggressive prostate cancer has been well validated in both scientific and clinical studies.

Results from the clinical validation study for Select mdx confirmed its superior performance compared to other commonly used biomarker tests and risk calculators. The test’s NPV of 95% in the validation study means that if the test identifies a

very low risk, the physician and patient can be 95% sure that a subsequent biopsy will not detect Gleason score  $\geq 7$  prostate cancer, information that may provide a level of confidence needed to avoid a biopsy. The test has a very high predictive accuracy (AUC 0.85) for high-grade prostate cancer, which is significantly better than the PCPT risk calculator version 2. There are twelve published studies assessing the Select mdx test and which together demonstrate its analytical validity, clinical validity, clinical utility and positive health economic outcomes. These studies, all of which have been published in peer-reviewed publications, evaluated more than 4,500 patients in the aggregate.

The following is a summary that highlights key findings from some of these studies.

- **Analytical validity.** A study published in 2017 illustrated, in an independent laboratory, the performance characteristics and robustness of the Select mdx mRNA assay, covering all aspects of analytical method validation including assay sensitivity, specificity, linearity, precision, repeatability and reproducibility using pre-specified acceptance criteria.
- **Clinical validity.** In a study published in 2019, the Select mdx test demonstrated an NPV of 95%. Urine samples were collected from 1,955 men from The Netherlands, France and Germany prior to an initial prostate biopsy. Select mdx molecular biomarker results were combined with other risk factors in a clinical model optimized to detect International Society of Urological Pathology Grade Group 2 or greater prostate cancer in men. Results in the validation cohort were compared with the independent PCPT risk calculator version 2. The full validation cohort of 916 men including all prostate specific antigen levels yielded an AUC of 0.85 with 93% sensitivity, 47% specificity and 95% negative predictive value. The Prostate Cancer Prevention Trial Risk Calculator (“PCPTRC”) AUC was 0.76. In the 715-patient validation cohort, limited to subjects with PSA less than 10 ng/ml, the AUC was 0.82 with 89% sensitivity, 53% specificity and 95% negative predictive value. The PCPTRC AUC was 0.70.
- **Clinical utility.** In a 2019 study, Select mdx had a significant impact on initial prostate biopsy decision-making in a U.S. community urology setting. Biopsy rates in Select mdx positive men were 5-fold higher than in Select mdx negatives.



- **Health economic outcomes.** A 2018 study demonstrated that routine use of the Select mdx test to guide biopsy decision making improved health outcomes and significantly lowered costs in American men at risk for prostate cancer. Compared to the current standard of care, Select mdx implementation would result in an average of 0.045 quality-adjusted life years (“QALYs”) gained at a cost savings of \$1,694 per patient. Assuming approximately 300,000 men are biopsied each year, this translates to an incremental 14,000 QALYs gained at cost savings of \$500,000 annually.

*Confirm mdx for Prostate Cancer Tissue Test*

Approximately 30% of men with a cancer-negative prostate biopsy actually have cancer. Prostate cancer is difficult to diagnose because it is both heterogenous and multi-focal. The standard of care for diagnosing prostate cancer is a transrectal ultrasound guided biopsy. However, this procedure samples less than 1% of the entire gland, leaving men at risk for undetected prostate cancer.

Confirm mdx is a well-validated epigenetic test that guides the detection of occult prostate cancer on a patient’s previously biopsied negative tissue. The test can help urologists determine a man’s risk for harboring clinically significant prostate cancer despite having a cancer-negative biopsy result, and it has a number of unique features/advantages.

For patients with an initial negative biopsy, few options are currently available to guide a urologist in determining whether or when an additional biopsy procedure is warranted. Fear of occult (hidden) prostate cancer leads to additional procedures, leading many men to receive multiple follow-up biopsy procedures to rule out the presence of cancer.

The Confirm mdx test addresses prostate biopsy sampling concerns, helping urologists to:

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

For men with a negative biopsy, independently published clinical studies have shown that the Confirm mdx test is the most significant, independent predictor of prostate biopsy outcomes relative to other available clinical factors such as age, PSA and DRE results. Incorporating Confirm mdx into clinical practice can reduce the number of unnecessary repeat biopsies, yielding clinical and economic value for healthcare providers, patients and payors. Confirm mdx can aid urologists with patient management decisions regarding the need for follow-up testing and procedures with the identification of low-risk patients testing negative for DNA hypermethylation.

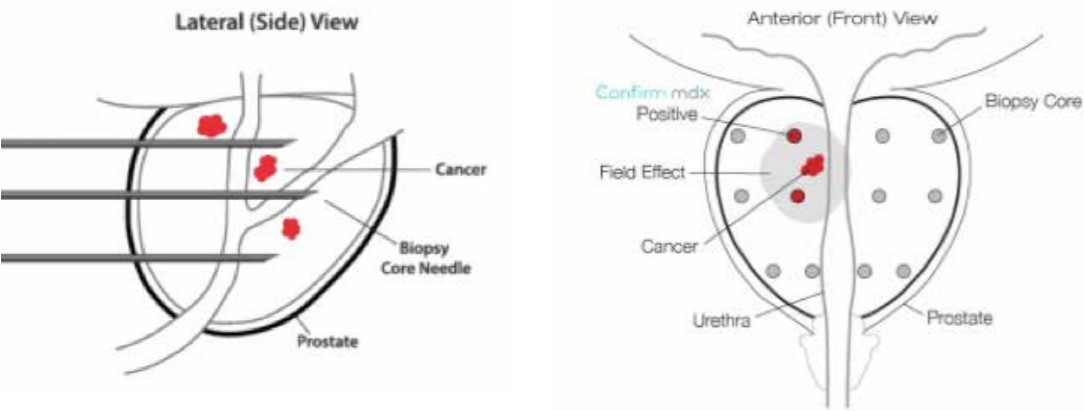
The use of Confirm mdx for prostate cancer detection using methylation-specific PCR (MSP) and cancer-associated epigenetic biomarkers to improve upon histopathology has been well validated in both scientific and clinical studies. DNA methylation, the most common and useful measure of epigenetic abnormality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

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

The epigenetic field effect is a molecular mechanism whereby cells adjacent to cancer foci can contain DNA methylation changes, which may be indistinguishable by histopathology, but detectable by MSP testing. The presence of epigenetic field effects associated with prostate cancer has been widely published and is the basis of activity for the Confirm mdx assay to aid in the detection of occult prostate cancer on previously biopsied, histopathologically negative tissue.

The following image depicts how the Confirm mdx test identifies false-negative biopsies:

Confirm mdx Field Effect



Guidelines Inclusion

Confirm mdx has been included in the NCCN Prostate Cancer Early Detection guidelines since 2016. Confirm mdx has also been included in the EAU Prostate Cancer guidelines since 2018.

Confirm mdx Clinical Validation Studies

The use of Confirm mdx for prostate cancer detection to improve upon histopathology has been well validated in both scientific and clinical studies.

There are more than 55 published studies on the genes and technology used in the Confirm mdx test. Among these, studies demonstrating the analytical validity, clinical validity, clinical utility and positive health economic outcomes of the Confirm MDx test evaluated more than 1,200 patients in the aggregate.

The following is a summary that highlights key findings from some of these studies.

- **Analytical validity.** A study published in 2012 illustrated the performance characteristics and robustness of the Confirm mdx multiplex DNA methylation assay, covering the analytical method including assay sensitivity, specificity, linearity, precision, repeatability and reproducibility using pre-specified acceptance criteria.
- **Clinical validity.** The clinical validity of the Confirm mdx test has been demonstrated in two large, blinded clinical validation studies published in 2013 and 2014, yielding a NPV of ~90% for all prostate cancer, which is significantly higher ( $p < 0.001$ ) than that afforded by standard histopathology review, as well as a NPV of 96% for clinically significant prostate cancer. Further, when compared to all pertinent risk factors for prostate cancer detection (patient's age, serum PSA level, digital rectal exam (DRE), histopathological findings on the previous cancer- negative biopsy and the epigenetic assay), Confirm mdx was shown to be the most significant, independent predictor for prostate cancer in a repeat biopsy with an odds ratio of 3.24 (and a  $p$ -value  $< 0.001$ ). An additional clinical validity study published in 2017 demonstrated that the Confirm mdx test improved the identification of African American men at risk for aggressive cancer missed by a prostate biopsy, with accuracy equivalent to prior studies in predominantly Caucasian populations.
- **Clinical utility.** A 2014 study reported on the real-world use of the Confirm mdx assay, demonstrating that the test impacts physician behavior. A very low rate of repeat biopsies (4.4%) was observed in the Confirm mdx negative men, as compared to the expected 43% rate of repeat biopsy reported in a large population-based randomized trial sponsored by the National Cancer Institute.

- **Health economic outcomes.** In a study published in 2013, a budget impact model developed to evaluate the effect of the Confirm mdx assay on healthcare spending demonstrated significant potential healthcare savings associated with the reduction of repeat biopsies and complications avoided. Under the study's model, utilization of Confirm mdx would bring approximately \$500,000 in annual savings per 1 million covered patients.

Confirm mdx robust clinical evidence

Over 55 published studies on genes and technology

- ✓ Analytical validity
- ✓ Clinical validity
- ✓ Clinical utility
- ✓ Health economics

Pivotal clinical studies

Analytical validation	Van Neste et al., BMC Urology 2013
Validation of high NPV	Partin et al., Journal of Urology 2014
Meta analysis validating high NPV	Partin et al., Trans. of the Am. Clin. and Clin. Assoc 2016
Risk score development NPV 96% CS PCa	Van Neste et al., The Prostate 2016
Validated in African American men	Waterhouse et al., Urology 2016
Validation of clinical utility/actionability	Wojno, et al 2014
Savings to health care system	Aubry et al., American Health Drug and Benefits 2013



Genomic Prostate Score (GPS) Tissue Test

Currently, most cases of detected prostate cancer remain indolent and men often die from other causes. Patients who have indolent prostate cancer may be appropriately managed with observation or Active Surveillance (AS), while those with aggressive cancers may benefit from immediate treatment . The use of AS has increased in recent years and it is now estimated that up to 50% of clinically low-risk patients choose AS, while the remainder choose some type of immediate treatment.

The tissue-based GPS test assesses 17 genes in total – 12 cancer-related genes representing 4 important biologic pathways (androgen signaling, cellular organization, stromal response, proliferation) together with 5 references genes (to control for RNA quantity and quality). The test uses reverse transcription polymerase chain reaction (RT-PCR) to measure gene expression in very small amounts of prostate tumor tissue (requiring as little as 5 ng of RNA). Genetic expression of the 12 cancer-related genes, normalized by the 5 reference genes, is used in an algorithm to generate a GPS result that ranges from 0 to 100, with higher scores associated with more aggressive disease. The GPS test, in conjunction with clinical risk factors, is predictive of a finding of adverse pathology (AP) upon a radical prostatectomy (RP) and clinical recurrence following RP, and consequently provides clinicians and patients with information about the likely aggressiveness of their cancer to help guide initial treatment decisions.

For patients with NCCN very low- to favorable intermediate- prostate cancer, the GPS test provides information on the risk of AP to help physicians guide personalized treatment for patients at the initial decision point. For the unfavorable intermediate- and high-risk groups, the GPS test helps inform decisions on the intensity of definitive treatment. The patient results report gives the risk of a patient developing metastasis within 10 years, risk of PCD within 10 years, and risk of tumor aggressiveness based on AP result. outlining the clinical characteristics of each NCCN risk group.

The GPS test is intended for men with clinically localized prostate cancer who have undergone biopsy within 3 years and have not yet started treatment. Patients with any NCCN risk category between very low- and high-risk are eligible for GPS testing.

Guidelines Inclusion

GPS has been included in the NCCN Prostate Cancer guidelines since 2019.

Clinical Validation Studies

The use of GPS as a predictive test to identify men at low risk for aggressive prostate cancer has been well validated in both scientific and clinical studies.

The following is a summary that highlights key findings from clinicial studies regarding the GPS test.

- **Clinical validity.** In a prospective and retrospective study on 402 patients published in 2015, the GPS test demonstrated its ability to discriminates prostate cancer aggressiveness in biopsy tissue despite tumor heterogeneity and multifocality. Further, the test demonstrated its ability to improve prediction of adverse pathology.
- **Clinical utility.** Numerous clinical studies have shown the impact of GPS on treatment recommendations and have demonstrated that generally, use of GPS increases the proportion of men for whom AS is recommended, when the background AS rates are similar to the national average for these risk groups.
  - In a prospective decision impact study by Badani et al. (2015) of 158 patients with NCCN very low-, low- and low intermediate-risk disease, the GPS test resulted in a 26% change in recommended treatment modality or intensity and patients who received GPS testing had a 24% relative increase in AS recommendations.
  - In a chart review study by Dall’Era et al. (2015) of 211 patients with NCCN very low- or low risk-disease, biological risk predicted by GPS differed from NCCN clinical risk alone in 62 men (39%). AS use increased by 24% in patients who received the GPS test versus patients who did not receive the GPS test.
  - In a study by Eure et al. (2017) of 297 patients, 23% of patients’ risk was restratified. In the NCCN low-risk group, the change in the management plan between AS and immediate treatment was 28%; 51% of the men who were initially recommended immediate treatment pre-GPS testing switched to AS post-GPS testing, while 14% of those initially recommended AS switched to immediate treatment post-GPS testing. Among the men who elected AS, their one-year AS persistence rates remained high at 89%.
  - A fourth study by Lynch et al. (2017) demonstrated utility in a US Department of Veterans Affairs population, an equal-access healthcare system with high baseline AS rates without testing. The study compared management patterns for men with NCCN very low-, low-, and intermediate-risk PCa with and without molecular profiling. Overall, use of AS was 12% higher (absolute; relative increase 19%) in GPS-tested versus untested men, with the biggest increases observed in low-risk patients (90% versus 72% for tested versus untested, respectively) and patients under the age of 60 (75% versus 42% for tested versus untested, respectively).
- **Health economic outcomes.** A 2016 publication in Reviews in Urology presented a comprehensive economic analysis of the GPS test in low-risk prostate cancer patients. Results showed that use of the GPS test results in a net savings of \$2,286 USD per patient — including the cost of the test — by decreasing unnecessary immediate invasive treatments. The study demonstrated that incorporation of the GPS test as part of the treatment decision algorithm for patients with NCCN very low- and low-risk disease (64% of the study population) led to a 21% net increase in the use of AS. Of these, treatment patterns and cost for 80 men tested with GPS were compared to 100 patients in the same practice without genomic testing. Based on a real-world practice setting in the US Northeast with a contemporary patient population and using current treatment cost averages, these results demonstrated that the use of the GPS test represented a reduction in cost of unnecessary intermediate interventions (by more than 50%) over a 6-month period. Additional savings can also be expected by removing the cost of management of associated side effects of treatment such as impotence and incontinence.

GPS robust clinical evidence

Over 20 published clinical validation and utility studies

- ✓ Analytical validity
- ✓ Clinical validity
- ✓ Clinical utility
- ✓ Health economics

Pivotal clinical studies

Analytical validation	Knezevic et al., 2013
Clinically validated as an independent predictor of adverse pathology	Klein et al., 2014, Cullen et al., 2015, Eeden et al., 2017, Eggebo et al., 2019
Clinical validated in African American men	Cullen et al., 2015, Murphy et al., 2021
Validation of clinical utility	Badani et al., 2015, D
Validation of clinical utilityactionability	Badani et al., 2015, Dall’Era et al., 2015, Eure et al., 2017, Lynch et al., 2017, Murphy et al., 2021, Moschovas et al., 2021
Cost savings by decreasing unnecessary immediate treatment	Albala et al., 2016



Resolve mdx for Urinary Tract Infection

Urinary tract infections (UTIs) affect around 10 million people who seek medical attention every year. It is estimated that 2-3 million of these cases lead to emergency department visits. UTIs can be complicated and recurrent, resulting in painful symptoms such as abdominal and rectal pain, frequent urination, burning or pain during urination, and fatigue. Antibiotic resistance is a significant issue, observed in up to one-third of UTI infections, causing about 2.8 million infections and 35,000 deaths annually, according to the CDC.

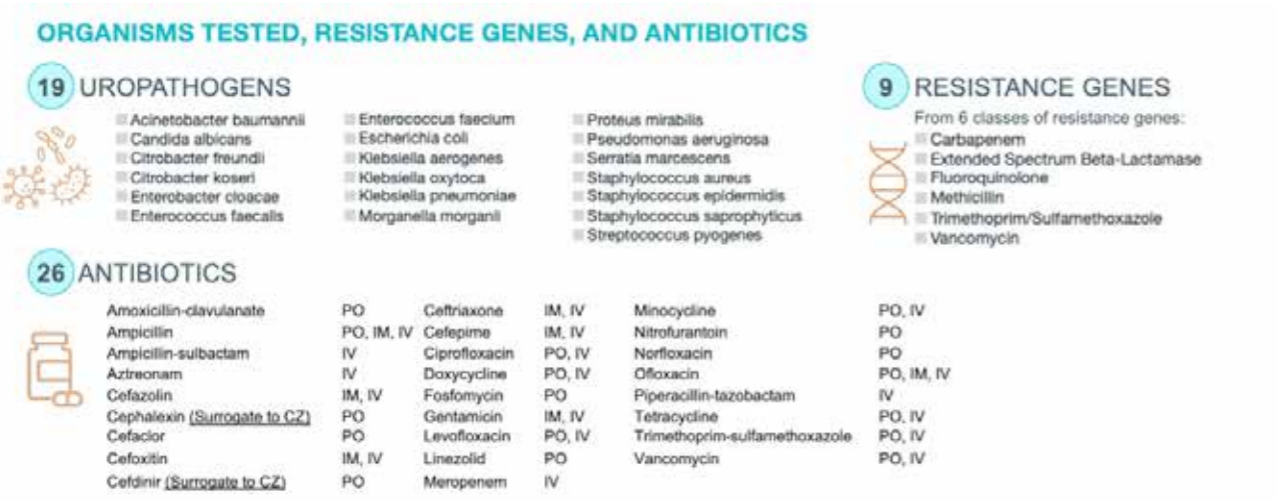
The traditional method of conducting a UTI test, urine culture, can take up to 3 to 5 days to produce results. Unfortunately, relying solely on culture-based testing may produce equivocal results of "mixed flora" in up to 30% of cases, Often clinicians will rely on empiric therapy to treat UTIs, which can lead to overuse/misuse of antibiotics. Through the use of Resolve mdx, we help support antibiotic stewardship initiatives, as our test identifies personalized antibiotic options that would be expected to be more effective against the patient’s infection.

To address this unmet clinical need, with Resolve mdx we developed an advanced urine test that utilizes Polymerase Chain Reaction (PCR) technology to detect and quantify both infectious pathogens and resistance genes. Resolve mdx also includes susceptibility testing to identify the antibiotics which may be best suited to resolve the urinary tract infection. This approach provides prompt and accurate pathogen identification and personalized antibiotic recommendations. PCR-based testing offers improved sensitivity and specificity in identifying pathogens, addressing the problem of "mixed flora" results associated with traditional testing methods. This increased accuracy provides physicians with clinically actionable information to guide their decision-making for patient care.

Our proprietary Antibiotic Susceptibility Testing method, called ASTX, determines how each pathogen responds to the 26 antibiotics tested. The unique aspect of ASTX is that it tests whole urine samples, ensuring accurate results and identifying the most effective treatment options for patients.

Our goal is to help pinpoint not only the offending organisms, regardless of how many are identified, but also the most likely oral antibiotics capable of clearing the entire infection. We estimate the addressable market in the United States for UTI testing at approximately 2 million cases annually, or \$1 billion.

Resolve mdx Pathogens Tested, Resistance Genes and Antibiotics



Pipeline

We intend to build on our leadership in the urologic diagnostic space by expanding our menu of tests beyond Select mdx, Confirm mdx, GPS and Resolve mdx. We are currently developing an additional product for the prostate cancer diagnostic and treatment pathway. Active surveillance is a management approach for prostate cancer that involves closely monitoring the cancer's progression through regular tests and imaging, without immediately initiating active treatment such as surgery or radiation therapy. Since not all prostate cancers progress the same manner, there is a significant unmet clinical need to help physicians identify which patients may benefit from AS, distinguishing those at risk for disease progression.

Monitor mdx for Men being considered for a Surveillance Biopsy

Men on Active Surveillance are monitored using PSA, MRI and periodic biopsies to determine if their prostate cancer has progressed and whether definitive treatment is necessary. We are actively analyzing urine and blood biomarker panels with the goal of developing a non-invasive test for monitoring these patients. A testing solution that allows a physician to forego or delay their patient's surveillance biopsy would represent a significant business opportunity with little or no direct competition.

If our development efforts are successful, MDxHealth would have a full offering of biomarker-based prostate cancer tests from early detection to treatment and management. Select mdx and Confirm mdx help determine which patients should (or should not) undergo a prostate biopsy, while our GPS test guides the decision to enter into Active Surveillance upon an initial diagnosis of prostate cancer. In the AS setting, Monitor mdx would provide methods to identify and monitor patients who could remain on Active Surveillance as a treatment option.



# 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>

## Introduction

This Corporate Governance Statement is included in the Company's report of the Board of Directors on the statutory accounts for the financial year ended on 31 December 2022 in accordance with article 3:6, §2 of the Belgian Companies and Associations Code of 23 March 2019 (as amended) (the "**Belgian Companies and Associations Code**").

On 14 April 2021, in accordance with the Belgian Royal Decree of 12 May 2019 designating the corporate governance code to be complied with by listed companies, the Company designated the new 2020 Belgian Corporate Governance Code (the "**2020 Code**") as reference code within the meaning of article 3:6, §2 of the Belgian Companies and Associations Code. At the same occasion, the Company's corporate governance charter was adopted in accordance with the recommendations set out in the 2020 Code, which replaces the previous 2009 Belgian Corporate Governance Code.

For the financial year ended on 31 December 2022, the Company complied to a large extent with the provisions of the 2020 Code, except for the following deviations which the Company believed were justified in view of the Company's specific situation. Notably, in line with the "comply-or-explain" principle of said 2020 Code, mdxHealth does not fully comply with the following provisions:

- Given the size of the Company, no internal audit function is in place. In line with provision 4.14 of the 2020 Code, the need for an internal audit function will be reviewed annually.
- Following the modification of the Directors' remuneration on 30 July 2020, effective as from 1 July 2020, the Non-Executive Directors that are not Independent Directors shall not be entitled to a remuneration in cash, but shall each year be entitled to receive share options for a maximum of 10,000 shares of the Company. This is contrary to provision 7.6 of the 2020 Code, which provides that no share options should be granted to Non-Executive Directors. The Company believes that this provision of the 2020 Code is not appropriate and adapted to take into account the realities of companies in the biotech and life sciences industry. Notably, the ability to remunerate Non-Executive Directors with share options allows the Company to limit the portion of remuneration in cash that the Company would otherwise need to pay to attract or retain renowned experts with the most relevant skills, knowledge and expertise. The Company is of the opinion that granting Non-Independent Non-Executive Directors the opportunity to be remunerated in part in share-based incentives rather than all in cash enables the Non-Independent Non-Executive Directors to link their effective remuneration to the performance of the Company and to strengthen the alignment of their interests with the interests of the Company's shareholders. The Company believes that this is in the interest of the Company and its stakeholders. Furthermore, the Company believes that this is customary for Directors active in companies in the life sciences industry.
- In accordance with provision 7.6 of the 2020 Code, Non-Executive Directors should receive a part of their remuneration in the form of shares of the Company. The Company has however no distributable reserves and therefore does not meet the legal requirements to proceed to a share buy-back. As a result, the Company does not own any treasury shares and is unable to grant existing shares to Non-Executive Directors as part of their remuneration.

The interests of the Non-Independent Non-Executive Directors are currently considered to be sufficiently oriented to the creation of long-term value for the Company. Finally, the Board will propose to remunerate the Independent Directors in cash, but leaving it at the own initiative of the Independent Directors whether or not they wish to use such funds (in whole or in part) to acquire existing shares of the Company.

- In accordance with provision 7.9 of the 2020 Code, the Board should set a minimum threshold of shares to be held by the executive management. A part of the remuneration of the executive management consists of options to subscribe for the Company's shares, which should allow the executive management over time to acquire shares of the Company, in line with the objectives of the option plans.
- Pursuant to article 7:91 of the Belgian Companies and Associations Code and provision 7.11 of the 2020 Code, shares should not vest and share options should not be exercisable within three years as of their granting. It has been expressly provided by the Company's general shareholders' meeting that the Board of Directors is explicitly authorized to deviate from the provisions of 7:91 of the Belgian Companies and Associations Code, for all persons who fall within the scope of these provisions (whether directly or pursuant to articles 7:108 and 7:121 of the Belgian Companies and Associations Code, or otherwise). The Company is of the opinion that this allows for more flexibility when structuring share-based awards. For example, it is customary for option plans to provide for a vesting in several instalments over a well-defined period of time, instead of vesting after three years only. This seems to be more in line with prevailing practice.
- In accordance with provision 7.12 of the 2020 Code, the Board of Directors should include provisions that would enable the Company to recover variable remuneration paid, or withhold the payment of variable remuneration, and specify the circumstances in which it would be appropriate to do so, insofar as enforceable by law. The Company believes that this provision of the 2020 Code is not appropriate and adapted to take into account the realities of companies in the biotech and life sciences industry, including, notably, for management teams located in the United States. The share option plans set up by the Company do however contain bad leaver provisions that can result in the share options, whether vested or not, automatically and immediately becoming null and void. Notwithstanding the company's position that share options are not to be qualified as variable remuneration, the Board of Directors is of the opinion that such bad leaver provisions sufficiently protect the Company's interests and that it is therefore currently no necessary to provide for additional contractual provisions that give the company a contractual right to reclaim any (variable) remuneration from the members of the executive management. For that reason, there are no contractual provisions in place between the Company and the members of the executive management that give the Company a contractual right to reclaim from said executives any variable remuneration that would be awarded.

The performance and functioning of the Board of Directors, its committees, and the executive management team are summarized below.

On 8 November 2021, following the Company's initial public offering in the United States of 3,750,000 American Depositary Shares (each, an "**ADS**", and each ADS representing 10 ordinary shares of the Company with no nominal value per share) and the listing of the ADSs on the Nasdaq Capital Market, the Board of Directors approved a revised version of the Company's corporate governance charter to reflect the fact that, under United States securities law, the Company is currently eligible for treatment as a "foreign private issuer" and "emerging growth company". As a foreign private issuer and emerging growth company, the Company may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to U.S. public companies. For further details on the qualification of the Company as "foreign private issuer" and "emerging growth company", reference is made to section 1.9 of the Company's corporate governance charter.

The articles of association and the corporate governance charter are available on the Company's website (<https://mdxhealth.com/>) and can be obtained free of charge at the Company's registered office.

The 2020 Code can be accessed on the following website: [www.corporategovernancecommittee.be/](http://www.corporategovernancecommittee.be/)

## Board of Directors

The Company has opted for a "one tier" governance structure whereby the Board of Directors is the ultimate decision-making body, with the overall responsibility for the management and control of the Company, and is authorized to carry out all actions that are considered necessary or useful to achieve the Company's object. The Board of Directors has all powers except for those reserved to the general shareholders' meeting by law or the Company's articles of association. The Board of Directors acts as a collegiate body.

The Board of Directors' role is to pursue sustainable value creation by the Company, by determining the Company's strategy, putting in place effective, responsible and ethical leadership, and monitoring the Company's performance. The Board of Directors acts as a collegiate body. Pursuant to the Belgian Companies and Associations 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 2020 Code, the Board of Directors should have a composition appropriate to the company's purpose, its operations, phase of development, structure of ownership and other specifics. The Board of Directors shall be composed of at least three Independent Directors and a majority of the Board shall consist of Non-Executive Directors. Currently, the Board of Directors comprises 8 Directors, of which 5 are Independent Non-Executive Directors and 2 are Non-Independent Non-Executive Directors. The Directors of the Company are appointed by the general shareholders' meeting.

The Company's Board of Directors strives to maintain a well-balanced general diversity at the Board of Directors. Currently, there are 3 female Directors among a total of 8 Board members (representing a ratio of 37.50% female Directors against 62.50% male Directors). The Belgian Companies and Associations Code requires that at least one third of the members of the Board of Directors should be of the opposite gender. In order to calculate the required number of directors of a different gender, fractions must be rounded to the nearest whole number, which means that the Company's Board in its current composition must include at least 3 female Directors. The Company has met the one-third gender diversity requirement since 1 January 2018 and continues to comply with such requirement at the date of this Annual Report.

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 16 times throughout 2022. All Directors were present or represented at these 16 meetings, except that Hilde Windels BV, represented by its permanent representative, Ms. Hilde Windels, did not participate to 2 meetings during this period and Regine Slagmulder BV, represented by its permanent representative, Dr. Regine Slagmulder, did not participate to 1 meeting during this period. In addition, in accordance with article 7:95 of the Belgian Companies and Associations Code and article 23 of the Company's articles of association, the Board of Directors passed resolutions with unanimous and written consent of all Directors at 1 occasion.

The Board of Directors meets at least once, and usually several times per year, without any executive board members or other executives in attendance, including when executive remuneration matters are considered and approved.

### Chair

The chair of the Board of Directors is responsible for the leadership of the Board of Directors. The chair 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 chair promotes effective interaction between the Board and the executive management. The chair 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 chair amongst the Non-Executive Directors. Currently, Ahok BV, with Mr. Koen Hoffman as permanent representative, is the chair of the Board of Directors. Mr. Hoffman assumed the role of Board chair in 2022.

Independent Directors

The Company has currently five Independent (Non-Executive) Directors.

A Director in a listed company is considered to be independent if he or she does not have a relationship with that company or with a major shareholder of the Company that compromises his or her independence. If the Director is a legal entity, his or her independence must be assessed on the basis of both the legal entity and his or her permanent representative. A Director will be presumed to qualify as an Independent Director if he or she meets at least the criteria set out in article 7:87 of the Belgian Companies and Associations Code and Clause 3.5 of the 2020 Code, which can be summarized as follows:

1. Not being an executive, or exercising a function as a person entrusted with the daily management of the company or an affiliated company or person, and not have been in such a position for the previous three years before their appointment. Alternatively, no longer enjoying share options of the company related to this position.
2. Not having served for a total term of more than twelve years as a Non-Executive Board member.
3. Not being an employee of the senior management (as defined in article 19,2° of the law of 20 September 1948 regarding the organization of the business industry) of the company or an affiliated company or person, and not have been in such a position for the previous three years before their appointment. Alternatively, no longer enjoying share options of the company related to this position.
4. Not receiving, or having received during their mandate or for a period of three years prior to their appointment, any significant remuneration or any other significant advantage of a patrimonial nature from the company or an affiliated company or person, apart from any fee they receive or have received as a Non-Executive Board member.
5. Not holding shares, either directly or indirectly, either alone or in concert, representing globally one tenth or more of the company’s capital or one tenth or more of the voting rights in the company at the moment of appointment.
6. Not having been nominated, in any circumstances, by a shareholder fulfilling the conditions covered under point 5.
7. Not having, nor having had in the past year before their appointment, a significant business relationship with the company or an affiliated company or person, either directly or as partner, shareholder, Board member, member of the senior management (as defined in article 19,2° of the law of 20 September 1948 regarding the organization of the business industry) of a company or person who maintains such a relationship.
8. Not being or having been within the last three years before their appointment, a partner or member of the audit team of the company or person who is, or has been within the last three years before their appointment, the external auditor of the company or an affiliated company or person.
9. Not being an executive of another company in which an executive of the company is a Non-Executive Board member, and not have other significant links with executive Board members of the company through involvement in other companies or bodies.
10. Not having, in the company or an affiliated company or person, a spouse, legal partner or close family member to the second degree, exercising a function as Board member or executive or person entrusted with the daily management or employee of the senior management (as defined in article 19,2° of the law of 20 September 1948 regarding the organization of the business industry), or falling in one of the other cases referred to in 1 to 9 above, and as far as point 2 is concerned, up to three years after the date on which the relevant relative has terminated their last term.

If the Board of Directors submits the nomination of an Independent Director who does not meet the abovementioned criteria to the general meeting, it shall explain the reasons why it assumes that the candidate is in fact independent.

The Company is of the view that the Independent Directors comply with each of the criteria of the Belgian Companies and Associations Code and the 2020 Code.

An Independent Director who ceases to satisfy the requirements of independence must immediately inform the chair of the Board of Directors thereof.

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 24 Apr 2023	Position	Term Start	Term End (1) (2)	Professional Address
Ahok BV, represented by <b>Mr. Koen Hoffman</b>	53	Chair, Independent Non-Executive Director	2021	2024	CAP Business Center, Rue d’Abhooz 31, B-4040 Herstal, Belgium
<b>Dr. Eric Bednarski</b>	50	Non-Executive Director	2020	2023	CAP Business Center, Rue d’Abhooz 31, B-4040 Herstal, Belgium
<b>Mr. Michael K. McGarrity</b>	60	Executive Director	2019	2023	CAP Business Center, Rue d’Abhooz 31, B-4040 Herstal, Belgium
Regine Slagmulder BV, represented by <b>Dr. Regine Slagmulder</b>	55	Independent Non-Executive Director	2020	2023	CAP Business Center, Rue d’Abhooz 31, B-4040 Herstal, Belgium
<b>Mr. Donnie M. Hardison Jr.</b>	71	Independent Non-Executive Director	2021	2023	CAP Business Center, Rue d’Abhooz 31, B-4040 Herstal, Belgium
Valiance Advisors LLP, represented by <b>Mr. Jan Pensaert</b>	50	Non-Executive Director	2021	2024	CAP Business Center, Rue d’Abhooz 31, B-4040 Herstal, Belgium
Qaly-Co BV, represented by <b>Dr.Lieve Verplancke</b>	62	Independent Non-Executive Director	2021	2024	CAP Business Center, Rue d’Abhooz 31, B-4040 Herstal, Belgium
Hilde Windels BV, represented by <b>Ms. Hilde Windels</b>	56	Independent Non-Executive Director	2020	2023	CAP Business Center, Rue d’Abhooz 31, B-4040 Herstal, Belgium

Notes:

<sup>(1)</sup> The term of the mandates of each Director will expire immediately after the ordinary general shareholders’ meeting held on the last Thursday (or the Wednesday immediately preceding, if the last Thursday is a recognized holiday) of the month of May in the calendar year indicated.

<sup>(2)</sup> In 2022, Mr. Rudi Mariën, as permanent representative of RR-Invest S.à.r.l., was Non-Executive Director (until his resignation effective as of 26 May 2022).



**Mr. Koen Hoffman** obtained a Master in Applied Economics and an MBA at Vlerick Business School. Between 1992 and July 2016, he was active at KBC Group in which he started his career in the corporate finance department and later became the CEO of KBC Securities as from October 2012. Since August 2016, he is the CEO of Value Square asset management. Mr Koen Hoffman serves also as board member at Fagron (Chair), Greenyard (chair), Mithra Pharmaceuticals and SnowWorld.



**Dr. Eric Bednarski** currently serves as a Partner of MVM Partners LLP. Before joining MVM in 2008, he was a Partner at Advent Healthcare Ventures and a Principal at Advent International Corporation. Prior to Advent, he was a Director in the Corporate Finance Group of Silicon Valley Bank. Dr. Bednarski has a B.S. degree in Neural Science from Brown University and a Ph.D. in Biological Sciences from the University of California, Irvine.



**Mr. Michael K. McGarrity** has more than 25 years of experience in the healthcare industry with a unique combination of device, diagnostics and biotechnology experience. Michael was most recently the CEO of Sterilis Medical. Prior to Sterilis Michael was the CEO of Nanosphere (NASDAQ: NSPH), a nanotechnology-based molecular diagnostics company, where he engineered an operational and strategic turnaround that resulted in its successful sale to Luminex (NASDAQ: LMNX) in 2016. Prior to Nanosphere, McGarrity spent 13 years at Stryker Corporation (NYSE: SYK).



**Mr. Donnie M. Hardison Jr.** currently is the sole proprietor of DMH Consulting, a management consulting firm that he founded and previously operated from April 2016 to January 2017. He was most recently the President and Chief Executive Officer, and served on the board of directors, of Biotheranostics, Inc., a molecular diagnostic company focused on oncology, from February 2017 until it was acquired by Hologic, Inc. in February 2021. From April 2010 to March 2016, Mr. Hardison was the President and Chief Executive Officer of Good Start Genetics, a molecular genetic testing and information company. For more than 20 years prior to that, Mr. Hardison held various executive and senior management positions at companies including Laboratory Corporation of America (LabCorp) a clinical laboratory company, Exact Sciences Corporation, a molecular diagnostics company, OnTarget, Inc., a sales and marketing consulting company, Quest Diagnostics Inc., a clinical laboratory company, SmithKline Beecham Corporation, a pharmaceutical company, and others. He served on the board of directors of Exact Sciences Corporation (Nasdaq: EXAS) from May 2000, through its initial public offering in February 2001, until August 2007. Mr. Hardison received his Bachelor of Arts degree, in political science, from the University of North Carolina, Chapel Hill.



**Mr. Jan Pensaert** is the Founding Managing Partner of Valiance. He brings over 20 years of experience in growth investing. He leads the Investment Committee for the Valiance Funds and is responsible for all aspects of the Funds' investment processes. Jan currently serves on the Board of several Valiance entities funds and portfolio companies including MDxHealth, JenaValve, NeoSync and 4Tech. Prior to founding Valiance, Jan was CEO of La Fayette, where during his tenure the La Fayette Funds increased in AUM from USD 750 million to USD 5.5 billion. Before that, he was responsible for the Permal Group's European-based investment management and research activities, and prior to that he worked at Lazard in Corporate Finance M&A. Jan holds a BA in Business Economics from Gent University in Belgium, and a Masters in Banking & Finance from the University of Aix-Marseille, France.



**Dr. Lieve Verplancke MD**, a Belgian national, began her career in 1984 with The Beecham Group (now part of GlaxoSmithKline), and has since held key management positions with Merck & Co., as well as Bristol-Myers Squibb, where she served as Managing Director, leading their Belgian/GDL subsidiary, until 2012. Ms. Verplancke also serves as a Board Member for Brussels-based Europe Hospitals; the Imelda Hospital in Bonheiden; and the Euronext fund, Quest for Growth and Materialise. She is also the Founder and Managing Director of Qaly@Beersel, an elderly care center in Belgium. In addition to being a medical doctor (MD-KULeuven University), Ms. Verplancke holds a postgraduate degree in Economics and an MBA from the University of Antwerp. She has also completed courses at INSEAD, CEDEP, Columbia University and the Vlerick Business School, and is a certified Executive Coach (PCC).



**Ms. Hilde Windels** is the CEO of immunodiagnostic company Antelope Dx BV and has 20 years of experience in the biotechnology sector with a track record of building and structuring organizations, fundraising, M&A, public capital markets and corporate strategies. At Biocartis, she was CEO ad interim and Deputy CEO from September 2015 until September 2017 and CFO from 2011 until September 2015. Previously, Mrs. Windels worked as independent CFO for several private biotech companies and from 1999 to 2008 she was CFO of Devgen. Currently, Mrs. Windels serves as a board member at Erytech and Celyad. In the past, she also served on the boards of Devgen, Biocartis, Ablynx, VIB and FlandersBio. Mrs. Windels holds a Masters in Economics (commercial engineer) from the University of Leuven, Belgium.



**Dr. Regine Slagmulder** is a partner and full professor in management accounting & control at Vlerick Business School and a visiting professor of accounting & control at INSEAD. Previously, she worked as a strategy practice consultant at McKinsey & Company. She also previously worked as a professor of management accounting at INSEAD and at the University of Tilburg. She serves as an independent director and member of the audit committee on the board of the investment company Quest for Growth (since 2011) and as an independent director and chair of the audit committee of Ekopak (since 2021), both listed on Euronext. Dr. Slagmulder graduated in civil electrotechnical engineering and industrial management from the University of Gent, after which she received a management doctorate at Vlerick Business School. As part of her research activities, she was a research fellow attached to INSEAD, Boston University (USA) and the P. Drucker Graduate Management Center at Claremont University (USA). She is an INSEAD certified director (IDP-C).

## Committees of the Board of Directors

The Board of Directors of MDxHealth has set up two permanent Board committees which are responsible for assisting the Board of Directors and making recommendations in specific fields: the audit committee (in accordance with article 7:99 of the Belgian Companies and Associations Code and provision 4.10 of the 2020 Code) and the nomination and remuneration committee (in accordance with article 7:100 of the Belgian Companies and Associations Code and provision 4.17 and 4.19 of the 2020 Code). The terms of reference of these Board committees are primarily set out in the corporate governance charter.

### Audit committee

MDxHealth has had an audit committee in place since the Company's inception. According to article 7:99 §3 of the Belgian Companies and Associations Code, MDxHealth would meet the size criteria in order to operate without a separate audit committee, but the Company has chosen to continue operating with a separate audit committee.

The audit committee of the Company consists of three Directors, all of whom are currently Independent Non-Executive Directors. According to the Belgian Companies and Associations Code, all members of the audit committee must be Non-Executive Directors, and at least one member must be independent within the meaning of article 7:87 of the Belgian Companies and Associations Code. Furthermore, each member of the committee must meet the criteria for independence set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended. The chairperson of the audit committee is to be appointed by the members of the audit committee. The composition of the audit committee complies with the 2020 Code, which requires that a majority of the members of the audit committee are independent.

The members of the audit committee must have a collective competence in the business activities of the Company as well as in accounting, auditing and finance, and at least one member of the audit committee must have the necessary competence in accounting and auditing. According to the Board of Directors, the members of the audit committee satisfy this requirement, as evidenced by the different senior management and Director mandates that they have held in the past and currently hold.

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 inform the Board of Directors of the result of the audit of the financial statements and the manner in which the audit has contributed to the integrity of the financial reporting and the role that the audit committee has played in that process;
- to monitor the financial reporting process, and to make recommendations or proposals to ensure the integrity of the process;
- to monitor the effectiveness of the Company's internal control and risk management systems, and the Company's internal audit process and its effectiveness;
- to monitor the audit of the annual statutory and consolidated financial statements, including the follow-up questions and recommendations by the statutory auditor and, as the case may be, the auditor responsible for the audit of the consolidated financial statements;
- to assess and monitor the independence of the statutory auditor, in particular with respect to the appropriateness of the provision of additional services to the Company. More specifically, the audit committee analyses, together with the statutory auditor, the threats for the statutory auditor's independence and the security measures taken to limit these threats, when the total amount of fees exceeds the criteria specified in article 4 §3 of Regulation (EU) No 537/2014; and
- to make recommendations to the Board of Directors on the selection, appointment and remuneration of the Company's statutory auditor in accordance with article 16 § 2 of Regulation (EU) No 537/2014.

On the date of this report, the following Non-Executive Independent Directors are members of the audit committee: Regine Slagmulder BV, represented by its permanent representative, Dr. Regine Slagmulder (chair); Qaly-Co BV, represented by its permanent representative; Dr. Lieve Verplancke; and Hilde Windels BV, represented by its permanent representative, Ms. Hilde Windels. As required by Belgian law, the chair of the audit committee is competent in accounting and auditing, as is evidenced by her role as partner and full professor in management accounting and control at Vlerick Business School, as well as serving as chair of the audit committee of multiple publicly listed companies.

The audit committee is a collegial body and deliberates and makes decisions as such. The audit committee met three times in 2022. All members of the audit committee were present or represented at all meetings.

### Nomination and remuneration committee

According to article 7:100 §4 of the Belgian Companies and Associations Code, MDxHealth would meet the size criteria in order to operate without a separate remuneration committee, but the Company has chosen to continue operating with a separate 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 who have the necessary competence in terms of remuneration policy. A majority of its members must be Independent Directors. The nomination and remuneration committee is chaired by the chair of the Board of Directors or another Non-Executive Director appointed by the committee. The chair of the Board of Directors should not chair the committee when dealing with the designation of his successor. The CEO should participate in an advisory capacity in the meetings of the committee when it deals with the remuneration of other executive managers.

The Board of Directors has determined that three members of its nomination and remuneration committee are independent under, the applicable rules of the Belgian Companies and Association Code and the Belgian Corporate Governance Code.

Pursuant to the Belgian Companies and Associations Code, a remuneration committee must have the necessary expertise in terms of remuneration policy. The Board of Directors has determined that the members of the nomination and remuneration committee satisfy this requirement.

The role of the nomination and remuneration committee is to make recommendations to the Board of Directors with regard to the appointment and remuneration of Directors and members of the executive management and, in particular, to:

- identify, recommend and nominate, for the approval of the Board of Directors, candidates to fill vacancies in the Board of Directors and executive management positions as they arise. In this respect, the nomination and remuneration committee must consider and advise on proposals made by relevant parties, including management and shareholders;
- advise the Board of Directors on any proposal for the appointment of the chief executive officer and on the chief executive officer's proposals for the appointment of other members of the executive management;
- draft appointment procedures for members of the Board of Directors and the chief executive officer;
- ensure that the appointment and re-election process is organized objectively and professionally;
- periodically assess the size and composition of the Board of Directors and make recommendations to the Board of Directors with regard to any changes;
- consider issues related to succession planning;
- make proposals to the Board of Directors on the remuneration policy for Directors and members of the executive management and the persons responsible for the day-to-day management of the Company, as well as, where appropriate, on the resulting proposals to be submitted by the Board of Directors to the shareholders' meeting;

- make proposals to the Board of Directors on the individual remuneration of Directors and members of the executive management, and the persons responsible for the day-to-day management of the Company, including variable remuneration and long-term incentives, whether or not share-related, in the form of share options or other financial instruments, and arrangements on early termination, and where applicable, on the resulting proposals to be submitted by the Board of Directors to the shareholders’ meeting;
- prepare a remuneration report to be included by the Board of Directors in the annual corporate governance statement;
- present and provide explanations in relation to the remuneration report at the ordinary general shareholders’ meeting; and
- report regularly to the Board of Directors on the exercise of its duties.

On the date of this report, the following Non-Executive Directors are members of the nomination and remuneration committee: Mr. Donnie M. Hardison Jr. (chair); Dr. Eric Bednarski; Qaly-Co BV, represented by its permanent representative, Dr. Lieve Verplancke; Ahok BV, represented by its permanent representative, Mr. Koen Hoffman; and Valiance Advisors LLP, represented by its permanent representative, Mr. Jan Pensaert.

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

The nomination and remuneration committee met four times in 2022. All of the committee members with the were present or represented at all of the committee meetings.

Process for evaluating the Board, its committees, and its individual Directors

The Board should assess at least every three years its own performance and its interaction with the executive management, as well as its size, composition, functioning and that of its committees. The evaluation should be carried out through a formal process, whether or not externally facilitated, in accordance with a methodology approved by the Board.

At the end of each Board member’s term, the nomination and remuneration committee should evaluate this Board member’s presence at the Board or committee meetings, their commitment and their constructive involvement in discussions and decision-making in accordance with a pre-established and transparent procedure. The nomination and remuneration committee should also assess whether the contribution of each Board member is adapted to changing circumstances.

The Board will act on the results of the performance evaluation. Where appropriate, this will involve proposing new Board members for appointment, proposing not to re-appoint existing Board members or taking any measure deemed appropriate for the effective operation of the Board.

Executive management

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.

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 the 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 executive management team

The composition of the Management Team is set out below and reflects the situation at the date of this Annual Report:

Name	Age on 24 Apr 2023	Position	Permanent Address
Mr. Michael K. McGarrity	60	Chief Executive Officer	15279 Alton Parkway Ste 100, Irvine, CA 92618 USA
Mr. John Bellano	54	Chief Commercial Officer	15279 Alton Parkway Ste 100, Irvine, CA 92618 USA
Mr. Ron Kalfus	48	Chief Financial Officer	15279 Alton Parkway Ste 100, Irvine, CA 92618 USA
Mr. Joseph Sollee	58	Executive Vice President of Corporate Development & General Counsel	15279 Alton Parkway Ste 100, Irvine, CA 92618 USA

In 2022 the Management Team consisted of Mr. Michael McGarrity, as Chief Executive Officer, Mr. Ron Kalfus, as Chief Financial Officer, Mr. John Bellano, as Chief Commercial Officer, and Mr. Joseph Sollee, as Executive Vice President of Corporate Development and General Counsel.

Following are biographies of the executive management team members (also referred to as executives) as of the date of this Annual Report:

**Mr. Michael K. McGarrity, Chief Executive Officer**

See “Board of Directors - Composition of the Board of Directors”.

**Mr. John Bellano, Chief Commercial Officer**

Mr. Bellano joined MDxHealth in June 2019. He has more than 25 years of experience in the healthcare Industry. Mr. Bellano started his career in pharmaceuticals and transitioned to molecular diagnostics where he has spent the past 20 years of his career, most recently as Chief Commercial Officer of Sterilis Solutions Prior to Sterilis Solutions he served as the commercial leader for pharmacogenomic companies Assurex Health and AltheaDx. While at Assurex Health (Myriad Genetics) revenue grew from USD 700 thousand to a run rate of USD 100 Million during his 5-year span with the organization.

**Mr. Ron Kalfus, Chief Financial Officer**

Mr. Kalfus joined MDxHealth in July 2019. He has over 20 years of leadership experience in both public and private companies within diagnostics/biotech and other sectors, and brings extensive knowledge in financial operations and management. Mr. Kalfus joined MDxHealth from Rosetta Genomics, where he helped lead efforts to reposition the company for commercial success with its oncology diagnostic products, and raised over USD 60 million in capital to fund these efforts. Prior to Rosetta, Mr. Kalfus served as the CFO and Treasurer of MabCure, a Belgium-based publicly-traded biotechnology startup in the field of early cancer detection using antibodies.

**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.

# Internal control and risk management

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

## Introduction

The Company operates a risk management and control framework in accordance with the Belgian Companies and Associations Code and the 2020 Code. MDxHealth is exposed to a wide variety of risks within the context of its business operations that can result in its objectives being affected or not achieved. Controlling those risks is a core task of the Board of Directors (including the audit committee), the executive management and all other employees with managerial responsibilities.

The risk management and control system has been set up to reach the following goals:

- achievement of the Company's objectives;
- achieving operational excellence;
- ensuring correct and timely financial reporting; and
- compliance with all applicable laws and regulations.

## Control environment

### Three lines of defense

The Company applies the 'three lines of defense model' to clarify roles, responsibilities and accountabilities, and to enhance communication within the area of risk and control. Within this model, the lines of defense to respond to risks are:

- First line of defense: line management is responsible for assessing risks on a day-to-day basis and implementing controls in response to these risks.
- Second line of defense: the oversight functions like Finance and Controlling and Quality and Regulatory oversee and challenge risk management as executed by the first line of defense. The second line of defense functions provide guidance and direction and develop a risk management framework.
- Third line of defense: independent assurance providers such as external accounting and external audit challenge the risk management processes as executed by the first and second line of defense.

*Policies, procedures and processes*

The Company fosters an environment in which its business objectives and strategy are pursued in a controlled manner.

This environment is created through the implementation of different Company-wide policies, procedures and processes such as the Company's values, the Quality Management System and the Delegation of Authorities rule set.

The employees are regularly informed and trained on these subjects in order to develop sufficient risk management and control at all levels and in all areas of the organization.

**Risk management**

Sound risk management starts with identifying and assessing the risks associated with the Company's business and external factors. Once the relevant risks are identified, the Company strives to prudently manage and minimize such risks, acknowledging that certain calculated risks are necessary to ensure that the Company achieves its objectives and continues to create value for its stakeholders. All employees of the Company are accountable for the timely identification and qualitative assessment of the risks within their area of responsibility.

**Control activities**

Control measures are in place to minimize the effect of risks on the Company's ability to achieve its objectives. These control activities are embedded in the Company's key processes and systems to assure that the risk responses and the Company's overall objectives are carried out as designed. Control activities are conducted throughout the organization, at all levels and within all departments.

**Information and communication**

The Company recognizes the importance of timely, complete and accurate communication and information both top down as well as bottom-up. The Company therefore put several measures in place to assure amongst others:

- security of confidential information;
- clear communication about roles and responsibilities; and
- timely communication to all stakeholders about external and internal changes impacting their areas of responsibility.

**Monitoring of control mechanisms**

Monitoring helps to ensure that internal control systems operate effectively. The quality of the Company's risk management and control framework is assessed by the following functions:

- Quality and Regulatory: All employees of the Company are instructed on the rules and policies of the Company via a booklet of work rules, the terms of their employment arrangements, standard operating procedures defined by task/ area, and by numerous documents (such as the Code of Business Conduct and Ethics and the Dealing Code) that are distributed and explained to the personnel.
- External Audit: In the Company's review of the annual accounts, the statutory auditor focuses on the design and effectiveness of internal controls and systems relevant for the preparation of the financial statements. The outcome of the audits, including work on internal controls, is reported to management and the audit committee.
- Audit Committee: The Board of Directors and the audit committee have the ultimate responsibility with respect to internal control and risk management.

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

The Board of Directors has established a Code of Business Conduct and Ethics to aid MDxHealth's Directors, officers and employees in making ethical and legal decisions when conducting Company business and performing their day-to-day duties. The Code of Business Conduct and Ethics is available in its entirety on the Company's website ([www.mdxhealth.com](http://www.mdxhealth.com)). In addition, the Board has appointed a Chief Compliance Officer to oversee ongoing compliance with the Code of Business Conduct and Ethics and existing laws and external regulations, and to report regularly to the Board of Directors and the Audit Committee on compliance matters.

**Risk management and internal control with regard to the process of financial reporting**

The accurate and consistent application of accounting rules throughout the Company is assured by means of set of control procedures, including:

- The audit committee reviews all financial information before it is released
- The Board of Directors reviews internal monthly financial information
- The financial auditors not only audit the year-end financial statements, but at the request of the Company they also perform a limited review of the Interim half-year financial statements
- The Company managers and finance department personnel explain all material variances in historical figures and between the budget and actual figures
- The Board of Directors, the Company managers and finance department personnel perform reviews and controls of the key financial figures at each reporting period, some of which are described below
- At the Board of Directors level, there is a periodic review and approval of the following main topics:
  - Overall strategy and strategic options;
  - Multi-year business plan and company goals;
  - Ensuing year budget and targets;
  - Comparison of actual results and budgeted figures;
  - Hiring, motivation, and retention of key talent;
  - Remuneration and benefits;
  - Financial statements; and
  - Internal controls.

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

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

- The appointment of qualified personnel in key positions with all entities of the Company;
- The definition of a set of standard procedures for key activities such as steps for the approval, purchasing and payment of services and goods;
- The request for the external auditors to pay special attention to areas with specific company and industry risk;
- The request for specialized consultants to assist in designing and/or reviewing key procedures, systems, or reports;
- The audit committee or individual Directors periodically review and are consulted on key matters and procedures and when needed external specialist assistance is sought.

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

# Shareholder information

## Principal shareholders

The Company has an international shareholder base with both large and smaller specialised shareholders focused on the healthcare and life sciences sectors, and a number of more local retail investors. Based on the number of shares on the date of this report, transparency notifications received by the Company until that date, and statements of acquisition of beneficial ownership filed with the SEC under U.S. securities law until that date, the shareholder base of the Company is as set out in the table below. It is possible that the information below in relation to a shareholder is not or no longer up-to-date. All notifications and declarations are available on the Company's website (<https://mdxhealth.com/>).

		On a non-diluted basis	On a fully diluted basis
	Date of notification	% of the voting rights attached to shares <sup>(1)</sup>	% of the voting rights attached to shares <sup>(2)</sup>
MVM Partners LLP <sup>(3)</sup>	28 February 2023	17.31%	9.40%
Bleichroeder LP <sup>(4)</sup>	3 February 2023	14.75%	8.01%
Valiance Asset Management Limited <sup>(5)</sup>	12 April 2023	7.74%	4.22%
Biovest NV <sup>(6)</sup>	17 March 2023	4.41%	2.39%

Notes:

- <sup>(1)</sup> The percentage of voting rights is calculated on the basis of the number of outstanding shares at the date of the notification. On the date of this report, the share capital of the Company amounts to EUR 163,471,629.58. It is divided into 270,380,936 shares of no nominal value, each representing the same fraction of the share capital.
- <sup>(2)</sup> The percentage of voting rights is calculated on the basis of a total of 497,890,952 shares, consisting of 270,380,936 shares outstanding on the date of this report and the issuance 227,510,016 additional shares, assuming that (i) 512,000 new shares were issued upon the exercise of 512,000 share options, issued under the form of subscription rights on 23 June 2014 (of which 68,500 share options have not yet been granted), (ii) 1,936,155 new shares were issued upon the exercise of 1,936,155 share options, issued under the form of subscription rights on 19 June 2017, (iii) 2,848,687 new shares were issued upon the exercise of 2,848,687 share options, issued under the form of subscription rights on 21 June 2019 (of which 26,500 share options have not yet been granted), (iv) 3,538,750 new shares were issued upon the exercise of 3,538,750 share options, issued under the form of subscription rights on 27 May 2021 (of which 5,000 share options have not yet been granted), (v) 3,685,000 new shares were issued upon the exercise of 3,685,000 share options, issued under the form of subscription rights on 25 May 2022 (of which 1,232,500 share options have not yet been granted), (vi) 204,881,266 new shares were issued to the benefit of Exact Sciences (as defined below) by settlement through a contribution in kind of receivables due by the Company to Exact Sciences up to the Earn-Out Consideration (i.e., USD 70,000,000.00), assuming an issue price per new share equal to EUR 0.309 (i.e., the closing price on 14 April 2023) , (vii) 9,366,982 new shares were issued to the benefit of Innovatus (as defined below) upon exercise of the Innovatus Conversion Right (as defined below), assuming that the full amount of USD 70,000,000.00 is drawn by the Company under the loan and security agreement with Innovatus before 2 August 2025 and the applicable exchange rate is EUR 1.00 for USD 1.1057 (as published by the ECB on 14 April 2023), and (viii) 741,176 new shares were issued to the benefit of Kreos Capital (as defined below) upon the contribution in kind of the Kreos Convertible Loan Payable (as defined below).
- <sup>(3)</sup> The Company was notified that the number of shares with respect to which MVM Partners, LLC can exercise voting rights passively crossed below the threshold of 20% of the outstanding shares and voting rights of the Company on 7 February 2023. Notably, it follows from the notification by MVM Partners, LLC, who notified alone, that an aggregate of 45,504,584 shares of the Company, representing 17.31% of the 262,880,936 outstanding shares and voting rights of the Company at the time of the notification, is held through the following entities: MVM V LP (which owns 1,877,945 ADSs and 25,805,845 shares of the Company) and MVM GP (No. 5) LP (which owns 38,721 ADSs and 532,079 shares of the Company). The notification also stated that MVM Partners, LLC is not a controlled entity, acts as fund manager of the aforementioned two entities, and can exercise the voting rights attached to the securities at its own discretion, without specific instruction. Furthermore, it is stated that the fund management of MVM V LP and MVM GP (No.5) LP was previously done by MVM Partners LLP, but, on July 1, 2022, MVM Partners LLC replaced MVM Partners, LLP as fund manager of MVM V LP and

<sup>1</sup> For the purpose of the full-dilution scenario, the maximum 5% shareholding cap (as described below) is not taken into account in the simulation.

MVM GP (No.5) LP.MVM Partners LLC provides investment advisory services to MVM V LP and MVM GP (No.5) LP, which directly hold the shares reflected as being beneficially owned by such entities, and in such capacity MVM Partners LLC has voting and dispositive power over such shares. Investment decisions for MVM V LP and MVM GP (No.5) LP are made by an investment committee at MVM Partners LLC which consists of two individuals. No single individual member of the investment committee, or any other individual, has the power to unilaterally make investment decisions for MVM Partners LLC or the entities or to direct the voting or disposition of the shares.

<sup>(4)</sup> The Company was notified that the number of shares with respect to which Bleichroeder LP can exercise voting rights crossed below the threshold of 15% of the outstanding shares and voting rights of the Company on 3 February 2023. Notably, it follows from the notification that an aggregate of 38,783,335 shares of the Company, representing 14.75% of the 262,880,936 outstanding shares and voting rights of the Company at the time of the notification, is held through the following entities: 21 April Fund LP (8,024,518 shares), 21 April Fund LTD (20,342,162 shares), Hill Family Alternative Investments LLC (10,000,000 shares), and White Clover SA (416,670 shares) (the “Funds”). The notification also stated that the voting rights attached to the shares are exercised on behalf of the Funds by the investment adviser Bleichroeder LP, a Delaware limited partnership, at its discretion, in the absence of specific instructions, that Bleichroeder Holdings LLC, a Delaware limited liability company, is the general partner of Bleichroeder LP, that, as the general partner, Bleichroeder Holdings LLC holds control over voting rights of Bleichroeder LP, and that Bleichroeder Holdings LLC is not a controlled entity. The Company has been informed that voting and investment power over the shares held by the Bleichroeder entities is exercised jointly by three or more natural persons and voting and disposition decisions require the approval of a majority of such persons. Accordingly, no single natural person has voting or dispositive power over such shares.

<sup>(5)</sup> Valiance Asset Management Limited (“Valiance Management”), TopMDx Ltd. (“TopMDx”), Valiance Life Sciences Growth Investments SICAV-SIF (“LSGI Fund”) and Valiance Life Sciences Growth Investments GP S.à r.l. (“LSGI GP”) (collectively, the “Valiance Entities”) jointly filed with the SEC a statement on Schedule 13D/A according to which the aggregate number of shares beneficially owned by the Valiance Entities represents 7.74% of the outstanding shares and voting rights of the Company at the time of statement on Schedule 13D/A. Notably, it follows from the statement on Schedule 13D/A that an aggregate of 20,931,094 ordinary shares are beneficially owned by Valiance Management, which consist of (i) 8,834,387 ordinary shares, and 350,491 ADSs (representing 3,504,910 ordinary shares) held by TopMDx, an exempted closed-ended fund registered in British Virgin Islands of which Valiance Asset Management is the investment manager, and (ii) 8,591,797 ordinary shares held by LSGI Fund, a Luxembourg investment fund of which LSGI GP serves as investment manager. The statement on Schedule 13D/A also specifies that (i) Jan Pensaert, the Founding Managing Partner of Valiance Asset Management, which is affiliated with the Valiance Entities, serves as a member of the Company's board of directors and, in such capacity, may have influence over the corporate activities of the the Company; and (ii) Valiance Management serves as the investment manager of LSGI GP, which is the investment manager of LSGI Fund; however, no agreement exists between Valiance Management and LSGI GP for the purposes of acquiring, holding, voting, or disposing of the equity securities of the Company and, accordingly, the Valiance Entities disclaim the existence of, or membership in, a “group” for purposes of the statement on Schedule 13D/A. The shareholding on a fully diluted basis takes into account the exercise of 80,000 share options for new shares of the Company, held by Valiance Advisors LLP, a Director of the Company and a related person to Valiance Asset Management Limited, TopMDx Limited and Valiance Life Sciences Growth Investments SICAV-SIF.

<sup>(6)</sup> Biovest NV and RMM, S.A. (collectively, the “Biovest Entities”) jointly filed with the SEC a statement on Schedule 13G according to which the aggregate number of shares beneficially owned by the Biovest Entities represents 4.41% of the outstanding shares and voting rights of the Company at the time of statement on Schedule 13G. Notably, it follows from the statement on Schedule 13G that 11,923,587 ordinary shares are held by Biovest NV, which consist of 11,090,257 ordinary shares and 83,333 ADSs. The statement on Schedule 13G also specifies that (i) RMM, S.A. is the sole owner of Biovest NV and pursuant to an understanding with Biovest NV, decisions relating to the voting and dispositive power of the shares are shared between Biovest NV and the board of directors of RMM, S.A., and (ii) voting and investment power over the shares managed by the board of directors is exercised jointly by more than three natural persons and voting and disposition decisions require the approval of a majority of such persons. Accordingly, no single natural person has a controlling decision and no individual director of RMM, S.A. should be deemed to be a beneficial owner of the shares.

No other shareholders, acting alone or in concert with other shareholders, notified the Company of a participation or an agreement to act in concert in relation to 3% or more of the current total existing voting rights attached to the voting securities of the Company.

Each shareholder of the Company is entitled to one vote per share.

## Share capital and shares

On the date of this report, the share capital of the Company amounts to EUR 163,471,629.58 and is fully paid-up. It is represented by 270,380,936 ordinary shares, each representing a fractional value of (rounded) EUR 0.6046 and representing one 270,380,936th of the share capital. The Company's shares do not have a nominal value.

In addition to the outstanding shares, on March 31, 2023, the Company has a number of outstanding options that are exercisable into ordinary shares, consisting of:

- 512,000 outstanding share options issued under the form of subscription rights on 23 June 2014 ("2014 Share Options") (of which 68,500 share options have not yet been granted);
- 1,936,155 outstanding share options issued under the form of subscription rights on 19 June 2017 ("2017 Share Options");
- 2,848,687 outstanding share options issued under the form of subscription rights on 21 June 2019 ("2019 Share Options") (of which 26,500 share options have not yet been granted);
- 3,538,750 outstanding share options issued under the form of subscription rights on 27 May 2021 ("2021 Share Options") (of which 5,000 share options have not yet been granted); and
- 3,685,000 outstanding share options issued under the form of subscription rights on 25 May 2022 ("2022 Share Options") (of which 1,232,500 share options have not yet been granted).

On 23 September 2019, the Company entered into loan agreements with Kreos Capital VI (UK) Limited ("**Kreos Capital**") with respect to a loan facility of up to EUR 9,000,000, which was fully drawn on 1 November 2019. The Company and Kreos Capital agreed that a drawdown fee equal to 7% of the amounts drawn down under the loan agreements (being EUR 630,000 in aggregate) would remain outstanding as a payable (without accruing interest), and would be convertible into ordinary shares by means of a contribution in kind to the share capital of the Company at a price of EUR 0.85 per share (the "**Kreos Convertible Loan Payable**"). As part of the loan and security agreement entered into with Innovatus Life Sciences Lending Fund I, LP ("**Innovatus**"), the Company's loan facility with Kreos Capital was repaid in cash, except that the Kreos Convertible Loan Payable was not repaid, but remains outstanding in accordance with its terms. Should the full amount of the Kreos Convertible Loan Payable be converted into new shares of the Company, by means of a contribution in kind, 741,176 new shares would have to be issued by the Company to the benefit of Kreos Capital.

On 2 August 2022, the Company entered into a USD 70 million loan and security agreement with Innovatus, which also replaced the Company's EUR 9 million debt facility with Kreos Capital. At closing, an amount of USD 35 million was drawn, with an additional USD 35 million remaining available as a USD 20 million term B loan and a USD 15 million term C loan that can be drawn in 2024 and 2025 respectively, subject to certain conditions. The loans are secured by assets of MDxHealth including intellectual property rights. Remaining proceeds of the loans will be used for working capital purposes and to fund general business requirements. The loans accrue interest at a floating per annum rate equal to the sum of (a) the greater of (i) the prime rate published in The Wall Street Journal in the “Money Rates” section or (ii) 4.00%, plus (b) 4.25%, and require interest-only payments for the initial four years. At the election of the Company, a portion of the interest may be payable in-kind by adding an amount equal to 2.25% of the outstanding principal amount to the then outstanding principal balance on a monthly basis until 2 August 2025. The loans mature on 2 August 2027. Under the loan and security agreement, Innovatus has the right to convert (through contribution in kind of the relevant underlying receivables due by the Company), prior to 2 August 2025, up to 15% of the outstanding principal amount of the loans into ADSs of the Company at a 45% premium to the relevant volume-weighted average price before entering into the loan and security agreement, yielding at a conversion price per ADS equal to USD 11.21 (i.e., USD 1.121 by shares on the basis of the ratio of 1 ADS per 10 shares), prior to 2 August 2025 (the "**Innovatus Conversion Right**"). Amounts converted into ADSs of the Company will be reduced from the principal amount outstanding of the loan. The Innovatus debt facility has been accounted for as a hybrid financial instrument which includes a host financial liability as well as an embedded derivative financial instrument being an equity conversion call option at a fixed rate of up to 15% of the aggregate outstanding principal amount through 2 August 2025.

Should the Innovatus Conversion Right be exercised, assuming that the full amount of USD 70,000,000.00 is drawn by the Company under the loan and security agreement with Innovatus before 2 August 2025 and the applicable exchange rate is EUR 1.00 for USD 1.1057 (as published by the ECB on 14 April 2023), 9,366,982 new shares would have to be issued by the Company to the benefit of Innovatus.

On 2 August 2022, the Company entered into an agreement with Genomic Health, Inc. (a subsidiary of Exact Sciences Corporation referred to herein as ("Exact Sciences"), to acquire the GPS test from Exact Sciences. MDxHealth acquired GPS in order to expand its menu of tests targeted into urology and prostate cancer and in order to position the Company as one of the leaders in the urology and prostate cancer space with one of the most comprehensive menus of precision diagnostics. Under the terms of the agreement, the Company acquired the GPS prostate cancer business of Exact Sciences for an aggregate purchase price of up to USD 100 million, of which an amount of USD 25 million was paid in cash and an amount of USD 5 million was settled through the delivery of 691,171 ADSs of the Company, at a price per ADS of USD 7.23. Following the closing, which took place on 2 August 2022, an additional aggregate earn-out amount of up to USD 70,000,000.00 is to be paid by the Company to Exact Sciences upon achievement of certain revenue milestones related to fiscal years 2023 through 2025, with the maximum earn-out payable in relation to 2023 and 2024 not to exceed USD 30,000,000.00 and USD 40,000,000.00, respectively (the "**Exact Sciences Earn-Out Consideration**"). At the option of the Company, amounts reflecting the Exact Sciences Earn-Out Consideration can be settled in cash or through the issuance of additional shares of the Company by contribution in kind of the relevant receivables due by the Company (at an issue price per share valued in function of a volume weighted average trading price of the Company's Shares at the end of the relevant earn-out period), to be delivered in the form of ADSs to Exact Sciences, provided that the aggregate number of shares representing the ADSs held by Exact Sciences shall not exceed more than 5% of the outstanding Shares of the Company. Should the Exact Sciences Earn-Out Consideration be converted into new shares of the Company, by means of a contribution in kind of receivables due by the Company to Exact Sciences up to the Earn-Out Consideration (i.e., USD 70,000,000.00), assuming an issue price per new share equal to EUR 0.309 (i.e., the closing price on 14 April 2023), 204,881,266 new shares would have to be issued by the Company to the benefit of Exact Sciences.

History of share capital

At the end of 2022, the issued capital of MDxHealth amounted to EUR 123,539,165.19 represented by 162,880,936 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 through 31 December 2022. 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 <sup>(7)</sup>	4.80 <sup>(7)</sup>	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
Exercise of Warrants								
May 5, 2017	Capital increase through exercise of warrants	103,813	1.94	1.94	82,811.63	39,844,140.38	83,529,614.08	49,949,408
Private Placement								
Mar. 26, 2018	Capital increase in cash	9,989,881	3.60	3.60	7,968,928.07	47,813,068.45	111,524,257.61	59,939,289
Private Placement								
Oct. 1, 2019	Capital increase in cash	10,589,236	0.85	0.85	8,447,033.56	56,260,102.01	112,078,074.65	70,528,525
Private Placement								
May 15, 2020	Capital increase in cash	20,162,924	0.63	0.63	12,738,632.94	68,998,734.95	112,078,074.65	90,691,449
Private Placement								
Jan. 26, 2021	Capital increase in cash	27,777,777	0.90	0.90	21,133,332.74	90,132,067.69	115,944,741.21	118,469,226
Initial Public Offering Nasdaq								
Nov. 8, 2021	Capital increase	37,500,000 <sup>(1)</sup>	1.04	1.04	28,530,000.00	118,662,067.69	126,480,632.34	155,969,226
Business Combination								
Aug. 11,2022	Capital increase through issuance of shares	6,911,710 <sup>(2)</sup>	0.71	0.71	4,877,097.50	123,539,165.19	126,480,632.34	162,880,936
Per statutory accounts						123,539,165.19	126,480,632.34	162,880,936
Per IFRS consolidated accounts						110,975,364.56	126,480,632.34	162,880,936

<sup>(1)</sup> represented by 3,750,000 American Depositary Shares

<sup>(2)</sup> represented by 691,171 American Depositary Shares

## Authorized capital

### Description of the authorized capital

By virtue of the resolution of the extraordinary general shareholders' meeting of the Company held on 27 May 2021, as published by excerpt in the Annexes to the Belgian Official Gazette of 1 June 2021 under number 21333389, the Board of Directors of the Company has been granted certain powers to increase the Company's share capital in the framework of the authorized capital. The powers under the authorized capital have been set out in Article 6 of the Company's articles of association.

In the framework of this authorization granted by the extraordinary general shareholders' meeting, the Board of Directors is authorized to increase the share capital of the Company on one or several occasions by a maximum aggregate amount of EUR 90,132,067.69 (excluding issue premium, as the case may be), for a period of five years as from 1 June 2021.

The Board of Directors may increase the share capital by contributions in cash or in kind, by capitalization of reserves, whether available or unavailable for distribution, and capitalization of issue premiums, with or without the issuance of new shares, with or without voting rights, that will have the rights as will be determined by the Board of Directors. The Board of

Directors is also authorized to use this authorization for the issuance of convertible bonds or subscription rights, bonds with subscription rights or other securities.

In the event of a capital increase decided by the Board of Directors within the framework of the authorized capital, all issue premiums booked, if any, will be accounted for in accordance with the provisions of the Company's articles of association.

The Board of Directors is authorized, when exercising its powers within the framework of the authorized capital, to restrict or cancel, in the interest of the Company, the preferential subscription rights of the shareholders. This restriction or cancellation of the preferential subscription rights can also be done in favor of members of the personnel of the Company or of its subsidiaries, or in favor of one or more persons other than members of the personnel of the Company or of its subsidiaries.

The Board of Directors is authorized, with the right of substitution, to amend the articles of association, after each capital increase that has occurred within the framework of the authorized capital, in order to bring them in conformity with the new situation of the share capital and the shares.

### *Available amount in the framework of the authorized capital*

As of the date of this report, the Board of Directors has used its powers under the authorized capital on (i) 8 November 2021, by issuing 37,500,000 new shares (3,750,000 ADSs) for an aggregate amount of EUR 28,530,000.00 (excluding issue premium), (ii) 11 August 2022 by issuing 6,911,710 new shares (691,171 ADSs) for an aggregate amount of EUR 4,877,097.50, and (iii) 7 February 2023 and 8 March 2023 by issuing 107,500,000 new shares (10,750,000 ADSs) for an aggregate amount of EUR 39,932,464.39.

As a result, the Board of Directors still has the authority under the authorized capital to increase the share capital of the Company with an aggregate amount of EUR 16,792,505.80 (excluding issue premium, as the case may be).]

## Form and transferability of the shares

The shares of the Company can take the form of registered and dematerialized shares. All the Company's shares are fully paid-up and are freely transferable.

On 2 August 2022, the Company and Exact Sciences entered into an asset purchase agreement (the "**Asset Purchase Agreement**") pursuant to which, among other things and subject to the terms and conditions included in the Asset Purchase Agreement, Exact Sciences agreed to sell and assign, and the Company agreed to purchase and assume, the business of developing, marketing and performing the Oncotype DX Genomic Prostate Score test (the "**GPS Test Business**"). On 11 August 2022, in the framework of the Asset Purchase Agreement, the Board of Directors decided to increase the share capital of the Company within the framework of the authorized capital, with an amount of EUR 4,877,097.50, against the issuance by the Company of 6,911,710 new ordinary shares, to be delivered to Exact Sciences in the form of 691,171 ADSs (on the basis of a ratio of 1 ADS per 10 New Shares), at an issue price per new share of EUR 0.7056, as contemplated by the Asset Purchase Agreement, for the purpose of the settlement of a portion of the purchase price for the GPS Test Business in shares of the Company to be delivered in ADSs, by means of a contribution in kind.

On 27 January 2023, the Board of Directors decided to increase the share capital of the Company within the framework of the authorized capital through the issuance of new shares, the maximum number and the issue price of which still had to be determined, with dis-application of the preferential subscription right of the existing shareholders of the Company and, in so far as required, of the existing holders of subscription rights (share options) of the Company, all or part of the new shares being represented by ADSs, which were to be registered under the United States Securities Act of 1933, as amended and were to be listed on the Nasdaq Capital Market (the number of new shares to be represented by one ADS was still to

be determined). The new shares, represented by ADSs, were to be offered (i) via a public offering to retail and institutional investors in the United States, and (ii) via private placements with qualified, professional, institutional and other investors, as the case may be, in countries and jurisdictions outside of the United States in accordance with applicable securities laws and regulations. On that basis, the Company decided to instruct investment banks to organize, launch and close the public offering of new shares represented by ADSs in the United States. The transaction was launched on 1 February 2023 and, on 3 February 2023, the Company announced the pricing of its public offering in the United States of 10,000,000 ADSs (representing 100,000,000 new shares) at a price of USD 4.00 per ADS for total gross proceeds of USD 40.0 million before deducting underwriting discounts and commissions and estimated offering expenses. The offered shares represented by the ADSs were issued by the Company on 7 February 2023 in the framework of the Offering and were issued pursuant to a capital increase that was decided by the Company's board of directors within the framework of the authorised capital with dis-application of the preferential subscription rights of existing shareholders of the Company and, in so far as required, of existing holders of subscription rights (share options) or ADSs issued by the Company. All of the ADSs were placed at a price of USD 4.00 per ADS, which represents an issue price of USD 0.40 per new share (or EUR 0.37 (rounded) per offered Share based on a conversion rate of USD 1.0776 per EUR).

In the context of the offering, the Company granted the underwriters an option to purchase up to 1,500,000 additional ADSs from the Company for a period ending on the date falling 30 days after 3 February 2023. On 6 March 2023, the Company announced that the Underwriters exercised the Option, on the same terms and conditions as in the offering, in the amount of 7,500,000 shares represented by 750,000 ADSs at a price of USD 4.00 per ADS for gross proceeds of USD 3.0 million. These "option" shares represented by the ADSs were issued by the Company on 8 March 2023 in the framework of the Offering and were issued pursuant to a capital increase that was decided by the Company's board of directors within the framework of the authorised capital with dis-application of the preferential subscription rights of existing shareholders of the Company and, in so far as required, of existing holders of subscription rights (share options) or ADSs issued by the Company. All of the ADSs were placed at a price of USD 4.00 per ADS, which represents an issue price of USD 0.40 per new share (or EUR 0.37 (rounded) per share based on a conversion rate of USD 1.0665 per EUR).

Of the 270,380,936 outstanding shares of the Company, 162,880,936.00 shares have been admitted to listing and trading on the regulated market of Euronext Brussels, while 107,500,000 shares issued in February and March 2023 are still to be admitted to listing and trading on the regulated market of Euronext Brussels pursuant to a listing prospectus.

## Currency

The Company's shares do not have a nominal value, but each reflect the same fraction of the Company's share capital, which is denominated in euro.

## Rights attached to shares

### *Dividend and dividend policy*

All of the shares of the Company entitle the holder thereof to an equal right to participate in dividends in respect of the financial year ending 31 December 2022 and future years. All of the shares participate equally in the Company's profits (if any). Pursuant to the Belgian Companies and Associations Code, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the ordinary general shareholders' meeting, based on the most recent statutory audited financial statements, prepared in accordance with Belgian GAAP and based on a (non-binding) proposal of the Company's Board of Directors. The Belgian Companies and Associations Code and the Company's articles of association also authorize the Board of Directors to declare interim dividends without shareholder approval. The right to pay such interim dividends is, however, subject to certain legal restrictions.

The Company has never declared or paid any cash dividends on its shares. The Company does not anticipate paying cash dividends on its equity securities in the foreseeable future and intends to retain all available funds and any future earnings for use in the operation and expansion of its business.

The Company's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of the Company's stand-alone statutory accounts prepared in accordance with Belgian GAAP. 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, except in exceptional cases, to be disclosed and justified in the notes to the annual accounts, 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, pursuant to Belgian law and the Company's articles of association, the Company must allocate an amount of 5% of its Belgian GAAP annual net profit (nettowinst/bénéfices nets) to a legal reserve in its stand-alone statutory accounts, until the legal reserve amounts to 10% of the Company's share capital. The Company's legal reserve currently does not meet this requirement. Accordingly, 5% of its Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, limiting the Company's ability to pay out dividends to its shareholders.

Under the senior secured loan agreement entered into between with Innovatus and the Company on 2 August 2022, no distributions can be declared or made without consent of Innovatus.

Finally, additional financial restrictions and other limitations may be contained in future credit agreements.

## American Depositary Shares

Following the initial public offering in the United States of 37,500,000 new shares represented by 3,750,000 ADSs closed by the Company on 8 November 2021.

The Bank of New York Mellon, as depositary, registers and delivers the ADSs. Each ADS represents the right to receive 10 shares. ING Belgium SA/NV acts as custodian for the depositary in Belgium. The depositary's principal office is located at 240 Greenwich Street, New York, New York 10286.

An ADS holder is not be treated as one of the Company's shareholders and does not have any shareholder rights. The depositary will be the holder of the shares represented by the ADSs. A holder of ADSs will have ADS holder rights. A deposit agreement among the Company, the depositary and all persons directly and indirectly holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The depositary has agreed to pay ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses.

An ADS holder may surrender its ADSs for the purpose of withdrawal of shares. Upon payment of the depositary's fees and expenses and of any taxes or charges, such as stamp taxes or share transfer taxes or fees, the depositary will deliver the shares and any other deposited securities represented by the ADSs to the ADS holder or a person designated by it at the office of the custodian or through a book-entry delivery.

The ADS holder may instruct the depositary to vote the number of whole deposited shares its ADSs represent. The depositary will notify the ADS holder of shareholders' meetings or other solicitations of consents and arrange to deliver its

voting materials to ADS holders if the Company asks it to in a timely fashion. Those materials will describe the matters to be voted on and explain how the ADS holder may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary.

The depositary will try, as far as practical, and subject to the laws of Belgium and the provisions of the Company's articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders.

### *Preferential Subscription Rights*

In the event of a capital increase for cash with the issue of new shares of the Company, or in the event of an issue of convertible bonds or subscription rights, the existing shareholders have a preferential right to subscribe, pro rata, to the new shares of the Company, convertible bonds or subscription rights. These preferential subscription rights are transferable during the subscription period.

The general shareholders' meeting may decide to limit or cancel this preferential subscription right, subject to special reporting requirements. Such decision by the general shareholders' 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 Companies and Associations Code. As mentioned above, the Board of Directors of the Company has been granted certain powers to increase the Company's share capital in the framework of the authorized capital and to cancel the statutory preferential subscription rights of the shareholders (within the meaning of articles 7:191 and 7:193 of the Belgian Companies and Associations Code). The powers under the authorized capital have been set out in article 6 of the Company's articles of association.

Generally, unless expressly authorized in advance by the general shareholders' meeting, the authorization of the Board of Directors to increase the share capital of the Company through contributions in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to the Company by the FSMA of a public takeover bid on the financial instruments of the Company. The Company's general shareholders' meeting did not grant such express authorization to the Board of Directors.

### *Voting Rights*

Each shareholder of the Company is entitled to one vote per share. Shareholders may vote by proxy, subject to the rules described in the Company's articles of association.

Voting rights can be mainly suspended in relation to shares:

- which are not fully paid up, notwithstanding the request thereto of the Board of Directors of the Company;
- to which more than one person is entitled or on which more than one person has rights in rem (droits réels) on, except in the event a single representative is appointed for the exercise of the voting right vis-à-vis the Company;
- which entitle their holder to voting rights above the threshold of 3%, 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 calendar 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.

Pursuant to the Belgian Companies and Associations Code, the voting rights attached to shares owned by the Company, or a person acting in its own name but on behalf of the Company, or acquired by a subsidiary of the Company, as the case may be, are suspended. Generally, the general shareholders' meeting has sole authority with respect to:

- the approval of the annual financial statements of the Company;
- the distribution of profits (except interim dividends);
- the appointment (at the proposal of the Board of Directors and upon recommendation by the remuneration and nomination committee) and dismissal of Directors of the Company;
- the appointment (at the proposal of the Board of Directors and upon recommendation by the audit committee) and dismissal of the statutory auditor of the Company;
- the granting of release from liability to the Directors and the statutory auditor of the Company;
- the determination of the remuneration of the Directors and of the statutory auditor for the exercise of their mandate;
- the advisory vote on the remuneration report included in the annual report of the Board of Directors, the binding vote on the remuneration policy (which was approved for the first time by the general shareholders' meeting held on 27 May 2021), and subsequently upon every material change to the remuneration policy and in any case at least every four years, and the determination of the following features of the remuneration or compensation of Directors, members of the executive management and certain other executives (as the case may be): (i) in relation to the remuneration of Executive and Non-Executive Directors, members of the executive management and other executives, an exemption from the rule that share based awards can only vest after a period of at least three years as of the grant of the awards, (ii) in relation to the remuneration of Executive Directors, members of the executive management and other executives, an exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years, (iii) in relation to the remuneration of Non-Executive Directors, any variable part of the remuneration (provided, however that no variable remuneration can be granted to Independent Non-Executive Directors), and (iv) any service agreements to be entered into with Executive Directors, members of the executive management and other executives providing for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, eighteen (18) months' remuneration);
- the filing of a claim for liability against Directors;
- the decisions relating to the dissolution, merger and certain other reorganisations of the Company; and
- the approval of amendments to the articles of association.

*Right to attend and vote at general shareholders' meetings*

**ORDINARY GENERAL SHAREHOLDERS' MEETING**

The ordinary general shareholders' meeting is held at the registered office of the Company or at the place determined in the notice convening the general shareholders' meeting. The meeting is held every year on the last Thursday of May at 3:00 p.m. If this day would be a Belgian public holiday, the ordinary general shareholders' meeting shall be held on the previous business day. At the ordinary general shareholders' meeting, the Board of Directors submits to the shareholders the audited non-consolidated and consolidated annual financial statements and the reports of the Board of Directors and of the statutory auditor with respect thereto.

The general shareholders' meeting then decides on the approval of the statutory annual financial statements, the proposed allocation of the Company's profit or loss, the release from liability of the directors and the statutory auditor, the approval of the remuneration report included in the annual report of the Board of Directors (it being understood that the vote on the remuneration report is only an advisory vote and that the Company must explain in the remuneration report of the

subsequent financial year how it took into account the advisory vote of the general shareholders' meeting of the previous financial year), of the remuneration policy (as the case may be), and, when applicable, the (re-)appointment or dismissal of the statutory auditor and/or of all or certain directors. In addition, as relevant, the general shareholders' meeting must also decide on the approval of the remuneration of the directors and statutory auditor for the exercise of their mandate, and on the approval of provisions of service agreements to be entered into with executive directors, members of the executive management and other executives providing (as the case may be) for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, 18 months' remuneration).

**SPECIAL AND EXTRAORDINARY GENERAL SHAREHOLDERS' MEETINGS**

The Board of Directors or the statutory auditor (or the liquidators, if appropriate) may, whenever the interest of the Company so requires, convene a special or extraordinary general shareholders' meeting. Such general shareholders' meeting must also be convened every time one or more shareholders holding, alone or together, at least 10% of the Company's share capital so request. Shareholders that do not hold at least 10% of the Company's share capital do not have the right to have the general shareholders' meeting convened.

**RIGHT TO PUT ITEMS ON THE AGENDA OF THE GENERAL MEETING AND TO TABLE DRAFT RESOLUTIONS**

Shareholders who hold alone or together with other shareholders at least 3% of the Company's share capital have the right to put additional items on the agenda of a general shareholders' meeting that has been convened and to table draft resolutions in relation to items that have been or are to be included in the agenda. This right does not apply to general shareholders' meetings that are being convened on the grounds that the quorum was not met at the first duly convened meeting. Shareholders wishing to exercise this right must prove on the date of their request that they own at least 3% of the outstanding share capital. The ownership must be based, for dematerialised shares, on a certificate issued by the applicable settlement institution for the shares concerned, or by a certified account holder, confirming the number of shares that have been registered in the name of the 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 register for the meeting concerned with at least 3% of the outstanding share capital. 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 new draft resolution, the text of the draft resolution. The request must reach the Company at the latest on the twenty-second calendar day preceding the date of the general shareholders' meeting concerned. If the Company receives a request, it will have to publish at the latest on the fifteenth calendar day preceding the general shareholders' meeting an update of the agenda of the meeting with the additional agenda items and draft resolutions.

**NOTICES CONVENING THE GENERAL MEETING**

The notice convening the general shareholders' meeting must state the place, date and hour of the meeting and must include an agenda indicating the items to be discussed and the proposed resolutions. The notice must, as the case may be, include the proposal of the audit committee to nominate a statutory auditor responsible for auditing the consolidated financial statements. The notice also needs to contain a description of the formalities that security holders must fulfil in order to be admitted to the general shareholders' meeting and (as the case may be) exercise their voting right, information on the manner in which shareholders can put additional items on the agenda and table draft resolutions, information on the manner in which security holders can ask questions during the general shareholders' meeting and prior to the meeting via the Company's email address or a specific email address mentioned in this notice, information on the procedure to participate to the general shareholders' meeting by means of a proxy or to vote by means of a remote vote, and, as applicable, the registration date for the general shareholders' meeting. The notice must also mention where shareholders can obtain a copy of the documentation that will be submitted to the general shareholders' meeting, the agenda with the proposed resolutions

or, if no resolutions are proposed, a commentary by the Board of Directors, updates of the agenda if shareholders have put additional items or draft resolutions on the agenda, the forms to vote by proxy or by means of a remote vote, and the address of the webpage on which the documentation and information relating to the general shareholders' meeting will be made available. This documentation and information, together with the notice and the total number of outstanding voting rights, must also be made available on the Company's website at the same time as the publication of the notice convening the meeting, for a period of five years after the relevant general shareholders' meeting. If shares are held by an intermediary on behalf of a shareholder of the Company, the relevant intermediary is required to transmit the following information, without delay, from the Company to the shareholder: (a) the information which the Company is required to provide to the shareholder, to enable the shareholder to exercise rights attached to its shares, and which is directed to all shareholders in shares of that class; or (b) where the information referred to in point (a) is available to shareholders on the website of the Company, a notice indicating where on the website that information can be found, unless the Company provides this information directly to the shareholder.

The notice convening the general shareholders' meeting has to be published at least 30 calendar days prior to the general shareholders' meeting in the Belgian Official Gazette, in a newspaper that is published nation-wide in Belgium, in paper or electronically, in media that can be reasonably relied upon for the dissemination of information within the EEA in a manner ensuring fast access to such information on a non-discriminatory basis, and on the Company's website. A publication in a nation-wide newspaper is not needed for ordinary general shareholders' meetings taking place on the date, hour and place indicated in the articles of association of the Company if the agenda is limited to the treatment and approval of the financial statements, the annual report of the Board of Directors, the report of the statutory auditor, the remuneration report, the severance pay for executive directors, and the discharge from liability of the directors and statutory auditor. In addition to this publication, the notice has to be distributed at least 30 calendar days prior to the meeting via the normal publication means that the Company uses for the publication of press releases and regulated information. The term of 30 calendar days prior to the general shareholders' meeting for the publication and distribution of the convening notice can be reduced to 17 calendar days for a second meeting if, as the case may be, the applicable quorum for the meeting is not reached at the first meeting, the date of the second meeting was mentioned in the notice for the first meeting and no new item is put on the agenda of the second meeting.

At the same time as its publication, the convening notice must also be sent to the holders of registered shares, holders of registered convertible bonds, holders of registered subscription rights, holders of registered certificates issued with the co-operation of the Company (if any), and, as the case may be, to the directors and statutory auditor of the Company. This communication needs to be made by e-mail unless the addressee has informed the Company that it wishes to receive the relevant documentation by another equivalent means of communication. If the relevant addressee does not have an e-mail address or if it did not inform the Company thereof, the relevant documentation will be sent by ordinary mail.

**FORMALITIES TO ATTEND THE MEETING**

All holders of shares, profit-sharing certificates, non-voting shares, convertible bonds, subscription rights or other securities issued by the Company, as the case may be, and all holders of certificates issued with the co-operation of the Company (if any) can attend the general shareholders' meetings insofar as the law or the articles of association entitles them to do so and, as the case may be, gives them the right to participate in voting.

In order to be able to attend a general shareholders' meeting, a holder of securities issued by the Company must satisfy two criteria: being registered as holder of securities on the registration date for the meeting, and notify the Company:

- Firstly, the right to attend general shareholders' meetings applies only to persons who are registered as owning securities on the fourteenth calendar day prior to the general shareholders' meeting at midnight (Belgian time) 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 (for dematerialized securities or securities in book-entry form).

- Secondly, in order to be admitted to the general shareholders' meeting, securities holders must notify the Company at the latest on the sixth calendar day prior to the general shareholders' meeting whether they intend to attend the meeting and indicate the number of shares in respect of which they intend to do so. For the holders of dematerialized securities or securities in book-entry form, the notice should include a certificate confirming the number of securities that have been registered in their name on the record date. The certificate can be obtained by the holder of the dematerialized securities or securities in book-entry form with the certified account holder or the applicable settlement institution for the securities concerned.

The formalities for the registration of securities holders, and the notification of the Company must be further described in the notice convening the general shareholders' meeting.

**Electronic participation**

The Board of Directors has the possibility to organize the general shareholders' meeting by means of electronic communication which must (i) allow the Company to verify the capacity and identity of the shareholders using it; (ii) at least enable (a) the securities holders to directly, simultaneously and continuously follow the discussions during the meeting and (b) the shareholders to exercise their voting rights on all points on which the general shareholders' meeting is required to take a decision; and (iii) allow the securities holders to actively participate to the deliberations and to ask questions during the meeting.

**Voting by proxy or remote voting**

Each shareholder has, the right to attend a general shareholders' meeting and to vote at the general shareholders' meeting in person or through a proxy holder, who need not be a shareholder. A shareholder may designate, for a given meeting, only one person as proxy holder, except in circumstances where Belgian law allows the designation of multiple proxy holders. The appointment of a proxy holder may take place in paper form or electronically (in which case the form shall be signed by means of an electronic signature in accordance with applicable Belgian law), through a form which shall be made available by the Company. The signed original paper (handwritten) or electronic form must be received by the Company at the latest on the sixth calendar day preceding the meeting. The appointment of a proxy holder must be made in accordance with the applicable rules of Belgian law, including in relation to conflicts of interest, the keeping of a register and other transparency requirements.

The notice convening the meeting may allow shareholders to vote remotely in relation to the general shareholders' meeting, by sending a paper form or, if specifically allowed in the notice convening the meeting, by sending a form electronically (in which case the form shall be signed by means of an electronic signature in accordance with applicable Belgian law). These forms shall be made available by the Company. The original signed paper form must be received by the Company at the latest on the sixth calendar day preceding the date of the meeting. Voting through the signed electronic form may occur until the last calendar day before the meeting.

The Company may also organize a remote vote in relation to the general shareholders' meeting through other electronic communication methods, such as, among others, through one or several websites. The Company shall specify the practical terms of any such remote vote in the convening notice.

When votes are cast electronically, an electronic confirmation of receipt of the votes is sent to the relevant shareholders that cast the vote. After the general shareholders' meeting, shareholders can obtain, at least upon request (which must be made no later than three months after the vote), the confirmation that their votes have been validly recorded and taken into account by the Company, unless that information is already available to them. If an intermediary receives such confirmation, it must transmit it without delay to the shareholder.

Holders of securities who wish to be represented by proxy or vote remotely must, in any case comply with the formalities to attend the meeting. Holders of shares without voting rights, profit-sharing certificates without voting rights, convertible bonds, warrants or certificates issued with the cooperation of the Company may attend the general shareholders' meeting but only with an advisory vote.

Quorum and majorities

In general, there is no attendance quorum requirement for a general shareholders' meeting and decisions are generally passed with a simple majority of the votes of the shares present or 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 Companies and Associations Code do not only require the presence or representation of at least 50% of the share capital of the Company but also a majority of at least 75% of the votes cast. An amendment of the Company's corporate purpose requires the approval of at least 80% of the votes cast at a general shareholders' meeting, which can only validly pass such resolution if at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, are present or represented. In the event where the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second general shareholders' meeting may validly deliberate and decide regardless of the number of shares present or represented. The special majority requirements, however, remain applicable.

Right to ask questions

Within the limits of article 7:139 of the Belgian Companies and Associations Code, security holders have a 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 general shareholders' meeting. However, directors may, in the interest of the Company, refuse to answer questions when the communication of certain information or facts is likely to cause prejudice to the Company or is contrary to the obligations of confidentiality entered into by them or by the Company.

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 to the statutory auditor must be submitted to the Company at the same time. The statutory auditor may, in the interest of the Company, refuse to answer questions when the communication of certain information or facts is likely to cause prejudice to the Company or is contrary to its professional secrecy or to obligations of confidentiality entered into by the Company. The statutory auditor has the right to speak at the general meeting in connection with the performance of its duties.

Written and oral questions will be answered during the meeting concerned in accordance with applicable law. In addition, in order for written questions to be considered, the shareholders who submitted the written questions concerned must comply with the formalities to attend the meeting.

Information that has an impact in case of public takeover bids

The Company provides the following information in accordance with article 34 of the Belgian Royal Decree dated 14 November 2007:

- (i) The share capital of the Company amounts to EUR 163,471,629.58 and is fully paid-up. It is represented by 270,380,936 ordinary shares, each representing a fractional value of (rounded) EUR 0.6046 and representing one 270,380,936th of the share capital. The Company's shares do not have a nominal value.
- (ii) Other than the applicable legislations on the disclosure of significant shareholdings and the Company's articles of association, there are no restrictions on the transfer of shares.
- (iii) There are no holders of any shares with special control rights.
- (iv) There are no share option plans for members of the personnel other than the share option plans disclosed elsewhere in this report. These share option plans contain provisions on accelerated vesting in case of change of control.
- (v) Each shareholder of the Company is entitled to one vote per share. Voting rights may be suspended as provided in the Company's articles of association and the applicable laws and articles.
- (vi) There are no agreements between shareholders which are known by the Company that may result in restrictions on the transfer of securities and/or the exercise of voting rights.
- (vii) The rules governing appointment and replacement of Board members and amendment to articles of association are set out in the Company's articles of association and the Company's Corporate Governance Charter.
- (viii) The powers of the Board of Directors, more specifically with regard to the power to issue or redeem shares are set out in the Company's articles of association. The Board of Directors was not granted the authorization to purchase its own shares "to avoid imminent and serious danger to the Company" (i.e., to defend against public takeover bids). The Company's articles of association of association do not provide for any other specific protective mechanisms against public takeover bids.
- (ix) At the date of this report, the Company is a party to the following significant agreements which, upon a change of control of the Company or following a takeover bid can enter into force or, subject to certain conditions, as the case may be, can be amended, be terminated by the other parties thereto or give the other parties thereto a right to an accelerated repayment of outstanding debt obligations of the Company under such agreements:

- The loan and security agreement that was entered into by the Company and Innovatus on 2 August 2022 provides that in case of change of control, without prior approval by Innovatus, the loan facility will immediately terminate and cease to be available for further use and all loans, accrued interest and other amounts owed by the Company under the loan agreement will become immediately due and payable;
- The trademark license agreement that was entered into by the Company, Genomic Health, Inc. and Exact Sciences Corporation on 2 August 2022, in the framework of the Asset Purchase Agreement entered into by the Company and Exact Sciences on 2 August 2022, which provides that in case of change of control, Genomic Health, Inc. and Exact Sciences Corporation may terminate the license agreement immediately on written notice to the Company;
- In addition, the Company's share option plans provide for an accelerated vesting of the subscription rights in case of a change of control event.

No takeover bid has been instigated by third parties in respect of the Company's equity during the current financial year.

## Notification of significant shareholdings

Pursuant to the Belgian Act of 2 May 2007 on the disclosure of significant shareholdings in issuers whose securities are admitted to trading on a regulated market and containing various provisions, as amended from time to time (the "**Belgian Transparency Act**"), a notification to the Company and to the FSMA is required by all natural persons and legal entities (i.e. legal person, enterprise without legal personality, or trust), in the following circumstances:

- an acquisition or disposal of voting securities, voting rights or financial instruments that are treated as voting securities;
- the reaching of a threshold by persons or legal entities acting in concert;
- the conclusion, modification or termination of an agreement to act in concert;
- the downward reaching of the lowest threshold;
- the passive reaching of a threshold;
- the holding of voting securities in the Company upon first admission thereof to trading on a regulated market;
- where a previous notification concerning the financial instruments treated as equivalent to voting securities is updated;
- the acquisition or disposal of the control of an entity that holds voting securities in the Company; and
- where the Company introduces additional notification thresholds in the articles of association,

in each case where the percentage of voting rights attached to the securities held by such persons reaches, exceeds or falls below the legal threshold, set at 5% of the total voting rights, and 10%, 15%, 20% and so on in increments of 5% or, as the case may be, the additional thresholds provided in the articles of association. The Company has provided for an additional threshold of 3% in its articles of association.

The notification must be made promptly and at the latest within four trading days following the moment on which the person who is subject to the notification obligation received knowledge or could be deemed to have received knowledge of the acquisition or disposal of the voting rights triggering the reaching of the threshold. Where the Company receives a notification of information regarding the reaching of a threshold, it has to publish such information within three trading days following receipt of the notification. Subject to certain exceptions, no shareholder may, pursuant to article 25/1 of the Belgian Transparency Act, cast a greater number of votes at a general shareholders' meeting of the Company than those attached to the rights and securities that it has notified in accordance with the aforementioned disclosure rules at least 20 calendar days prior to the date of the general shareholders' meeting.

The forms on which such notifications must be made, as well as further explanations, can be found on the website of the FSMA ([www.fsma.be](http://www.fsma.be)). Violation of the disclosure requirements may result in the suspension of voting rights, a court order to sell the securities to a third party and/or criminal liability. The FSMA may also impose administrative sanctions. The Company is required to publicly disclose any notifications received regarding increases or decreases in a shareholder's ownership of the Company's securities, and must mention these notifications in the notes to its financial statements. A list as well as a copy of such notifications will be accessible on the Company's website ([www.mdxhealth.com](http://www.mdxhealth.com)).

The obligation to disclose significant shareholdings as well as certain other provisions of Belgian law (e.g. merger control, authorized capital and the requirement to have certain change of control clauses approved by an extraordinary shareholders' meeting) that may apply to the Company, may make an unsolicited tender offer, merger, change in management or other change in control, more difficult. Such provisions could discourage potential takeover attempts that third parties may consider and that other shareholders may consider to be in their best interest and could adversely affect the market price of the shares and ADSs. These provisions may also deprive shareholders of the opportunity to sell their shares and ADSs at a premium (which is typically offered in the context of a takeover bid).

In accordance with U.S. federal securities laws, holders of shares and holders of ADSs will be required to comply with disclosure requirements relating to their ownership of the Company's securities. Any person that, after acquiring beneficial ownership of shares or ADSs, is the beneficial owners of more than 5% of shares or shares underlying ADSs must file with the SEC a Schedule 13D or Schedule 13G, as applicable, disclosing the information required by such schedules, including the number of shares or shares underlying ADSs that such person has acquired (whether alone or jointly with one or more other persons). In addition, if any material change occurs in the facts set forth in the report filed on Schedule 13D (including a more than 1% increase or decrease in the percentage of the total shares beneficially owned), the beneficial owner must promptly file an amendment disclosing such change.



## Statutory auditor

Services performed by the auditor and performance of exceptional activities or execution of special instructions (article 3:65 Belgian Companies and Associations Code)

BDO Réviseurs d'Entreprises. SRL, a limited liability company (*société à responsabilité limitée/besloten vennootschap*) organized and existing under the laws of Belgium, with registered office at Da Vincilaan 9, 1930 Zaventem, Belgium, was re-appointed on 27 May 2020 as the statutory auditor of the Company for a term of 3 years ending immediately after the closing of the ordinary general shareholders' meeting to be held in 2024. Mr. Bert Kegels is the permanent representative of the statutory auditor of the Company.

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 \$471,766 (€444,475) in fees to the auditor in 2022. The fees are broken down as follows:

- Audit fee for statutory and consolidated financials of \$238,500 (€225,775)
- Other audit fees: \$191,455 (€179,500)
- Audit related and other services \$41,181 (€39,200)

# Remuneration report

The following remuneration report has been prepared by the nomination and remuneration committee and approved by the Board of Directors of MDxHealth on 24 April 2023. This remuneration report is part of the Corporate Governance Statement, which is part of the Company's annual report of the Board of Directors on the statutory accounts for the financial year ended on 31 December 2022 in accordance to in article 3:6, §3 of the Belgian Companies and Associations Code (the “Remuneration Report”). The Company has reviewed the remuneration policy of its management, Executive and Non-Executive Directors in light of article 3:6 of the Belgian Companies and Associations Code, as supplemented by the relevant provisions of the 2020 Code, and has prepared this Remuneration Report in accordance with the requirements contained therein.

## Introduction

In accordance with article 3:6, §3 of the Belgian Companies and Associations Code, the Company prepared this remuneration report in order to provide an overview of the remuneration, including all benefits granted or due during the financial year ended on 31 December 2022 to each of the Directors and members of the executive management team, including newly recruited officers and former officers, in accordance with the Company's remuneration policy.

The remuneration for Non-Executive Directors was modified at a special general shareholders' meeting of 30 July 2020. In addition, the ordinary general shareholders' meeting held on 27 May 2021 approved an increase of the the additional maximum annual fixed remuneration of the chair of the Board of Directors from EUR 31,000.00 (ca. USD 36,673) to EUR 59,500.00 (ca. USD 70,388) (all amounts being exclusive of VAT and similar charges), effective as from 1 July 2021. 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.

In accordance with article 7:89/1 of the Belgian Companies and Associations Code, listed companies must establish a remuneration policy with respect to Directors, other officers and delegates for day-to-day management. This article details the objectives of, as well as the information that needs to be included in, the remuneration policy. The remuneration policy must be approved by a binding vote of the general shareholders' meeting and must be submitted to the general shareholders' meeting for approval whenever there is a material change and in any case at least every four years. In view hereof, in accordance with article 7:89/1 of the Belgian Companies and Associations Code, the shareholders approved a new remuneration policy that the Board of Directors submitted to the ordinary general shareholders' meeting held on 27 May 2021.

No significant change to the remuneration policy is envisaged for 2023 or the following accounting years. However, the Company will continuously review the remuneration of Directors and executive managers against market practice. The Company's current remuneration policy is based on meritocracy and a sense of ownership and is designed to reward performance in order to motivate members of the board of directors and the executive management of the Company in order to deliver increased shareholder value through superior business results.

This remuneration report will be submitted to a vote by the ordinary general shareholders' meeting.

## Procedure adopted in 2022 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 subscription rights to Non-Independent Non-Executive Directors were 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. The number of subscription rights granted in the past to Non-Executive Directors (including Independent Directors) has remained low compared to the number of total outstanding security instruments. Non-Executive Directors (including Independent 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 ordinary 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 executive 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 subscription rights, 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 subscription rights 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.

## Directors' remuneration in 2022

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.

The Directors' remuneration was last modified at the ordinary general shareholders' meeting of 27 May 2021.

### Independent Non-Executive Directors

Following the modification of the Directors' remuneration on 30 July 2020, effective as from 1 July 2020, and the modification of the remuneration of the chair of the Board of Directors on 27 May 2021, effective as from 1 July 2021, the Independent Non-Executive Directors are remunerated on the basis of a pre-defined fixed annual retainer fee as follows:

- EUR 35,000.00 (USD 36,872.50) <sup>1</sup> base fee for each Non-Executive Director;
- In addition to the base fee, the following fees apply:
  - EUR 59,500.00 (USD 62,683.25) for the chair of the Board of Directors;
  - EUR 17,500.00 (USD 18,436.25) for the chair of the audit committee;
  - EUR 9,000.00 (USD 9,481.50) for the members of the audit committee (other than the chair of the committee);
  - EUR 17,500.00 (USD 18,436.25) for the chair of the nomination and remuneration committee; and
  - EUR 5,500.00 (USD 5,794.25) for the members of the nomination and remuneration committee (other than the chair of the committee).

The foregoing additional remuneration amounts are in addition to the base fee and can be combined, depending on whether the applicable eligibility criteria have been met. The remuneration can be reduced pro rata temporis depending on the duration of the mandate, chairpersonship or membership of a Director during a given year.

This fee structure was proposed by the nomination and remuneration committee on the basis of a bench-mark study that was carried out in 2020 and is in line the existing market practices. The Company's Board of Directors considers that it contributes to the long-term performance of the company.

### Non-Independent Non-Executive Directors

Following the modification of the Directors' remuneration on 30 July 2020, effective as from 1 July 2020, the Non-Executive Directors that are not Independent Directors shall not be entitled to a remuneration in cash, but shall each year be entitled to receive share options for a maximum of 10,000 shares of the Company.

This is contrary to provision 7.6 of the 2020 Code, which provides that no share options should be granted to Non-Executive Directors. The Company believes that this provision of the 2020 Code is not appropriate and adapted to take into account the

realities of companies in the biotech and life sciences industry. Notably, the ability to remunerate Non-Executive Directors with share options allows the Company to limit the portion of remuneration in cash that the Company would otherwise need to pay to attract or retain renowned experts with the most relevant skills, knowledge and expertise. The Company is of the opinion that granting Non-Independent Non-Executive Directors the opportunity to be remunerated in part in share-based incentives rather than all in cash enables the Non-Independent Non-Executive Directors to link their effective remuneration to the performance of the Company and to strengthen the alignment of their interests with the interests of the Company's shareholders. The Company believes that this is in the interest of the Company and its stakeholders. Furthermore, the Company believes that this is customary for Directors active in companies in the life sciences industry.

Furthermore, as the Company currently does not hold any of its own shares as treasury stock and does not have the ability to acquire its own shares, in 2022, Non-Executive Directors did not receive a part of their remuneration in the form of shares of the Company. Even though this deviates from provision 7.6 of the 2020 Code, the Company's Board of Directors considers that this remuneration contributes to aligning the interests of the Non-Independent Non-Executive Directors with those of MDxHealth, amongst other things, by involving them in the risks and prospects of its activities in a long-term perspective. Their remuneration contributes to MDxHealth's long-term performance.

### Non-Executive Directors

Apart from the above remuneration, Non-Executive Directors are entitled to a reimbursement of out-of-pocket expenses actually incurred to participate to Board meetings.

The mandate of Non-Executive Directors can be terminated at any time without any compensation. Non-Executive Directors do not receive any form of pension plan benefits from the Company. The Company has not made any loans to the members of the Board of Directors.

### Executive Directors

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

### All Directors

- Relative importance of the components of remuneration: The relative importance of the various components of remuneration of the Directors as referred to in article 3:6, §3, indent. 3, 1°, b) of the Belgian Companies and Associations Code, is provided below under the "Remuneration earned by the Directors for the reported year" section of this remuneration report.
- No deviation from the remuneration, as decided by the general shareholders' meetings held on 30 July 2020 and 27 May 2021: During the course of 2022, the Company has not deviated from its remuneration for Directors. The total remuneration of the Board of Directors (excluding the Executive Director who is only remunerated for his role as CEO) in 2022 and 2021 was of EUR 313,000 (USD 333,000) and EUR 261,000 (USD 302,000) respectively (excluding VAT, share-based compensation and expenses reimbursement).

- Insurances: On 23 May 2006, the Board of Directors decided, with application of the old article 523 of the Belgian Company Code (article 7:96 of the Belgian Companies and Associations Code), that the Company would indemnify the Directors against any claim by a third party based on Directors' liability, except in the event of gross negligence and willful misconduct. Therefore, the Company has taken out Directors' liability insurance.

The insurance policy was renewed in 2022. 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.

- No possibility to recover variable remuneration: Once paid, the Company does not have the ability to recover the variable part of the remuneration of the Directors.

Remuneration earned by the Directors for the reported year

The following table provides the 2022 compensation of the Directors in function during 2022:

Name <sup>1</sup>	Position <sup>2</sup>	Pro-rata of annual retainer fee (€K)	Other services (€K)	Total (€K)
Mr. Koen Hoffman	INED – Board Chair, Member NRC	100	2	102
Dr. Eric Bednarski	NED – Member NRC	0	0	0
Mr. Michael K. McGarrity	ED – CEO	0 <sup>3</sup>	0 <sup>3</sup>	0 <sup>3</sup>
Dr. Regine Slagmulder	INED – Chair AC	53	6	59
Mr. Jan Pensaert	NED – member NRC	0	10	10
Dr. Lieve Verplancke	INED – member AC and NRC	50	2	52
Ms. Hilde Windels	INED – member AC	44	2	47
Mr. Donnie M. Hardison Jr.	INED – Chair NRC	67	4	71

Notes:

<sup>1</sup>: Mr. Koen Hoffman serves on the Board as a permanent representative of Ahok BV. Mr. Jan Pensaert serves on the Board as a permanent representative of Valiance Advisors LLP. Dr. Lieve Verplancke serves on the Board as a permanent representative of Qaly-Co BV. Ms. Hilde Windels serves on the Board as a permanent representative of Hilde Windels BV. Dr. Regine Slagmulder serves on the Board as a permanent representative of Regine Slagmulder BV.

<sup>2</sup>: “NED” = Non-Executive Director, “AC” = Audit Committee, “NRC” = Nomination & Remuneration Committee, “INED” = Independent Non-Executive Director, “ED” = Executive Director.

<sup>3</sup>: As CEO and Executive Director, Mr. McGarrity did not receive any remuneration for his position as a Director in 2022. Executive Directors are only remunerated for their role as executive managers. The remuneration of Mr. McGarrity as CEO is further described in the section “Executive management's remuneration in 2022” of this remuneration report.

Executive management's remuneration in 2022

Each member of 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 and each of the other members of executive management has a fixed remuneration and a variable bonus linked to the performance of the Company. 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 by the Company. The performance objectives of executive management, including the CEO, are primarily evaluated with regard to objective criteria established each year by nomination and remuneration committee of the Board of Directors. The various objectives and their weighting may differ for the individual managers. The nomination and remuneration committee 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. In addition, members of executive management may also be granted subscription rights. This policy contributes to aligning the interests of the members of executive management with those of MDxHealth, amongst other things, by involving them in the risks and prospects of its activities in a long-term perspective. Their remuneration contributes to MDxHealth's long-term performance.

Each member of 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 2022, all the members of executive management were engaged on the basis of an employment contract. The employment contracts are generally for an indefinite term. 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 below). 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 managers 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.

The relative importance of the various components of remuneration of the members of executive management as referred to in article 3:6, §3, indent. 3, 1°, b) of the Belgian Companies and Associations Code, is provided below under the “Remuneration earned by the CEO for the reported year”, “Remuneration earned by other executive managers for the reported year” sections of this remuneration report.

During the course of 2022, the Company has not deviated from its executive management's remuneration policy.

Remuneration earned by the CEO for the reported year

Mr. McGarrity is remunerated on the basis of his executive management position. As CEO, as of December 31, 2022, Mr. McGarrity was entitled to a gross annual base salary of USD 535,000, which will be reviewed by the Board of Directors (or the nomination and remuneration committee) on an annual basis, and an annual bonus of up to 60% of the then applicable base salary. Furthermore, Mr. McGarrity is entitled to a reimbursement of expenses, and he and his dependents are eligible to participate in all group health, medical, dental, disability and insurance plans, incentive, savings and retirement plans, and other employee benefits that are established by the Company for its executives.

Excluding the value of subscription rights, the remuneration and benefits provided to the CEO in 2022 were composed as follows:

	Euro (€)	\$ equivalent	Relative importance (%)
Fixed gross remuneration <sup>1</sup>	€420,102	\$442,576	78.76%
Bonuses paid and awarded <sup>2</sup> (gross)	€47,461	\$50,000	8.90%
Pension benefits	€15,577	\$16,411	2.92%
Other benefits <sup>3</sup>	€50,256	\$52,945	9.42%
<b>Total</b>	<b>€533,396</b>	<b>\$561,932</b>	<b>100%</b>

Notes:

- <sup>1</sup>: Total cost to the Company, including employer social security contributions and vacation pay accrual.
- <sup>2</sup>: Excludes value of 1,000,000 subscription rights already created, issued, and accepted in 2022 under the Company's 2022 Share Option Plan.
- <sup>3</sup>: Includes Company-paid and other similar benefits, such as the employer's payroll taxes, meal tickets and health insurances. Excludes reimbursement of normal professional expenses such as telephone and Company travel expenses.

Remuneration earned by other executive managers for the reported year

The 2022 combined remuneration package of the other executive management team members in office in 2022 (excluding the CEO) - i.e. John Bellano, Joseph Sollee and Ron Kalfus - including employer taxes, was EUR 1,190,210.

	Euro (€)	\$ equivalent	Relative importance (%)
Fixed gross remuneration <sup>1</sup>	€931,897	\$981,754	77.9%
Bonuses paid and awarded <sup>2</sup> (gross)	€71,653	\$75,486	6.0%
Pension benefits	€35,439	\$37,336	3.0%
Other benefits <sup>3</sup>	€157,456	\$165,880	13.2%
<b>Total</b>	<b>€1,196,445</b>	<b>\$1,260,456</b>	<b>100%</b>

Notes:

- <sup>1</sup>: Includes employer taxes and vacation pay accrual. Excludes VAT.
- <sup>2</sup>: Excludes value of subscription rights already created, issued, and accepted in 2022 by certain other executive managers under the Company's 2022 Share Option Plan.
- <sup>3</sup>: 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 2022 and 2021 was EUR 1,723,606 (USD 1,815,819) and EUR 1,526,037 (USD 1,814,834) (gross amount, excluding VAT and share based compensation).

The primary performance objectives for the bonuses of the above executive managers in 2022 were set as a team, applicable equally to each member of the team, and based on the performance of the Company, as follows:

- respect of the Board-approved annual budget, with a focus on cash-flow management
- meeting measurable operational targets, including total revenues, unit volumes for the Confirm mdx test, revenues attributable to the Company's UTI testing solution, and achievement of Medicare reimbursement for the Select mdx test.

Each of these foregoing targets was based on minimum percentage attainment of defined, objective outcomes for the full calendar year, with the revenue, cash flow and unit volume targets tied to items that are reviewed by the Company's independent auditors in the ordinary course. Additionally, each performance target was assigned a pre-defined weighting as a percentage of the bonus eligibility applicable to each member of executive management, with the CEO being treated consistently with other members of the executive management team. In its assessment of executive management's performance against these established objectives for 2022, the nomination and remuneration committee of the Board of Directors did not deviate from the targets as established in advance for the calendar year – with the Board determining that certain targets were not met, while others were partially obtained in accordance with their terms.

Special provisions of the contractual relationship with the executive management

Each of the executive managers has a contractual employment agreement.

The Company hired Mr. Michael K. McGarrity, acting in the role of Chief Executive Officer, effective as of 18 February 2019. The executive employment agreement with Mr. McGarrity provides that if the Company terminates the employment agreement without cause or if Mr. McGarrity resigns for good reason, Mr. McGarrity shall be eligible to receive as severance an amount equal to twelve (12) months of base salary in effect at the time of the separation. In addition, the Company has the right, exercisable at any time, to terminate the executive employment agreement with immediate effect, for cause (as defined in the employment agreement) or without cause at its discretion (subject to a severance notice or payment in line with market standards), by providing written notice.

Acting under the direction of the Board, the Company hired Mr. Ron Kalfus, acting in the role of Chief Financial Officer, effective as of 22 July 2019. The employment agreement with Mr. Kalfus provides that if the Company terminates the employment agreement without cause or if Mr. Kalfus resigns for good reason, Mr. Kalfus shall be eligible to receive as severance an amount equal to six months of base salary in effect at the time of the separation, which amount was automatically increased to twelve (12) months of base salary after 22 July 2020. In addition, the Company has the right, exercisable at any time, to terminate the executive employment agreement with immediate effect, for cause (as defined in the employment agreement) or without cause at its discretion (subject to a severance notice or payment in line with market standards), by providing written notice.

Acting under the direction of Board, the Company hired Mr. John Bellano, acting in the role of Chief Commercial Officer, effective as of 19 June 2019. The employment agreement with Mr. Bellano provides that if the Company terminates the employment agreement without cause or if Mr. Bellano resigns for good reason, Mr. Bellano shall be eligible to receive as severance an amount equal to six months of base salary in effect at the time of the separation, which amount was automatically increased to twelve (12) months of base salary after 19 June 2020. In addition, the Company has the right, exercisable at any time, to terminate the executive employment agreement with immediate effect, for cause (as defined in the employment agreement) or without cause at its discretion (subject to a severance notice or payment in line with market standards), by providing written notice.

The employment contract with Mr. Joe Sollee dates from before the entry into force of the law of 6 April 2010 on corporate governance in public and listed companies and is in conformity with common employment law. The contract with Mr. Sollee provides that if his employment is terminated for a reason other than serious misconduct or if Mr. Sollee resigns for good reason, he will be entitled to a severance pay of nine (9) months gross remuneration and benefits. In addition, the Company has the right, exercisable at any time, to terminate the executive employment agreement with immediate effect, for cause (as defined in the employment agreement) or without cause at its discretion (subject to a severance notice or payment in line with market standards), by providing written notice.

The contracts with the executive managers and the Executive Director do not include any provision stating that the variable part of the remuneration based upon faulty financial information will be recovered by the Company.

Subscription rights

Share options granted by the Company generally take the form of subscription rights in the sense of article 7:67 and seq. of the Belgian Companies and Associations Code. Subscription rights can periodically be awarded to members of the personnel as defined under article 1:27 of the Belgian Companies and Associations code (with the exception of Non-Independent Directors), or even certain consultants, primarily as a retention and motivation tool. Subscription rights 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. During 2020, the Company modified its remuneration policy to provide that the Company will no longer grant share options to Independent Directors.

In the course of 2022, no subscription rights were exercised by Directors and executive managers.

2022 Share-based compensation of Directors and executive managers

During the course of 2022, the following share-based compensation was awarded to Directors and executive managers of MDxHealth:

- On 4 August 2022, each Non-Independent Non-Executive Director serving on the Board as of 25 May 2022 (at the occasion of the ordinary general shareholders meeting), were granted 10,000 new subscription rights with the following characteristics:
  - Exercise price of EUR 0.797 (one share option (subscription right) gives right to buy one share);
  - Cliff vesting over 1 year for all beneficiaries; and
  - Duration of options: 10 years.

Mr. Eric Bednarski, a Non-Independent Non-Executive Director serving on the Board, declined to accept any of the new subscription rights upon his receipt of notice of the grant.

- On 4 August 2022, a total of 2,200,000 subscription rights were granted to members of the executive management team.
  - Of these 2,200,000 granted subscription rights, 1,100,000 vest in accordance with a straight-line vesting schedule over three years for all beneficiaries, with the following additional characteristics:
    - Exercise price of EUR 0.684 (one subscription rights gives right to buy one share);
    - Vesting Period: the subscription rights vest in equal annual installments over a three-year period from the date of grant;
    - Duration of the subscription right: 10 years.

The 1,100,000 subscription rights were granted as follows:

- Mr. McGarrity received 500,000 subscription rights;
- Mr. Bellano received 200,000 subscription rights;
- Mr. Kalfus received 200,000 subscription rights;
- Mr. Sollee received 200,000 subscription rights.
- Of these 2,200,000 granted subscription rights, 1,100,000 were granted with the following characteristics:
  - Exercise price of EUR 0.684 (one subscription rights gives right to buy one share);
  - Cliff vesting in the first calendar quarter of 2024, if the Company attains specified corporate goals for the full fiscal year 2023 approved by the Board of Directors;
  - Duration of the subscription right: 10 years.

The 1,100,000 subscription rights were granted as follows:

- Mr. McGarrity received 500,000 subscription rights;
- Mr. Bellano received 200,000 subscription rights;
- Mr. Kalfus received 200,000 subscription rights;
- Mr. Sollee received 200,000 subscription rights.

Annual evolution in remuneration, performance and average annual remuneration of employees

Evolution of the remuneration of the Directors and executive managers <sup>1</sup>

	FY 2018 vs FY 2017		FY 2019 vs FY 2018		FY 2020 vs FY 2019		FY 2021 vs FY 2020		FY 2022 vs FY 2021	
	USD ('000)	%	USD ('000)	%	USD ('000)	%	USD ('000)	%	USD ('000)	%
Directors and executive managers	1,769	5%	1,236	(30)%	1,766	43%	1,847	5%	1,822	(1)%

The decrease in average remuneration in 2019 relates to changes in management during the year which caused certain vacancies throughout 2019, with those vacancies filled in 2020, which brought the average remuneration back to normal levels.

Evolution of the remuneration of the average remuneration on a full-time equivalent basis of employees other than Directors and members of the executive management <sup>2</sup>

	FY 2018 vs FY 2017		FY 2019 vs FY 2018		FY 2020 vs FY 2019		FY 2021 vs FY 2020		FY 2022 vs FY 2021	
	USD ('000)	%	USD ('000)	%	USD ('000)	%	USD ('000)	%	USD ('000)	%
Employees	107.1	2%	91.3	(15)%	91.5	0%	86.1	(6.2)%	87.0	1%

The decrease in average remuneration year-over-year primarily relates to the decrease in commissions paid to sales representatives.

Evolution of the performances of the Company

Performance Criteria	FY 2018 vs FY 2017		FY 2019 vs FY 2018		FY 2020 vs FY 2019		FY 2021 vs FY 2020		FY 2022 vs FY 2021	
	USD ('000)	%	USD ('000)	%	USD ('000)	%	USD ('000)	%	USD ('000)	%
Net result	(32,450)	164%	(43,100)	33%	(28,662)	(33)%	(29,002)	1%	(44,044)	51%
Net equity	52,117	20%	19,724	(62)%	5,849	(70)%	46,899	702%	9,315	(80)%
Paid dividends	0	0%	0	0%	0	0%	0	0%	0	0%
Market capitalization	126,966	(34)%	82,401	(35)%	97,835	19%	155,806	59%	103,890	(33)%

Notes:

<sup>(1)</sup> Includes the gross salary and bonuses paid to the executive management.

<sup>(2)</sup> Includes the gross salary and bonuses paid to full-time equivalent employees. The average employee remuneration is calculated on the basis of the ratio between the gross salary, excluding other components of the salary (such as benefits and pension plans), and the FTE number.

Ratio between the highest and the lowest remuneration

For the financial year 2022, the ratio, by country, between the highest and the lowest remuneration, expressed on a full-time equivalent basis is:

Country <sup>1</sup>	Ratio over 2020 <sup>2</sup>	Ratio over 2021 <sup>2</sup>	Ratio over 2022 <sup>2</sup>
Belgium	2.52	4.19	4.28
The Netherlands	2.14	2.24	2.21
United States of America	10.68	12.58	12.72

Notes:

<sup>(1)</sup> The CEO's remuneration is accounted for in the United States of America.

<sup>(2)</sup> A comparison is made between the lower and the higher yearly gross salary of each employee of the Company, by country (Highest salary/Lowest salary).

Done on 24 April 2023

On behalf of the Board of Directors

# Principle Risks & Uncertainties



Our business and our industry are subject to significant risks. You should carefully consider the risks and uncertainties described below, together with all of the other information in this annual report, including our audited consolidated financial statements and related notes. This annual report also includes forward-looking statements that involve risks and uncertainties. See “Special Note Regarding Forward-Looking Statements.” If any of the following risks are realized, our business, financial condition, operating results and prospects could be materially and adversely affected.

## Summary of Risk Factors

- We have a history of losses, and expect to incur net losses in the future and may never achieve profitability.
- We might require substantial additional funding to continue our operations and to respond to business needs or take advantage of new business opportunities, which may not be available on acceptable terms, or at all.
- Our commercial success will depend on the market acceptance and adoption of our current and future tests.
- Our financial results are largely dependent on sales of one test, and we will need to generate sufficient revenues from this and other future solutions to grow our business.
- We face uncertainties over the reimbursement of our tests by third party payors.
- Billing and collections processing for our tests is complex and time-consuming, and any delay in transmitting and collecting claims could have an adverse effect on revenue.
- Our business and reputation will suffer if we are unable to establish and comply with, stringent quality standards to assure that the highest level of quality is observed in the performance of our tests.
- We expect to make significant investments to research and develop new tests, which may not be successful.
- Failure to comply with governmental payor regulations could result in us being excluded from participation in Medicare, Medicaid or other governmental payor programs, which would adversely affect our business.
- We conduct business in a heavily regulated industry, and changes in regulations or violations of regulations may, directly or indirectly, adversely affect our results of operations and financial condition and harm our business.

- If the FDA were to begin requiring approval or clearance of our tests, we could incur substantial costs and time delays associated with meeting requirements for premarket clearance or approval. The dual listing of our ordinary shares and ADSs following the U.S. offering may adversely affect the liquidity and value of the ADSs.
- We are incurring significant increased costs as a result of operating as a company that is publicly listed on both NASDAQ in the U.S. and Euronext Brussels in Belgium, and our management is required to devote substantial time to compliance initiatives.
- As a result of being a U.S. public company, we are subject to additional regulatory compliance requirements, including Section 404, and if the Company fails to maintain an effective system of internal controls, it may not be able to accurately report its financial results or prevent fraud.
- Certain of our significant shareholders may have different interests from the Company and may be able to control the Company, including the outcome of shareholder votes.

Risks Related to Our Business and Industry

Mdxhealth has a history of losses and expects to incur net losses in the future and may never achieve profitability.

Mdxhealth has incurred substantial net losses since its inception and it may never achieve profitability. As of 31 December 2022, the Company had an accumulated deficit of USD 288.3 million and for the year ended 31 December 2022, the Company had a net loss of USD 44.0 million and net cash used in operating activities of USD 34.1 million, respectively. Mdxhealth expects its losses to continue as a result of costs relating to ongoing research and development and for increased sales and marketing costs for existing and planned solutions. These losses have had, and will continue to have, an adverse effect on the Company's working capital, total assets, and stockholders' equity. 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 or expand its business in accordance with its growth strategy. Historically, the Company has been able to raise capital at regular occasions, including most recently via the capital increase it completed on 7 February 2023. If it is unable to continue to do this, its ability to operate as a going concern could be seriously compromised.

Mdxhealth may require substantial additional funding to continue its operations and to respond to business needs or take advantage of new business opportunities, which may not be available on acceptable terms, or at all.

On the date of this report, the Company is of the opinion that, taking into account its available cash and cash equivalents, it has sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this report. Notwithstanding the foregoing, over the next several years, mdxhealth's capital outlays and operating expenditures are expected to increase as it commercialises its expanded menu of testing solutions. Additionally, under the terms of the asset purchase agreement in relation to the acquisition of the Oncotype DX GPS prostate cancer business of Exact Sciences, following the closing, an additional aggregate earn-out amount of up to USD 70 million is to be paid by mdxhealth to Exact Sciences over the course of 2024, 2025 and 2026, in an amount equal to a portion of the prior calendar year's reported revenues attributable to the Oncotype DX GPS prostate cancer business, with the maximum earn-out payable in 2024 and 2025 not to exceed USD 30 million and USD 40 million, respectively. At the option of mdxhealth, the earn-out amounts can be settled in cash or through the issuance of additional ADSs of the Company (valued in function of a volume weighted average trading price of the Company's shares at the end of the relevant earn-out period) to Exact Sciences, provided that the aggregate number of Shares representing the ADSs held by Exact Sciences shall not exceed more than 5% of the outstanding Shares of mdxhealth. Mdxhealth may require additional equity or debt funding from

time to time in case of a shortfall in cash inflows from operations or to respond to business needs or take advantage of new business opportunities, which may not be available at acceptable terms, or at all. For example, mdxhealth has previously raised capital in connection with its initial public offering in the United States as well as in March/February 2023, January 2021 and May 2020.

If additional funds are raised through the sale of equity, convertible debt or other equity-linked securities, security holders' ownership will be diluted. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of ordinary shares. If additional funds are raised by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of shareholders, 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's term loan contains restrictions that limit its flexibility in operating its business, and if the Company fails to comply with the covenants and other obligations under its loan agreement, the lenders may be able to accelerate amounts owed under the facility and may foreclose upon the assets securing its obligations.

On 2 August 2022, the Company entered into a USD 70 million loan and security agreement with Innovatus Life Sciences Lending Fund I, LP ("**Innovatus**"). This loan was to finance the acquisition of Genomic Prostate Score® (GPS) test (formerly Oncotype DX GPS) ("**GPS**") from Genomic Health, Inc., a subsidiary of Exact Sciences Corporation ("**Exact Sciences**"). At closing, an amount of USD 35 million was drawn, with an additional USD 35 million remaining available as a USD 20 million term B loan and a USD 15 million term C loan that can be drawn in 2024 and 2025 respectively, subject to certain conditions. The remaining proceeds of the loans will be used for working capital purposes and to fund general business requirements. The loans accrue interest at a floating per annum rate equal to the sum of (a) the greater of (i) the prime rate published in The Wall Street Journal in the "Money Rates" section or (ii) 4.00%, plus (b) 4.25%, and require interest-only payments for the initial four years. At the election of the Company, a portion of the interest may be payable in-kind by adding an amount equal to 2.25% of the outstanding principal amount to the then outstanding principal balance on a monthly basis until 2 August 2025. The loans mature on 2 August 2027. The lenders shall have the right to convert, prior to 2 August 2025, up to 15% of the outstanding principal amount of the loans into ADSs of the Company at a price per ADS equal to USD 11.21. As part of the new debt facility with Innovatus, the Company's debt facility with Kreos for an outstanding principal amount of EUR 9 million was fully repaid in cash as of 30 September 2022 for a total amount of USD 10.8 million.

The loan agreement with Innovatus is collateralised by substantially all of the Company's assets, including intellectual property related to its Confirm mdx and Select mdx tests. The loan agreement also subjects the Company to certain affirmative and negative covenants, including limitations on the Company's ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates. As a result of these covenants, the Company has certain limitations on the manner in which it can conduct its business, and it may be restricted from engaging in favourable business activities or financing future operations or capital needs until its current debt obligations are paid in full or it obtains the consent of Innovatus, which it may not be able to obtain. Mdxhealth cannot be certain that it will be able to generate sufficient cash flow or revenue to meet the financial covenants or pay the principal and accrued interest on the debt.

In addition, upon the occurrence of an event of default, Innovatus, among other things, can declare all indebtedness due and payable immediately, which would adversely impact liquidity and reduce the availability of cash flows to fund working capital needs, capital expenditures and other general corporate purposes. An event of default includes, but is not limited to, the Company's failure to pay any amount due and payable under the loan agreement, the breach of any representation or

warranty in the loan agreement, the breach of any covenant in the loan agreement (subject to a cure period in some cases), a change in control as defined in the loan agreement, the default on any debt payments to a third party or any voluntary or involuntary insolvency proceeding. If an event of default occurs and the Company is unable to repay amounts due under the loan agreement, Innovatus could foreclose on substantially all of the Company's assets, including secured intellectual property. Mdxhealth cannot be certain that future working capital, borrowings or equity financings will be available to repay or refinance its debt to Innovatus or any other debt it may incur in the future.

Furthermore, mdxhealth must meet certain covenants in order to draw down an additional USD 20 million term B loan and a USD 15 million term C loan that remain available under the USD 70 million Innovatus facility in 2024 and 2025, respectively. The availability of the USD 20 million term B loan and a USD 15 million term C loans are intended to coincide with the anticipated contingent earn-out payment obligations due under the terms of the asset purchase agreement in relation to the acquisition of the Oncotype DX GPS prostate cancer business of Exact Sciences. If mdxhealth does not have sufficient working capital to fund its earn-out payment obligations to Exact Sciences if and when they become due, and is also unable to meet loan covenants necessary to draw down one or more of the additional Innovatus term loans, mdxhealth may be unable to satisfy its contractual obligations to Exact Sciences, resulting in a material breach under the asset purchase agreement with Exact Sciences as well as an event of default under the loan agreement with Innovatus, 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 the GPS test from a subsidiary of Exact Sciences in August 2022, and the acquisition of NovioGendix, a privately held company based in Nijmegen (The Netherlands), in September 2015, the Company may enter into other transactions in the future to acquire other businesses, products or technologies. The Company may be unable to realize the anticipated benefits of the acquisitions or do so within the anticipated timeframe. 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 the Company may obtain from the seller. In addition, the Company 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. If the Company is unable to do so, the disruption to its operations could result in additional costs or could distract management's attention from other initiatives.

**Mdxhealth's federal loan subjects the Company to a variety of federal regulations and although the Company may apply for forgiveness of this loan it may not be forgiven.**

In April 2020, mdxhealth qualified for a USD 2.3 million loan through the Paycheck Protection Program (the "**PPP**") of the U.S. Coronavirus Aid, Relief and Economic Security Act (the "**CARES Act**"), under a loan agreement administered by the U.S. Small Business Administration. The maturity of the PPP loan is on 30 June, 2025. By participating in a federal loan program, the Company becomes subject to increased governmental oversight and federal regulatory compliance obligations, including potential civil and criminal liability for making false claims or statements under the U.S. False Claims Act, 31 U.S.C. § 3729 et seq. (the "**FCA**"). Liability under the FCA and similar federal statutes can carry significant potential monetary penalties and potential jail time, and can arise from both "knowing" and "wilful" misstatements. FCA violations will result in a civil penalty per false claim, of not less than USD 13,508 and not more than USD 27,018, plus treble the government's actual damages. A person who violates § 3729 will also be held liable for the government's costs for bringing a civil action to recover any penalty or damages. If, despite the Company's good faith belief that the Company satisfied all eligibility requirements for the PPP loan, the Company is found to have been ineligible to receive the PPP loan or in violation of any of the laws or regulations that apply to the Company in connection with the PPP loan, it may be subject to penalties, including under the FCA, and could be required to repay the PPP loan. Additionally, a review or audit by the SBA or other government entity

in connection with any future forgiveness application (if the Company chooses to apply for forgiveness) or claims under the False Claims Act could consume significant financial and management resources. Any of these events could harm its business, results of operations and financial condition.

**The molecular diagnostics industry is highly competitive and characterised by rapid technological changes and the Company may be unable to keep pace with its competitors.**

The molecular diagnostics field is characterised by rapid technological changes, frequent new product introductions, changing customer preferences, emerging competition, evolving industry and regulatory compliance 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 diagnosis or aggressiveness 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.

Regarding the Company's Confirm mdx for Prostate Cancer tissue-based test, several directly competitive products are currently commercially available. In 2014, OPKO Health, Inc., a NYSE listed company, launched the 4Kscore test, a blood based 4-plex test which combines the results of the blood test with clinical information in an algorithm that calculates a patient's percent risk for aggressive prostate cancer prior to a biopsy. OPKO is the third largest clinical laboratory in the United States, with a significantly larger sales and marketing team than the Company. The 4Kscore test obtained FDA marketing approval in December 2021. Offered at a lower price point, the 4Kscore test offers a competitive price advantage over the Confirm mdx test. The PCA-3 test from Hologic, a urine-based test, is on the U.S. market as an FDA approved test, which may be perceived as providing a competitive advantage since the Confirm mdx for Prostate Cancer test is not FDA approved. The PCA-3 test is intended for the same patient population as Confirm mdx for Prostate Cancer, but its performance has only been established in men who were already recommended by urologists for repeat biopsy.

Regarding the Company's Select mdx for Prostate Cancer urine-based test, several directly competitive products are currently commercially available. In 2016, ExosomeDx launched the ExoDx (Intelliscore), a urine-based test designed to assess whether a patient presenting for an initial or repeat biopsy is at greater risk for high-grade prostate cancer. The ExoDx test competes directly with Select mdx. In 2018, Bio-Techne Corporation, a large U.S.-based, diversified life sciences company, acquired the ExoDx test. Bio-Techne has greater resources and a significantly larger sales and marketing team than the Company. For instance, based on recent SEC filings, Bio-Techne had total assets in excess of USD 1 billion and of the latest practicable date prior to the date of this report, it had a market capitalisation of over USD 10 billion. In addition, the ExoDx test may also provide a competitive advantage since, unlike the Select mdx test, it does not require a prostate massage as part of its specimen collection procedures. In addition to ExoDx, the 4Kscore test offered by OPKO and the Prostate Health Index test, or the "phi score", offered by Beckman Coulter, both compete directly with the Select mdx test.

Regarding the Company's GPS tissue-based test, acquired in August 2022 from Exact Sciences, several directly competitive products are currently commercially available. Myriad Genetics offers the Prolaris test, a tissue-based genetic test to help identify those men who need treatment versus those who can choose active surveillance, which is directly competitive with the GPS test. Additionally, Veracyte offers the Decipher test, a tissue-based genetic test to help identify those men who need treatment versus those who can choose active surveillance, which is directly competitive with the GPS test.

In addition to directly competitive genomic tests, traditional methods used by pathologists and clinicians to estimate risk for disease progression also pose competitive threats. Companies combining these traditional methods with artificial intelligence could potentially emerge as competitors, though most of these technologies are currently in the research stage.

Each of OPKO, Beckman Coulter and Myriad Genetics have greater resources and a significantly larger sales and marketing team than mdxhealth. Beckman Coulter is owned by Danaher Corporation, which had total assets in excess of USD 50 billion based on recent SEC filings and a market capitalisation in excess of USD 150 billion. Myriad Genetics had total assets in excess of USD 1 billion based on recent SEC filings and a market capitalisation in excess of USD 1.5 billion. As a result of these significantly greater resources, these competitors are able to make larger investments into the tests they produce and the sales and marketing of these tests, which may cause the Company to lose market share. In addition to competitive products, the Confirm mdx, Select mdx and GPS tests also face competition from multiparametric MRI ("**mpMRI**"), a clinical diagnostic imaging procedure available to and used by physicians for many years, which focuses on visual tissue analysis. The mpMRI procedure can visually reveal potential locations of abnormal and potentially cancerous prostate tissue characteristics that distinguish tumours from healthy tissue. The visual aspect of diagnostic imaging may feel more accessible and be considered preferable by some physicians over molecular analysis, and there likely is an economic incentive for some physicians to earn a professional fee from the performance of mpMRI procedures. It may be difficult to change the methods or behaviour of physicians to incorporate the Company's testing solutions into their practices in conjunction with, or instead of, mpMRI clinical diagnostic imaging procedures. In addition, companies developing or offering capital equipment or point-of-care kits to physicians represent another source of potential competition. These devices are used directly by the physicians or their institutions, which can facilitate adoption.

If mdxhealth is unable to compete effectively with the abovementioned competitors and with new technologies and procedures such as mpMRI, it may lose market share, which could in turn adversely affect its revenues.

**The commercial success of mdxhealth will depend on the market acceptance and adoption of its current and future 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 Confirm mdx, Select mdx and GPS 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 and maintaining coverage for its diagnostic tests. The administration of clinical and economic utility studies is expensive and demands significant attention from the management team. The Company's largest ongoing study, a multicenter U.S. observational study of Confirm mdx and Select mdx entitled a Prospective Validation of Prostate Biomarkers for Repeat Biopsy ("**PRIORITY**"), encountered delays in enrolment and completion as a result of the COVID-19 pandemic. Additionally, the Company has several smaller post-marketing clinical studies ongoing or planned that are primarily intended to support expanded indications for its Confirm mdx, Select mdx, and GPS tests. The PRIORITY study or the Company's other clinical studies may not be successfully initiated, enrolled or completed. Also, 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 favourable 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. See also "*mdxhealth faces uncertainties over the reimbursement of its tests by third party payors*". The publication of clinical data in peer-reviewed journals is a crucial step in commercialising 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.

While the Company is unable to quantify the impact of its clinical studies being unsuccessful or producing adverse outcomes, any of these events could severely harm its ability to market or sell its tests.

**Mdxhealth faces uncertainties concerning the coverage and reimbursement of its tests by third-party payors.**

Successful commercialisation of the Company's tests depends, in large part, on the availability of coverage and adequate reimbursement from government and private payors. Favourable third-party payor coverage and reimbursement are essential to meeting the Company's immediate objectives and long-term commercial goals. In the United States, for new diagnostic solutions, each private and government payor decides whether to cover the test, the amount it will reimburse clinical laboratories or other providers for a covered test, and any specific conditions for coverage and reimbursement. Healthcare providers may be unlikely to order a specific diagnostic test unless an applicable third-party payor offers meaningful reimbursement for the test. Therefore, adequate coverage and reimbursement is critical to the commercial success of a diagnostic product, and if the Company is unable to secure and maintain favourable coverage determinations and reimbursement, this will undermine its ability to earn revenue from its products.

*Medicare*

Reimbursement for diagnostic tests furnished to Medicare beneficiaries (typically patients aged 65 or older) is usually based on a fee schedule set by the U.S. Centers for Medicare & Medicaid Services ("**CMS**"), a division of the U.S. Department of Health and Human Services ("**HHS**"). As a Medicare-enrolled provider with its primary laboratory based in California, the Company bills Noridian Healthcare Solutions ("**Noridian**"), the Medicare Administrative Contractor ("**MAC**") for California, and the Company's Select mdx, Confirm mdx, and GPS tests are subject to Noridian's local coverage and reimbursement policies. Noridian participates in the Molecular Diagnostic Services Program ("**MolDX**"), administered by Palmetto GBA, which handles technical assessments for U.S. laboratories that perform molecular diagnostic testing. The Confirm mdx test obtained a positive Medicare local coverage determination ("**LCD**") under the MolDX program in 2014, the GPS test obtained a positive Medicare coverage LCD in 2015, and the Select mdx test obtained a positive Medicare coverage LCD in April, 2023, each of which provides coverage for Medicare patients throughout the United States.

Medicare accounted for approximately 43% of mdxhealth's revenues in 2022, compared to 38% in 2021. See Note 4 "Revenue and Cost of goods & services" to the 2022 Annual Report for further detail.

*Commercial payors*

Obtaining coverage and reimbursement by commercial payors is a time-consuming and costly process, without a guaranteed outcome, since each commercial payor makes its own decision with respect to whether to cover a particular test and, if so, at what rate to reimburse providers for that test. In addition, several payors and other entities conduct technology assessments of new medical tests and devices and provide the results of these assessments for informational purposes to other parties. These assessments may be used by third-party payors and healthcare providers as grounds to deny coverage for a particular test, or to refuse to use or order a particular test or procedure. The Company's tests have received initial negative technology assessments from several of these entities and are likely to receive more negative technology assessments. The Company continues to work with third-party payors to obtain coverage and reimbursement for its tests and to appeal coverage denial decisions based on existing and ongoing studies, peer reviewed publications, and support from physician and patient groups. Commercial payors may not continue to issue positive coverage and reimbursement

policies and/or contracts and, if they do issue positive coverage or policies, they may not be maintained in the future. If the Company's tests are considered on a policy-wide level by major third-party payors, whether at its request or on the payor's own initiative, and the payor determines that such tests are ineligible for coverage and reimbursement, its revenue potential could be adversely impacted.

On 13 February 2023, mdxhealth announced that UnitedHealthcare would cover the GPS test under UnitedHealthcare's commercial policies to assist with treatment decisions for individuals newly diagnosed with localised prostate cancer and meeting coverage criteria. UnitedHealthcare is the largest healthcare providers in the United States.

As of the date of this report, mdxhealth had approximately 129 and 62 commercial payors for its Confirm mdx and Select mdx tests, respectively. See Note 4 "Revenue and Cost of goods & services sold" to the 2022 Annual Report for further detail.

*Outside the United States*

Outside of the United States, various coverage, pricing and reimbursement approvals are required, including through coverage determinations made at the national level under public benefit programs. 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 United States where the Company commercialises 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 encounter difficulties in satisfying. Reimbursement levels outside of the United States may vary considerably from the reimbursement amounts the Company receives in the United States. In addition, because mdxhealth plans in many circumstances to rely on distributors to obtain reimbursement for its tests, to the extent the distributor 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; further, if its agreement with a particular distributor is terminated or expires or a distributor fails to pay for other reasons, mdxhealth could lose reimbursement coverage in that jurisdiction.

Currently, the Company relies significantly on the sale of Confirm mdx tests in the United States for its revenues, with this test accounting for 59%, 93% and 96% of service revenue in 2022, 2021 and 2020, respectively. The Company has materially diversified its revenue through the acquisition of the GPS test, and has been further diversifying its revenue through the launch of an additional precision diagnostic test offering and the attainment of clinical guideline inclusion for Select mdx, which facilitates reimbursement. If reimbursement for the Company's tests were to be revoked either by CMS or any of the commercial payors, this could have an immediate impact on the Company's revenues. While mdxhealth does not believe that revocation of Medicare reimbursement for its Select mdx, Confirm mdx or GPS tests is likely, if this were to occur, the impact on the Company could be severe.

For further details on segmental revenue, see Note 4 "Revenue and Cost of goods & services sold" to the 2022 Annual Report.

**The ongoing outbreak of COVID-19, or any future pandemic, could impact the Company's sales volumes, and the Company's business may experience other adverse effects as a result of COVID-19 or future pandemics.**

The broad and extensive impact of the COVID-19 pandemic on virtually all aspects of the Company's business and society exacerbated many pre-existing risks to its business by making them more likely to occur or more impactful when they do occur. Accordingly, the risks described in this risk factor would be considered in addition to, and not in lieu of, the risks described elsewhere throughout these risk factors.

The level and nature of the disruption caused by COVID-19, or any future pandemic, is unpredictable, may be cyclical and long-lasting and may vary from location to location. The Company's sales representatives' contact with clinicians, as well as

patient access to clinicians, began to decline in March 2020 due to the COVID-19 pandemic and . This affected both Confirm mdx and Select mdx volumes and had a negative effect on revenues and cash flows. Overall, Confirm mdx and Select mdx billed volumes declined by 18% and 39% for the full year 2020, respectively, compared to 2019 pre-pandemic volumes.

To the extent COVID-19 conditions improve, the duration and sustainability of any such improvements will be uncertain and continuing adverse impacts and/or the degree of improvement may vary dramatically by geography and by product. In 2021 and 2022, compared to 2019 pre-pandemic volumes, Confirm mdx billed volumes were lower by 16% and 6%, respectively, and Select mdx billed volumes were lower by 37% and 42%. The actions we take in response to any improvements in conditions, such as our return-to-office plans, may also vary widely by geography and by business and will likely be made with incomplete information; pose the risk that such actions may prove to be premature, incorrect or insufficient and could have a material, adverse impact on our business and results of operations.

Despite the Company's efforts, the ultimate impact of COVID-19, or any future pandemic, depends on factors beyond the Company's knowledge or control, including the duration and severity of the outbreak, third-party actions taken to contain its spread and mitigate its public health effects, and short- and long-term changes in the behaviors of medical professionals and patients resulting from the pandemic.

**Risks Related to Our Intellectual Property**

**If mdxhealth is unable to retain intellectual property protection in relation to its Confirm mdx, Select mdx and GPS tests or if it is required to expend significant resources to protect its intellectual property position, its competitive position could be undercut.**

Mdxhealth's ability to protect its discoveries, know-how and technologies affects its ability to compete and to achieve profitability. Mdxhealth relies on a combination of U.S. and foreign patents and patent applications, copyrights, trademarks and trademark applications, confidentiality or non-disclosure agreements, material transfer agreements, licenses and consulting agreements to protect its intellectual property rights. Mdxhealth also maintains certain company know-how, algorithms, and technological innovations designed to provide it with a competitive advantage in the marketplace as trade secrets. As of 31 December 2022, the Company owns or has exclusive rights to more than 17 patent families related to its molecular technology and cancer-specific biomarkers. Specifically, there are 116 granted or pending patent applications in this group comprised of 16 issued or allowed U.S. patents, 7 pending U.S. provisional or non-provisional applications, 19 pending international patent applications filed under the Patent Cooperation Treaty ("**PCT**") and 74 granted patents in jurisdictions outside the United States, including Japan, Canada, Israel and the major European countries. The Company's issued U.S. patents expire at various times between 2024 and 2038. Of these issued patents, one covers intellectual property used in the Company's Confirm mdx test, which expires in 2024, seven cover intellectual property used in the Company's Select mdx test, the last of which expires in 2036, and 52 cover intellectual property used in the Company's GPS test, the last of which expires in 2038. Please see also chapter "Business overview", section "Material Agreements", paragraph three of the section "Intellectual property in-licensing agreements" of this report. While mdxhealth intends to pursue additional and future patent applications, it is possible that pending patent applications and any future applications may not result in issued patents. Even if patents are issued, third parties may independently develop similar or competing technology that avoids its patents. Third parties may also assert infringement or other intellectual property claims against mdxhealth or against its licensors, licensees, suppliers or strategic partners. Any actions regarding patents could be costly and time-consuming and could divert the attention of management and key personnel from other areas of the Company's business. Further, it cannot be certain that the steps mdxhealth has taken will prevent the misappropriation of its trade secrets and other confidential information as well as the misuse of mdxhealth's patents and other intellectual property, particularly in foreign countries with no patent protection.

Although mdxhealth has licensed and owns issued patents in the United States and foreign countries, it cannot be certain the claims will continue to be considered patentable by the United States Patent and Trademark Office (the "**USPTO**"), U.S. courts patent offices and courts in other jurisdictions. The U.S. Supreme Court, other federal courts and/or the USPTO, may change the standards of patentability and any such changes could have a negative impact on the Company's business. For instance, the Federal Circuit has recently ruled on several patent cases - such as Univ. of Utah Research Found. v. Ambry Genetics Corp., 774 F.3d 755 (Fed. Cir. 2014), Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015), Genetic Tech. Ltd. v. Merial LLC, 818 F.3d 1369 (Fed. Cir. 2016), and Cleveland Clinic Found. v. True Health Diagnostics, 859 F.3d 1352 (Fed. Cir. 2017) - that some diagnostic method claims are patent ineligible. These decisions have narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. Some aspects of the Company's technology involve processes that may be subject to this evolving standard and the Company cannot guarantee that any of its pending process claims will be patentable as a result of such evolving standards. In addition, this combination of decisions has created uncertainty as to the value of certain issued patents, in particular in the detection of prostate cancer and other cancers.

Also, patents and patent applications owned by mdxhealth may become the subject of post grant challenges or interference proceedings in the USPTO to determine validity and the priority of invention, which could result in substantial cost as well as a possible adverse decision as to the validity or priority of invention of the patent or patent application involved. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application subject to such a proceeding. Ultimately, the potential weakening of mdxhealth's intellectual property position as a result of the evolution of case law or otherwise may make it more vulnerable to competition. While mdxhealth is unable to quantify the impact of this risk, given that its patents remain untested in the courts, the impact could be severe if its competitors are able to take advantage of any weakening of its intellectual property position.

## Risks Related to Our Operations

**Billing and collections processing for the Company's tests is complex and time-consuming, and any delay in transmitting and collecting for claims could adversely impact revenue.**

A significant portion of mdxhealth's current revenue is derived from the use of its Confirm mdx test, which is billed on a fee-for-service basis and paid, for example by hospitals and direct payments from individual patients, and may be reimbursed by third-party payors, including Medicare and other governmental payor programs, private insurance plans and managed care organisations. Billing for molecular diagnostics testing services is complex, time-consuming, and expensive. Mdxhealth is often obligated to services bill in the specific manner required by each particular third-party payor. Failure to comply with these complex billing requirements (including complex federal and state regulations related to billing government health care programs, e.g., Medicare and Medicaid) may significantly hinder its collection and retention efforts, including not only potential write-offs of doubtful accounts and long collection cycles for accounts receivable, but also the potential disgorgement of previously paid claims based on third-party payor program integrity investigations into billing discrepancies, fraud, waste and abuse. With CMS' recent implementation of a comprehensive oversight regime that consolidates program integrity powers into a single Unified Program Integrity Contractor ("UPIC"), audit and investigatory activity into billing fraud, waste and abuse in the industry has significantly increased.

During the fourth quarter of 2019, and based on recent and historical collections data, mdxhealth updated certain assumptions to its estimates which affected its revenues. These included a revision to the period that a vast majority of collections would occur (from 24 months to 12 months); an updated lookback period for historical collection experience in order to use more recent and relevant collection data; and recognition on a cash basis if no historical payment experience is available. Updating these revenue recognition estimates negatively affected its revenues in 2019 in the amount of USD 10.1 million.

**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 mdxhealth 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, with or without merit, could increase its insurance rates or prevent mdxhealth from securing insurance coverage in the future. Additionally, any product liability lawsuit could harm its reputation, which could impact its results of operations, or cause collaboration partners to terminate existing agreements and potential partners to seek alternate partners, any of which could negatively impact its results of operations.

While the impact of any product liability claim on mdxhealth is inherently impossible to quantify given the unknown scope of any such claim, the impact could potentially be material depending on the quantum of damages sought and the merit of the claim.

**Mdxhealth's laboratory facilities may become inoperable due to natural or man-made disasters or regulatory sanctions.**

Mdxhealth currently performs its testing services in its laboratory facilities located in Irvine, California, Plano, Texas, and Nijmegen, The Netherlands. Its laboratory facilities could become inoperable due to circumstances that may be beyond its control, and such inoperability could adversely affect its business and operations. The facilities, equipment and 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, outbreak of disease (such as the ongoing COVID-19 pandemic), acts of terrorism or other criminal activities and power outages, which may render it difficult or impossible for mdxhealth to perform its tests for some period.

The U.S. federal Clinical Laboratory Improvement Amendments ("CLIA") and the laws of California and certain other states, impose certification requirements for clinical laboratories, and establishes standards for quality assurance and quality control, among other things. See chapter "Business overview", section "Regulatory environment", subsection "Certification Requirements for Clinical Laboratories". 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 action plan, and imposing civil monetary penalties. The Company's U.S. laboratory facilities in Irvine, California and Plano, Texas hold certificates of accreditation from CMS to perform high-complexity testing. To renew this certificate, the facilities are subject to survey and inspection every two years. Mdxhealth also holds a certificate of accreditation from the College of American Pathologists ("CAP"), which sets standards that are higher than those contained in the CLIA regulations. CAP is an independent, non-governmental organisation of board-certified pathologists that accredits laboratories nationwide on a voluntary basis. Sanctions for failure to comply with CAP or CLIA requirements, including proficiency testing violations, may include suspension, revocation, or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as the imposition of significant fines or criminal penalties. In addition, its U.S. facilities are subject to regulation under state laws and regulations governing laboratory licensure. Two states, one of which is New York, have enacted state licensure laws that are more stringent than the CLIA. Failure to maintain CLIA certification, CAP accreditation, or required state licenses could have a material adverse effect on the sales of its tests and results of operations.

CMS has primary responsibility for the enforcement of CLIA and may suspend, limit or revoke the certificate of the relevant clinical laboratory for non-compliance. If the Company's certificate were to be suspended, limited or revoked, whether under CLIA or under relevant state law, this would have an immediate impact on revenues which would be material.

**Mdxhealth relies on a limited number of third-party suppliers for services and items used in the production and operation of its testing solutions, and some of those services and items are supplied from a single source. Disruption of the supply chain, unavailability of third-party services required for the performance of the tests, modifications of certain items or failure to achieve economies of scale could result in a reduction in revenues, which could be material depending on the length of the supply disruption.**

To provide its testing services, mdxhealth is required to obtain customised components and services that are currently available from a limited number of sources. Most of these components and services are sourced externally from more than 40 external suppliers. Many of the consumable supplies and reagents used as raw materials in its testing process are procured from a limited number of suppliers, some of which are single source. In addition, mdxhealth relies on a limited number of suppliers, or in some cases a single supplier (for example, for the automation of its deparaffination steps for its Confirm mdx test), for certain equipment and services with which mdxhealth provides testing services. If mdxhealth has to switch to a replacement supplier for any of these items that are sub-components or for certain services required for the performance of its tests, or if mdxhealth has to commence its own manufacturing or services to satisfy market demand, mdxhealth may face additional delays. For example, in the past, a supplier has delivered critical non-conforming components that failed its acceptance testing, requiring mdxhealth to audit the supplier and assist the supplier in improving its internal quality processes. In addition, third party suppliers may be subject to circumstances which impact their ability to supply, including enforcement action by regulatory authorities, natural disasters (e.g., hurricanes, earthquakes, disease and terrorism), epidemics (e.g., the COVID-19 pandemic), industrial action (e.g., strikes), financial difficulties including insolvency, among a variety of other internal or external factors. Any such supply disruptions could in turn result in service disruptions for an extended period of time, which could delay completion of its clinical studies or commercialisation activities and prevent mdxhealth from achieving or maintaining profitability. While mdxhealth was able to qualify alternative suppliers to address COVID-19 related disruptions, in the future alternative suppliers may be unavailable, may be unwilling to supply, may not have the necessary regulatory approvals, or may not have in place adequate quality management systems. Furthermore, modifications to a service or items or inclusions of certain services or items made by a third-party supplier could require new approvals from the relevant regulatory authorities before the modified service or item may be used, for example any modifications to the assembly and packaging of items for its testing services supplied to healthcare providers. While mdxhealth has not experienced any material supply chain disruptions to date, if mdxhealth were to experience such disruptions, this could have an immediate impact on revenues, and the impact could be material depending on the length of the supply disruption.

**Security breaches or loss of data may harm mdxhealth's reputation and expose it to liability.**

If mdxhealth experiences any security breaches or loss of data or if mdxhealth fails to comply with data protection laws and regulations, mdxhealth could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect its results of operations and 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: (1) loss of access risk, (2) inappropriate disclosure or access risk, (3) inappropriate modification risk, and (4) the risk of being unable to identify and audit controls over the first three risks. While mdxhealth devotes significant resources to protecting such information, the measures mdxhealth introduces may not be sufficient to guard against security breaches, the loss or misappropriation of data, privacy violations or the failure to implement satisfactory remedial measures, which could in turn disrupt operations and lead to reputational damage, regulatory penalties and other material financial losses.

Furthermore, mdxhealth is subject to privacy and data security laws and regulations at the state, federal and international level. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., section 5 of the Federal Trade Commission Act), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in (1) government enforcement actions and potential liability thereunder (potentially including civil and/or criminal penalties), (2) private litigation, and/or (3) adverse publicity that could negatively affect its operations and/or business. In addition, mdxhealth obtains health information from third parties (e.g., healthcare providers) and is subject to privacy and security requirements under the Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"). These laws contain significant fines and other penalties for wrongful use or disclosure of protected data. For example, HIPAA violations can result in civil and criminal penalties. For example, HIPAA violations can result in civil and criminal penalties, as described below under " — Regulatory risks — 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".

**Risks Related to Regulation of Our Business**

**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 revenues, given the importance of reimbursement to its revenue base.**

Failure to comply with applicable Medicare, Medicaid and other governmental payor rules could result in mdxhealth being excluded 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. Additionally, with the recent implementation by CMS of a comprehensive oversight regime that consolidates program integrity powers into a single UPIC, audit and investigatory activity into potential billing fraud, waste and abuse in the industry has increased. These changes have adversely affected and may in the future adversely affect coverage and reimbursement for laboratory services, including the molecular diagnostics testing services mdxhealth provides. If mdxhealth was unable to receive reimbursement under a governmental payor program, this would have a severe impact on its revenues, given the importance of reimbursement under these programs in its revenue base. See also " — *Mdxhealth faces uncertainties concerning the coverage and reimbursement of its tests by third-party payors*".

**Mdxhealth conducts business in a heavily regulated industry, and changes in, or violations of, applicable regulations may, directly or indirectly, adversely affect its operational results and financial condition, which could harm its business.**

Mdxhealth's business operations and activities may be subject to a range of local, state, federal, and international healthcare laws and regulations, including investigatory and program integrity audits and other oversight federal and state health care programs. For a summary of the most important laws and regulations, see chapter "Business overview", section "Regulatory environment" of this report.

Mdxhealth's business practices, in operating a U.S. clinical laboratory, may face heightened scrutiny from U.S. government enforcement agencies such as the U.S. Department of Justice ("DOJ"), the HHS Office of Inspector General ("OIG"), and CMS. The OIG has issued fraud alerts in recent years that identify certain arrangements between clinical laboratories and referring physicians as implicating the federal Anti-Kickback Statute. The OIG has stated that it is particularly concerned about these types of arrangements because the choice of laboratory, as well as the decision to order laboratory tests, typically are made or strongly influenced by the physician, with little or no input from the patient. Moreover, the provision of payments or other items of value by a clinical laboratory to a referring physician could be prohibited under the Stark Law,

unless the arrangement meets all criteria of an applicable exception. The government has actively enforced these laws against clinical laboratories in recent years.

These U.S. laws and regulations are complex and are subject to interpretation by the U.S. courts and government agencies. Mdxhealth's failure to comply with such laws and regulations could lead to significant civil or criminal penalties, exclusion from participation in state and federal health care programs, individual imprisonment, disgorgement of profits, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if mdxhealth becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law, curtailment or restructuring of its operations, or prohibitions or restrictions on its laboratories' ability to provide or receive payment for its services, any of which could adversely affect its ability to operate its business and pursue its strategy. Even where mdxhealth is able to successfully defend against any such claims, any potential audit, enforcement action, or litigation would involve substantial internal and external resources, detract from its executives' day to day responsibilities, and result in legal expenditures, all of which could materially adversely affect its results of operations. While mdxhealth believes that it is in material compliance with all applicable laws and regulations, there remains a risk that one or more government agencies could take a contrary position, or that a private party could file suit under the qui tam provisions of the federal False Claims Act or a similar state law. Such occurrences, regardless of their outcome, could damage its reputation and adversely affect important business relationships with third parties, including managed care organisations, and other private third-party payors.

**If the FDA were to begin requiring approval or clearance of the Company's tests, the Company could incur substantial costs and time delays associated with meeting requirements for premarket clearance or approval.**

Although mdxhealth believes it is within the scope of the FDA's policy on enforcement discretion for laboratory-developed tests, commercial availability of laboratory developed tests ("**LDTs**") is subject to uncertainty given the FDA's latitude in interpreting and applying its laws and policies. For example, although the FDA has historically exercised enforcement discretion over most LDTs, it does not consider tests to be subject to this enforcement discretion if they were or are designed or manufactured completely, or partly, outside of the laboratory that offers and uses them, or if they are offered "over-the-counter" (as opposed to being available to patients only when prescribed by a health care provider). Even for tests that appear to fall within FDA's previously stated policy on enforcement discretion, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time.

Furthermore, the laws and regulations governing the marketing of diagnostic products are evolving, extremely complex and in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Pursuant to its authority under the federal Food, Drug, and Cosmetic Act (the "FDCA"), the FDA has jurisdiction over medical devices, including in vitro diagnostics and, therefore, potentially mdxhealth's clinical laboratory tests. Among other things, pursuant to the FDCA and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. Although the FDA has asserted that it has authority to regulate the development and use of LDTs, such as mdxhealth's and many other laboratories' tests, as medical devices, it has generally exercised enforcement discretion and is not otherwise regulating most tests developed and performed within a single high complexity CLIA-certified laboratory.

Even though the Company's tests are commercialised in the United States as LDTs, they may in the future become subject to more onerous regulation by the FDA. For example, the FDA may disagree with the assessment that the tests fall within the definition of an LDT and seek to regulate them as medical devices. The FDA has, for over the past decade, been introducing proposals to end enforcement discretion and to bring LDTs clearly under existing FDA regulatory frameworks and the U.S. Congress has recently been working on legislation to create an LDT and in vitro diagnostic regulatory framework that would be separate and distinct from the existing medical device regulatory framework. For further detail, see chapter "*Business overview*", section "*Regulatory environment*" of this report.

If the FDA begins to enforce its medical device requirements for LDTs, or if the FDA disagrees with mdxhealth's assessment that its tests are LDTs, mdxhealth and these tests could for the first time be subject to a variety of regulatory requirements, including registration and listing, medical device reporting, and adherence to good manufacturing practices under the quality system regulations, and mdxhealth could be required to obtain premarket clearance or approval for these existing tests and any new tests mdxhealth may develop, which may force mdxhealth to cease or delay marketing its tests until the required clearance or approval are obtained. The premarket review process for diagnostic products can be lengthy, expensive, time-consuming, and unpredictable. Further, obtaining premarket clearance or approval may involve, among other things, successfully completing clinical trials. Clinical trials require significant time and cash resources and are subject to a high degree of risk, including risks of experiencing delays, failing to complete the trial or obtaining unexpected or negative results. If mdxhealth is required to obtain premarket clearance or approval and/or conduct premarket clinical trials, development costs could significantly increase, the introduction of any new tests under development may be delayed, and sales of the Company's existing tests could be interrupted or stopped. If it were required to cease sales of the Confirm mdx test, this would have an immediate and severe impact on its revenues, given that 59% of service revenue in 2022 was attributable to the Confirm mdx test.

Any of these outcomes could reduce revenues or increase costs and materially adversely affect its business, prospects, results of operations, or financial condition. Moreover, any cleared or approved labelling claims may not be consistent with current claims or be adequate to support continued adoption of and reimbursement for its tests. For instance, if FDA requires that any of the Company's tests be labelled as investigational, or if the labelling claims the FDA allows are limited, order levels may decline and reimbursement may be adversely affected. If after commercialisation under the LDT framework its tests are allowed to remain on the market but there is uncertainty about the regulatory status of its tests, including questions that may be raised if competitors object to its regulatory positioning as an LDT, mdxhealth may encounter ongoing regulatory and legal challenges and related costs. Such challenges or related developments (for example if the labelling claims the FDA allows mdxhealth to make are more limited than the claims mdxhealth currently plans to make) may impact its commercialisation efforts as orders or reimbursement may be less than anticipated. As a result, mdxhealth could experience significantly increased development costs and a delay in generating additional revenue. Until the FDA finalises its regulatory position regarding LDTs, or federal legislation is passed concerning regulation of LDTs, it is unknown how the FDA may regulate its tests in the future and what testing and data may be required to support any required clearance or approval as a medical device or an "in vitro clinical test" (as that category is being defined in the VALID Act, as introduced).

The requirement of premarket review could negatively affect its business until such review is completed and regulatory clearance or approval is obtained. The FDA could require that sales of one or more of the Company's tests be halted pending premarket clearance or approval. In December 2018 the FDA Commissioner and the Director of the Center for Devices and Radiological Health (the "**CDRH**") expressed significant concerns regarding disparities between some LDTs and in vitro diagnostics that have been reviewed and cleared or approved by FDA. If the FDA were to determine that its tests are not within the policy for LDTs for any reason, including new rules, policies, or guidance, or due to changes in statute, mdxhealth's tests may become subject to FDA requirements, including premarket review. If required, the regulatory marketing authorisation process may involve, among other things, successfully completing additional clinical trials and submitting a premarket clearance (510(k)) submission or filing a de novo or premarket approval application with the FDA. If premarket review and authorisation is required by the FDA, mdxhealth may need to incur additional expenses or require additional time to seek it, or mdxhealth may be unable to satisfy FDA standards, and its tests may not be cleared or approved on a timely basis, if at all, and the labeling claims permitted by the FDA may not be consistent with its currently planned claims or adequate to support adoption of and reimbursement for its tests. If the FDA requires any form of premarket review, the Company's tests may not be cleared or approved on a timely basis, if at all. Mdxhealth may also decide voluntarily to pursue FDA premarket review and authorisation of its tests if it appears that doing so would be appropriate.

In addition, mdxhealth believes that the sample collection kits provided by mdxhealth for collection and transport of specimens from a health care provider to its clinical laboratories are considered a Class I medical devices subject to the FDA's general device controls but exempt from premarket review. However, the FDA could assert the specimen collection kits

are non-exempt or Class II devices, which would subject them to premarket clearance or approval processes, which could be time-consuming and expensive.

Failure to comply with any applicable FDA requirements could trigger a range of enforcement actions by the FDA, including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity. These impacts could be material for the Company, particularly given the broad enforcement powers of the FDA.

**Mdxhealth expects to make significant investments to research and develop new tests, which may not be successful.**

Mdxhealth is seeking to improve the performance of certain of its tests and to develop a pipeline for future products and services. For example, in August 2022, it announced that it had entered into an agreement to acquire the GPS test from Exact Sciences. In addition, it is currently developing an additional product for the prostate cancer diagnostic and treatment pathway. Not all men diagnosed with localized prostate cancer benefit from intervention as some tumors are slow growing and non-life threatening. Mdxhealth's Monitor mdx product, which is being developed as a non-invasive alternative that risk stratifies patients for continued active surveillance versus intervention, may also improve patient compliance with active surveillance protocols. Mdxhealth estimates the addressable market in the United States for the Monitor mdx test at approximately 1.5 million men annually, or U.S.\$1.5 billion. It is also recently developed and launched non-invasive urine test that identifies and quantifies infectious bacteria and their antibiotics susceptibility to help ensure patients receive the correct diagnosis and treatment as quickly as possible. Mdxhealth estimates the addressable market in the United States for UTI testing at approximately 2 million men annually, or U.S.\$1 billion. See also chapter "*Business Overview*, section "*Principal activities*", sub-section "*Pipeline*" of this report.

Developing new or improved diagnostic tests is a speculative and risky endeavour. Candidate products and services that may initially show promise, may fail to achieve the desired results in larger clinical validation studies, or may not achieve acceptable levels of clinical accuracy. Results from early studies or trials are not necessarily predictive of future clinical validation or clinical trial results, and interim results of a validation study or trial are not necessarily indicative of final results. From time to time, mdxhealth may publicly disclose then-available data from clinical validation studies before completion, and the results and related findings and conclusions may be subject to change following the final analysis of the data related to the particular study. As a result, such data should be viewed with caution until the final data are available. Additionally, such data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrolment and/or follow-up continues and more patient data become available. Significant differences between initial or interim data and final data from either its clinical validation studies or clinical trials could significantly alter its plans to proceed with additional studies or trials, and harm its reputation and business prospects. If mdxhealth determines that any of its current or future development programs is unlikely to succeed, mdxhealth may abandon it without any return on its investment into the program. Mdxhealth may need to raise additional capital to bring any new products or services to market, which may not be available on acceptable terms, if at all. See also " — *Mdxhealth might require substantial additional funding to continue its operations and to respond to business needs or take advantage of new business opportunities, which may not be available on acceptable terms, or at all*".

**Mdxhealth's research and development efforts will be hindered if it is not able to obtain samples, contract with third parties for access to samples or complete timely enrollment in future clinical trials.**

Access to human sample types, such as blood, tissue, stool, or urine is necessary for its research and product development. Acquiring samples from individuals with clinical diagnoses or associated clinical outcomes through purchase or clinical studies is necessary. Lack of available samples can delay development timelines and increase costs of development. Generally, the agreements under which mdxhealth gains access to human samples are non-exclusive. Other companies

may compete with mdxhealth for access. Additionally, the process of negotiating access to samples can be lengthy and it may involve numerous parties and approval levels to resolve complex issues such as usage rights, institutional review board approval and patient informed consent, privacy rights, publication rights, intellectual property ownership and research parameters. If mdxhealth is not able to negotiate access to clinical samples with research institutions, hospitals, clinical partners, pharmaceutical companies, or companies developing therapeutics on a timely basis, or at all, or if other laboratories or its competitors secure access to these samples before mdxhealth, its ability to research, develop and commercialise future products will be limited or delayed. Finally, mdxhealth may not be able to conduct or complete clinical trials on a timely basis if mdxhealth is not able to enroll sufficient numbers of patients in such trials, and its failure to do so could have an adverse effect on its research and development and product commercialisation efforts.

**Mdxhealth's expansion of its business beyond the United States has resulted in additional regulatory requirements with which it must comply.**

Mdxhealth's expansion of its business outside of the United States increases the potential of violating foreign laws similar to those described above under " — 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". In order to market its tests in other countries, mdxhealth may be required to obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. The European Union/European Economic Area (the "EU/EEA"), requires a CE conformity mark in order to market medical devices. Many other countries accept CE or FDA clearance or approval, although others, require separate regulatory filings. Further, the advertising and promotion of its products in the EEA is subject to the laws of individual EEA Member States implementing the EU Medical Devices Directives including Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State laws governing the advertising and promotion of medical devices. Going forward, CE marking will be pursuant to Regulation 2017/745 (the "**Medical Devices Regulation**" or "**MDR**") and Regulation 2017/746 (the "**In Vitro Diagnostic Medical Devices Regulation**" or "**IVDR**"), which were passed by the European Parliament on 5 April 2017 and became applicable from 26 May 2021 (previously 26 May 2020) for the MDR and from 26 May 2022 for the IVDR. The Medical Devices Regulation and the In Vitro Diagnostic Medical Devices Regulation contain further obligations for medical devices and in vitro diagnostic medical devices with which mdxhealth will be required to comply as applicable. These new laws are generally stricter than the requirements previously in place and contain increased evidence requirements for CE marking. They may limit or restrict the advertising and promotion of its tests to the general public and may impose limitations on promotional activities with healthcare professionals. The risk of being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against mdxhealth for violation of these or other laws or regulations, even in case of successful defence against it, could result in significant legal expenses and divert management's attention from the operation of its business. Since its business is primarily based in the United States, these laws or regulations would not have an immediate material impact on its revenues. However, in the longer term, its prospects could be seriously harmed.

**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. Its 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.

The net operating loss ("NOL") carry forwards of the Company's corporate subsidiaries may be unavailable to offset future taxable income because of restrictions under U.S. tax law. As of 31 December 2022, consolidated net tax loss carried forward amounted to USD 285.3 million. The Company's NOLs generated in tax years ending on or prior to 31 December 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law, and therefore could expire unused. The Company considers that it is highly likely that it will be unable to use at least a portion of these NOLs, in light of its continued losses. Under tax legislation commonly referred to as the Tax Cuts and Jobs Act ("TCJA"), as modified by the CARES Act, its federal NOLs generated in tax years ending after 31 December 2017 may be carried forward indefinitely and NOLs arising in taxable years beginning after 31 December 2017 and before 1 January 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after 31 December 2020 may not be carried back. In addition, under the TCJA, as modified by the CARES Act, for taxable years beginning after 31 December 2020, the deductibility of federal NOLs generated in taxable years beginning after 31 December 2017 is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to the TCJA, as modified by the CARES Act.

In addition, under sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset post-change income and taxes may be limited. Similar rules may apply under state tax laws. Its existing NOLs and other certain tax attributes may be subject to limitations arising from previous ownership changes, and if mdxhealth undergoes an ownership change in connection with, or mdxhealth undergoes an ownership change following, this offering, its ability to utilise NOLs and such other tax attributes could be further limited by Sections 382 and 383 of the Code. In addition, future changes in its stock ownership, many of which are outside of its control, could result in an ownership change under Sections 382 and 383 of the Code. Mdxhealth has not conducted any studies to determine annual limitations, if any, that could result from such changes in the ownership. Its ability to utilise those NOLs and certain other tax attributes could be limited by an "ownership change" as described above and consequently, mdxhealth may not be able to utilise a material portion of its NOLs and certain other tax attributes, which could have a material adverse effect on its cash flows and results of operations by effectively increasing its future tax obligations.

Also under Belgian tax law, certain restrictions regarding the use of Belgian tax losses carried forward apply and these losses may also be forfeited upon certain changes of control over Belgian corporate taxpayers. As a Coronavirus measure, some limited tax loss carried back mechanism was introduced in Belgian tax law.

Given that mdxhealth has historically generated operating losses, any change in its ability to use NOLs could have a severe impact on mdxhealth if and when mdxhealth becomes profitable. As of 31 December 2022, mdxhealth had an accumulated deficit of USD 288.3 million and for the year ended 31 December 2022, mdxhealth had a net loss of USD 44.0 million.

## Risks Related to the ADSs and Ordinary Shares.

### **The Company may lose its foreign private issuer status in the future, which could result in significant additional costs and expenses.**

As a foreign private issuer for U.S. purposes, the Company is not required to comply with all the periodic disclosure and current reporting requirements of the Exchange Act (as defined below) and related rules and regulations in the U.S. The determination of foreign private issuer status will be made annually on the last business day of the Company's most recently completed second fiscal quarter. Accordingly, the Company will next make a determination with respect to its foreign private issuer status on 30 June 2023. There is a risk that the Company will lose its foreign private issuer status in the future. The Company would lose its foreign private issuer status if, for instance more than 50% of its ordinary shares are owned by U.S. residents or persons and more than 50% of its assets are located in the United States and the Company continues to fail to meet additional requirements necessary to maintain its foreign private issuer status. The regulatory and compliance costs to the Company under U.S. securities laws as a U.S. domestic issuer may be significantly greater than the costs the Company incurs as a foreign private issuer. If the Company is not a foreign private issuer, it will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. For instance, it would be required to commence quarterly reporting on Form 10-Q, whereas it currently reports on a semi-annual basis. The Company would also be required under current SEC rules to prepare its financial statements in accordance with U.S. GAAP and modify certain of its policies to comply with corporate governance practices associated with U.S. domestic issuers. Such conversion and modifications would involve significant additional costs. In addition, the Company may lose its ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers, which could also increase the Company's costs, for example in relation to internal controls requirements.

### **The Company is incurring significant increased costs as a result of operating as a company that is publicly listed on both NASDAQ in the U.S. and Euronext Brussels in Belgium, and the Company's management is required to devote substantial time to compliance initiatives.**

As a U.S. public company listed on the NASDAQ Capital Market, the Company is incurring legal, accounting, and other expenses that it would not incur if it were only listed on Euronext Brussels. As a result of its listing on the NASDAQ Capital Market in the U.S., the Company is subject to the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the NASDAQ listing requirements and other applicable securities rules and regulations in the U.S. Compliance with these rules and regulations increase the Company's legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on its systems and resources, particularly after the Company would no longer be an "emerging growth company" and/or a foreign private issuer. The Exchange Act would require that, as a public company, the Company files annual, semi-annual and current reports with respect to its business, financial condition and result of operations. However, as a foreign private issuer, the Company is not required to file quarterly and current reports with respect to the mdxhealth's business and results. The Company currently makes annual and semi-annual reporting with respect to its listing on Euronext Brussels.

Moreover, these rules and regulations have increased the Company's legal and financial compliance costs and have made some activities more time-consuming and costly.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Further, being a U.S. listed company and a Belgian public company with shares admitted to trading on Euronext Brussels impacts the disclosure of information and requires compliance with two sets of applicable rules. From time to time, this may result in uncertainty regarding compliance matters and result in higher costs necessitated by legal analysis of dual legal regimes, ongoing revisions to disclosure and adherence to heightened governance practices. As a result of the enhanced disclosure requirements of the U.S. securities laws, business and financial information that the Company reports is broadly disseminated and highly visible to investors, which the Company believes may increase the likelihood of threatened or actual litigation, including by competitors and other third parties, which could, even if unsuccessful, divert financial resources and the attention of the Company's management from its operations. See also " — The Company may lose its foreign private issuer status in the future, which could result in significant additional costs and expenses".

**As a result of being a U.S. public company, the Company is subject to additional regulatory compliance requirements, including Section 404, and if the Company fails to maintain an effective system of internal controls, it may not be able to accurately report its financial results or prevent fraud.**

Pursuant to Section 404, the Company's management is required to assess and attest to the effectiveness of its internal control over financial reporting in connection with issuing its consolidated financial statements as of and for the year ending on 31 December 2022. Section 404 also requires an attestation report on the effectiveness of internal control over financial reporting be provided by the Company's independent registered public accounting firm beginning with its annual report following the date on which the Company is no longer an “emerging growth company”, which may be up to five fiscal years from the date of the Offering.

The cost of complying with Section 404 may significantly increase and management's attention may be diverted from other business concerns, which could adversely affect the Company's results. The Company may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will further increase expenses. If the Company fails to comply with the requirements of Section 404 in the required timeframe, it may be subject to sanctions or investigations by regulatory authorities, including the SEC and NASDAQ. Furthermore, if the Company is unable to attest to the effectiveness of its internal control over financial reporting, it could lose investor confidence in the accuracy and completeness of its financial reports, and the market price of its ADSs could decline, which could also have an impact on the trading of the Company's Shares on Euronext Brussels. Failure to implement or maintain effective internal control over financial reporting could also restrict the Company's future access to the capital markets and subject the Company, its directors and its officers to both significant monetary and criminal liability. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. The Company intends to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expense and a diversion of the Company's management's time and attention from revenue generating activities to compliance activities. If the Company's efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against the Company and its business, financial position, results and prospects may be materially adversely affected. See also " — The Company may lose its foreign private issuer status in the future, which could result in significant additional costs and expenses".

**The Company will likely not be in a position to pay dividends in the near future and intends to retain all earnings.**

The Company has not declared or paid dividends on the Shares in the past. Any declaration of dividends will be based upon the Company's earnings, financial condition, capital requirements and other factors considered important by the board of directors.

Belgian law and the Company's articles of association do not require the Company to declare dividends. Currently, the board of directors of the Company expects to retain all earnings, if any, generated by the Company's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the near future as the Company expects losses to continue as a result of costs relating to ongoing R&D and for increased sales and marketing costs for existing and planned solutions.

Under the senior secured loan agreement entered into between with Innovatus and the Company, no distributions can be declared or made without consent of Innovatus. Furthermore, additional financial restrictions and other limitations may be contained in future credit agreements.

**Certain significant shareholders of the Company may have different interests from the Company and may be able to control the Company, including the outcome of shareholder votes.**

The Company has a number of significant shareholders. For an overview of the shareholders that notified the Company pursuant to applicable transparency disclosure rules and the articles of association of the Company, up to the date of this report, reference is made to chapter "*Principal shareholders*", section "*Overview of the Company's shareholder structure*". These shareholders are MVM Partners LLC, Bleichroeder LP, Valiance Asset Management and Biovest NV.

As part of the subscription for new Shares completed on 15 May 2020, the Company entered into a subscription agreement dated 24 April 2020 with MVM V LP and MVM GP (No. 5) LP, funds managed by MVM Partners, LLC (collectively, "**MVM**") (the "**Subscription Agreement**"). Pursuant to the Subscription Agreement, MVM is entitled to have one observer at the board of directors of the Company for as long as MVM holds in aggregate 5% of the Company's outstanding Shares. At the date of this report, the observer of MVM to the Company's board of directors is Mr. Kyle Dempsey. In addition, the Company agreed that it would propose to the Company's general shareholders' meeting to appoint Dr. Eric Bednarski as director of the Company. The general shareholders' meeting held on 30 July 2020 approved the appointment of Dr. Eric Bednarski as a director of the Company for a term of three years, up to and including the closing of the annual general shareholders' meeting to be held in 2023 which will have decided upon the financial statements for the financial year ended on 31 December 2022.

On the basis of the transparency notifications received by the Company as of the date of this report, the four main shareholders of the Company hold the following percentages of the voting rights attached to the Shares: MVM Partners, LLC holds an aggregate of 17.31%; Bleichroeder LP holds an aggregate of 14.75%; Valiance Asset Management Limited holds an aggregate of 7.74%; and Biovest NV holds 4.41%. As a consequence, the four main shareholders of the Company hold together 44.21% of the voting rights attached to the Shares.

The Company is not aware of shareholders of the Company that have entered into a shareholders' agreement or have agreed to act in concert. Nevertheless, they could, alone or together, have the ability to elect or dismiss directors, and, depending on how widely the Company's Shares are held, take certain shareholders' decisions that require at least 50%, 75% or 80% of the votes of the shareholders that are present or represented at general shareholders' meetings where such items are submitted to voting by the shareholders. Alternatively, to the extent that these shareholders have insufficient votes to impose certain shareholders' decisions, they could still have the ability to block proposed shareholders' resolutions that require at

least 50%, 75% or 80% of the votes of the shareholders that are present or represented at general shareholders' meetings where such decisions are submitted to voting by the shareholders. Any such voting by the shareholders may not be in accordance with the interests of the Company or the other shareholders of the Company.

**The market price of the Shares may fluctuate widely in response to various factors.**

Publicly traded securities from time to time experience significant price and volume fluctuations that may be unrelated to the results of operations or the financial condition of the companies that have issued them. In addition, the market price of the Shares has historically been volatile, ranging during the last 12 months prior the date of this report from a high of EUR 0.97 on 20 May 2022 and a low of EUR 0.25 on 14 March 2023. The market price of the Shares and ADSs may continue to fluctuate significantly in response to a number of factors, many of which are beyond mdxhealth's control, including fluctuations in the Company's results of operations, changes in estimates by securities analysts and potential or actual sales of the Shares.

In addition, stock markets have in the recent past experienced extreme declines and price and volume fluctuations. These fluctuations have not always been related to the performance of the specific companies whose shares are traded. These and other market and industry factors may cause the market price and demand for the Shares and ADSs to fluctuate substantially, regardless of the Company's actual operating performance, which may limit or prevent investors from readily selling their Shares or ADSs and may otherwise negatively affect the liquidity of the trading of the Shares and ADSs.

**The Company's securities are traded on more than one market and this may result in price variations; in addition, investors may not be able to easily move securities for trading between such markets.**

The Company's ordinary shares have traded on the Euronext Brussels since 2006 and the Company had its ADSs (representing part of the Shares) approved for listing on the NASDAQ Capital Market in November 2021. Trading in its ADSs or Shares on these markets take place in different currencies (USD on the NASDAQ Capital Market and EUR on Euronext Brussels), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and Belgium). The trading prices of its Shares and its ADSs on these two markets may differ due to these and other factors. Any decrease in the price of the Company's ADSs on the NASDAQ Capital Market could cause a decrease in the trading price of its Shares on the Euronext Brussels, and vice versa. Investors could seek to sell or buy the Shares to take advantage of any price differences between the markets through a practice referred to as arbitrage. Any arbitrage activity could create unexpected volatility in both the trading prices on one exchange, and the securities available for trading on the other exchange. In addition, holders of ADSs are immediately able to surrender their ADSs and withdraw the underlying ordinary shares for trading on the other market without effecting necessary procedures with the depositary. This could result in time delays and additional cost for holders of ADSs. Furthermore, the listing of the Shares on Euronext Brussels and the ADSs on the NASDAQ Capital Market may reduce the liquidity of these securities in one or both markets, and may adversely affect the development of an active trading market for the New Shares or ADSs.

**Future sales of substantial amounts of the Shares, or the perception that such sales could occur, could adversely affect the market value of the Shares.**

Any sale of a significant number of the Shares on the public markets, notably by one of its major shareholders (such as MVM Partners, LLC (who notified the Company on 28 February 2023 that it held 17.31% of the outstanding shares of the Company (on a non-diluted basis)), Bleichroeder LP (who notified the Company on 3 February 2023 that it held 14.75% of the outstanding shares of the Company (on a non-diluted basis)), Valiance Asset Management Limited (who notified the Company on 12 April 2023 that it held 7.74% of the outstanding shares of the Company (on a non-diluted basis)), and Biovest NV (who notified the Company on 17 March 2023 that it held 4.41% of the outstanding shares of the Company (on a non-diluted basis)), or the perception that such sales could or will occur, may adversely affect the market price of the Shares.

The Company cannot make any predictions as to the sale or perception thereof on the market price of the Shares. Within the framework of the Offering, the Company entered into a standstill undertaking for a period ending on the date falling 90 days after 3 February 2023. Notably, the Company undertook that during this period it will not, without the prior written consent of Cowen and Company, LLC and William Blair & Company, L.L.C., (1) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or dispose of, directly or indirectly, any ADSs, Shares or any securities convertible into, exercisable or exchangeable for or that represent the right to receive ADSs or Shares (including without limitation, ADSs or Shares which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a share option or warrant) whether now owned or hereafter acquired; (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the securities described in clause (1), whether any such transaction described in clause (1) or (2) above is to be settled by delivery of ADSs or Shares or such other securities, in cash or otherwise; (3) make any demand for or exercise any right with respect to, the registration of any ADSs, Shares or any security convertible into or exercisable or exchangeable for ADSs or Shares; or (4) publicly disclose the intention to do any of the foregoing.

In the framework of the Offering, each of mdxhealth's executive officers, directors and certain of its existing shareholders have also agreed, subject to limited exceptions, not to offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or subscription rights (warrant) to purchase or otherwise dispose of, directly or indirectly, or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the ADSs, Shares or such securities convertible or exercisable into ADS or Shares for a period of 90 days after 3 February 2023, or publicly disclose the intention to do any of the foregoing, without the prior written consent of the Underwriters.

**Any future capital increases by the Company could have a negative impact on the price of the Shares and could dilute the interests of existing shareholders.**

The Company announced on 3 February 2023 that it had successfully raised an amount of USD 40.0 million (or approximately EUR 37.1 million, on the basis of the exchange rate of EUR 1.00 for USD 1.0776 as published by the European Central bank ("**ECB**") on 6 February 2023) in gross proceeds by means of a public offering in the United States of Offered Shares represented by 10,000,000 ADSs at an issue price of USD 4.00 per ADS. The Company then announced on 6 March that Cowen and Company, LLC, William Blair & Company, L.L.C., BTIG, LLC and KBC Securities USA, LLC (the "**Underwriters**") exercised the Option (as defined below), on the same terms and conditions as in the Offering, in the amount of 750,000 ADSs at a price of USD 4.00 per ADS for gross proceeds of USD 3.0 million (or approximately EUR 2.8 million, on the basis of the exchange rate of EUR 1.00 for USD 1.0665 as published by the ECB on 7 March 2023). The New Shares represent approximately 66.00% of the Company's outstanding Shares before the Offering. The completion of the Offering resulted in a dilution of 39.76% of the then existing shareholders of the Company and of the relative voting power of each share in the Company at that time. For more information about the consequences of the Offering for the financial and shareholder rights of the shareholders of the Company, reference is made to the report of the board of directors in accordance with article 7:198 juncto articles 7:179, 7:191 and, insofar as needed and applicable, 7:197 of the Belgian Companies and Associations Code. This board report must be read together with the report in accordance with article 7:198 juncto articles 7:179 and 7:191 of the Belgian Companies and Associations Code and, insofar as needed and applicable, the report in accordance with article 7:198 juncto articles 7:179 and 7:197 of the Belgian Companies and Associations Code, both of which reports were prepared by the Company's statutory auditor, BDO Réviseurs d'Entreprises SRL, represented by Mr. Bert Kegels, auditor. The aforementioned reports are available on the Company's website and are incorporated by reference in this report.

The Company may in the future increase its share capital against cash or contributions in kind to finance any future acquisition or other investment or to strengthen its balance sheet. The Company may also issue subscription rights that are exercisable for new shares, or raise capital through public or private offerings of convertible debt or equity securities, or rights to acquire these securities. In connection with such transactions, the Company may, subject to certain conditions, limit or dis-apply preferential subscription rights of existing shareholders otherwise applicable to capital increases through contributions in cash. In addition, preferential subscription rights do not apply to capital increases through contributions in kind. Such transactions could therefore dilute the stakes in the Company's share capital held by shareholders and could have a negative impact on the price of the Shares (including the New Shares).



# Financial Statements

## Consolidated financial statements

MDxHealth SA's consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) and interpretations issued by the IFRS Interpretation Committee (IFRS-IC) applicable to companies reported under IFRS. The financial statements comply with IFRS as issued by the International Accounting Standards Board (IASB), collectively "IFRS". Additionally, the financial statements are also prepared in accordance with IFRS as endorsed by the European Union ("EU-IFRS"). 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 annual financial statements have been prepared in accordance with applicable accounting standards, and present a true and fair view of the various activities conducted by the Company during the past financial year. Mr. Mike McGarrity, the CEO and Managing Director, declares, on behalf of the Board of Directors that, to the best of the Board's knowledge, the annual financial statements, prepared in accordance with applicable accounting standards, present a true and fair view of the assets and liabilities of the Company, as well as the financial situation and operating results of the Company.

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 April 24, 2023. The financial statements have been signed by Mr. Michael McGarrity, 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 25, 2023.

*The official version of the annual financial report is the ESEF version.*

## Consolidated statement of profit and loss

Thousands of \$ (except per share amounts) For the years ended December 31	Notes	2022	2021
Services	4	36,965	21,937
Licenses	4	25	250
Royalties and other revenues	4	64	52
<b>Revenues</b>		<b>37,054</b>	<b>22,239</b>
Cost of goods & services sold	4	(17,835)	(11,675)
<b>Gross profit</b>		<b>19,219</b>	<b>10,564</b>
Research and development expenses	5	(7,557)	(6,673)
Selling and marketing expenses	5	(26,582)	(17,744)
General and administrative expenses	5	(23,539)	(14,149)
Other operating income, net	7	559	1,161
<b>Operating loss</b>		<b>(37,900)</b>	<b>(26,841)</b>
Financial expenses, net	8	(6,144)	(2,161)
<b>Loss before income tax</b>		<b>(44,044)</b>	<b>(29,002)</b>
Income tax	9	0	0
<b>Loss for the year</b>		<b>(44,044)</b>	<b>(29,002)</b>
<b>Loss per share attributable to parent</b>			
<b>Basic and diluted, \$</b>	20	<b>(0.28)</b>	<b>(0.24)</b>

## Consolidated statement of comprehensive income

Thousands of \$ For the years ended December 31	Notes	2022	2021
<b>Loss for the year</b>		<b>(44,044)</b>	<b>(29,002)</b>
<b>Other comprehensive income (loss)</b>			
<i>Items that will be reclassified to profit or loss:</i>			
Exchange differences arising from translation of foreign operations		593	264
<b>Total other comprehensive income (loss)</b>		<b>593</b>	<b>264</b>
<b>Total comprehensive loss for the year (net of tax)</b>		<b>(43,451)</b>	<b>(28,738)</b>

## Consolidated statement of financial position

Thousands of \$ For the years ended December 31	Notes	2022	2021
<b>ASSETS</b>			
<b>Non-current assets</b>			
Goodwill	3/10	35,926	0
Intangible assets	11	46,166	3,448
Property, plant and equipment	12	3,791	1,671
Right-of-use assets	12	4,103	3,347
<b>Total non-current assets</b>		<b>89,986</b>	<b>8,466</b>
<b>Current assets</b>			
Inventories	13	2,327	1,911
Trade receivables	14/19	9,357	4,582
Prepaid expenses and other current assets	14	1,962	1,615
Cash and cash equivalents	15/19	15,503	58,498
<b>Total current assets</b>		<b>29,149</b>	<b>66,606</b>
<b>TOTAL ASSETS</b>		<b>119,135</b>	<b>75,072</b>
<b>EQUITY</b>			
Share capital	22	133,454	128,454
Issuance premium	22	153,177	153,177
Accumulated deficit		(288,346)	(244,302)
Share-based compensation	24	11,474	10,607
Translation reserve		(444)	(1,037)
<b>Total equity</b>		<b>9,315</b>	<b>46,899</b>
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Loans and borrowings	16/19	34,914	7,651
Lease liabilities	16	3,091	2,624
Other non-current financial liabilities	16/19	53,537	1,466
<b>Total non-current liabilities</b>		<b>91,542</b>	<b>11,741</b>
<b>Current liabilities</b>			
Loans and borrowings	16/19	616	4,441
Lease liabilities	16	1,172	840
Trade payables	18/19	10,178	7,455
Other current liabilities	18	3,985	2,735
Other current financial liabilities	16/19	2,327	961
<b>Total current liabilities</b>		<b>18,278</b>	<b>16,432</b>
<b>Total liabilities</b>		<b>109,820</b>	<b>28,173</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>119,135</b>	<b>75,072</b>

## Consolidated statement of changes in equity

Thousands of \$ (except number of shares)	Number of shares	Attributable to owners of mdxhealth sa				Total equity
		Share capital & issuance premium	Accumulated Deficit	Share-based compensation	Translation reserve	
<b>Notes</b>		<b>22</b>		<b>24</b>		
<b>Balance at January 1, 2021</b>	<b>90,691,449</b>	<b>213,065</b>	<b>(215,300)</b>	<b>9,385</b>	<b>(1,301)</b>	<b>5,849</b>
Loss for the year			(29,002)			(29,002)
Other comprehensive income					264	264
<b>Total comprehensive income for the year</b>			<b>(29,002)</b>		<b>264</b>	<b>(28,738)</b>
<b>Transactions with owners in their capacity as owners:</b>						
Issuance of shares	65,277,777	75,339				75,339
<b>Deduction of transaction costs</b>		(6,773)				(6,773)
Share-based compensation costs				1,222		1,222
<b>Balance at December 31, 2021</b>	<b>155,969,226</b>	<b>281,631</b>	<b>(244,302)</b>	<b>10,607</b>	<b>(1,037)</b>	<b>46,899</b>
<b>Balance at January 1, 2022</b>	<b>155,969,226</b>	<b>281,631</b>	<b>(244,302)</b>	<b>10,607</b>	<b>(1,037)</b>	<b>46,899</b>
Loss for the year			(44,044)			(44,044)
Other comprehensive income					593	593
<b>Total comprehensive income for the year</b>			<b>(44,044)</b>		<b>593</b>	<b>(43,451)</b>
<b>Transactions with owners in their capacity as owners:</b>						
Issuance of shares as part of GPS acquisition	6,911,710	5,000				5,000
Share-based compensation costs				867		867
<b>Balance at December 31, 2022</b>	<b>162,880,936</b>	<b>286,631</b>	<b>(288,346)</b>	<b>11,474</b>	<b>(444)</b>	<b>9,315</b>

## Consolidated statement of cash flow

Thousands of \$ For the years ended December 31	Notes	2022	2021
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
<b>Operating loss</b>		<b>(37,900)</b>	<b>(26,841)</b>
Depreciation and amortization	11/12	4,909	3,036
Impairment	11	44	0
Share-based compensation	24	867	1,222
Other non-cash transactions		(473)	(325)
<b>Cash used in operations before working capital changes</b>		<b>(32,553)</b>	<b>(22,908)</b>
Increase (-) / Decrease (+) in inventories	13	(416)	413
Increase (-) in receivables	14	(5,122)	(1,383)
Increase (+) in payables	18/19	3,973	1,330
<b>Net cash outflow from operating activities</b>		<b>(34,118)</b>	<b>(22,548)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Purchase of property, plant and equipment	12	(2,789)	(896)
Acquisition and generation of intangible assets	11	(1,374)	0
Acquisition of Genomic Prostate Score Business	11	(25,000)	0
<b>Net cash outflow from investing activities</b>		<b>(29,163)</b>	<b>(896)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Proceeds from issuance of shares (net of transaction costs)	22	0	68,566
Proceeds from loan obligation	16	34,291	0
Repayment of loan obligation and debt extinguishment costs		(10,805)	0
Payment of lease liability	16	(1,358)	(1,057)
Payment of interest		(1,412)	(1,011)
Interests received	8	125	11
<b>Net cash inflow from financing activities</b>		<b>20,841</b>	<b>66,509</b>
<b>Net Decrease (-) / increase (+) in cash and cash equivalents</b>		<b>(42,440)</b>	<b>43,065</b>
Cash and cash equivalents at beginning of the financial year		58,498	15,953
Effect on exchange rate changes		(555)	(520)
<b>Cash and cash equivalents at end of the financial year</b>	<b>14/18</b>	<b>15,503</b>	<b>58,498</b>



# Notes

## Notes to consolidated financial statements

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NOTE 29:	Principal audit fees and services

## NOTE 1: Status and principal activity

When used in this report, all references to "MDxHealth", the "company", "we", "our" and "us" refer to MDxHealth, SA and its subsidiaries. MDxHealth is a limited liability company domiciled in Belgium, with offices and labs in Belgium, the United States and The Netherlands.

MDxHealth is a commercial-stage precision diagnostics company committed to providing non-invasive, clinically actionable and cost-effective urologic solutions to improve patient care. The Company's novel prostate cancer genomic testing solutions combine advanced clinical modeling with genomic data to provide each patient with a personalized cancer risk profile, which provides more accurate and actionable information than standard risk factors (e.g., PSA, DRE, age) used by clinicians.

The Company's Select mdx and Confirm mdx solutions address men at risk for developing prostate cancer, providing physicians with a clear clinical pathway to accurately identify clinically significant prostate cancer while minimizing the use of invasive procedures that are prone to complications. The Company's Genomic Prostate Score (GPS) solution addresses men newly diagnosed with early-stage prostate cancer, providing physicians with a clear clinical pathway to make the most informed treatment decision for their individual disease, including active surveillance. The Company's collective decades of experience in precision diagnostics and its portfolio of novel biomarkers for diagnostic, prognostic and predictive molecular assays supports its active pipeline of new testing solutions for prostate and other urologic diseases.

MDxHealth offers its laboratory solutions from its state-of-the-art, 13,448 square feet, College of American Pathologists (CAP)-accredited and Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified, molecular laboratory facility located at its U.S. headquarters in Irvine, California as well as a CLIA-certified lab in Plano, Texas. MDxHealth also operates a molecular laboratory facility, MDxHealth B.V., located in Nijmegen, the Netherlands. This site is ISO 13485:2016 certified and operates a management quality system with the following scope: The design and development, manufacture, service laboratory activities and client services of in vitro diagnostic test kits, in vitro diagnostic reagents used for molecular diagnostic detection of oncological diseases.

The Company is headquartered in Belgium. The parent company, MDxHealth SA, has its registered and corporate office in Cap Business Center, Rue d'Abhooz 31, 4040 Herstal, Belgium. MDxHealth, Inc., the Company's U.S. 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 Transistorweg 5, 6534 Nijmegen, The Netherlands.

NOTE 2: Summary of Significant Accounting Policies

2.1. BASIS OF PREPARATION AND STATEMENT OF COMPLIANCE

MDxHealth’s consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) and interpretations issued by the IFRS Interpretation Committee (IFRS-IC) applicable to companies reported under IFRS. The financial statements comply with IFRS as issued by the International Accounting Standards Board (IASB) collectively “IFRS”. Additionally, the financial statements are also prepared in accordance with IFRS as endorsed by the European Union (“EU-IFRS”).

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. The functional and presentation currency is the U.S. Dollar and all amounts are presented in thousands of U.S. Dollars (\$), rounded to the nearest thousand, unless otherwise indicated.

2.2. BASIS OF CONSOLIDATION

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

Subsidiaries are all entities over which the Company has control. The Company controls an entity when the Company is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Company. The acquisition method of accounting is used to account for business combinations by the Company.

All intercompany balances, profits and transactions are eliminated upon consolidation.

2.3. GOING CONCERN

The Company has experienced net losses and significant cash used in operating activities since its inception in 2003, and as of December 31, 2022, had an accumulated deficit of \$288.3 million, a net loss of \$44.0 million, and net cash used in operating activities of \$34.1 million. Management expects the Company to continue to incur net losses and have significant cash outflows for at least the next twelve months. While these conditions, among others, could raise doubt about its ability to continue as a going concern, these consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of its assets and the satisfaction of liabilities in the normal course of business. A successful transition to attaining profitable operations is dependent upon achieving a level of positive cash flows adequate to support the Company’s cost structure.

As of December 31, 2022, the Company had cash and cash equivalents of \$15.5 million. In February 2023, the Company raised \$40 million in gross proceeds by means of a public offering of 10,000,000 American Depositary Shares (ADSs) being the equivalent of 100,000,000 new shares (approximately 38% of the Company’s outstanding shares) at an issue price of \$4.00 per ADS (or approximately €0.37 per share) through a public offering. In March 2023, the Company received additional gross proceeds of \$3.0 million from the underwriters’ exercise of their overallotment option (for further details of this transaction, refer to Note 27 Subsequent Events). Taking into account the above financial situation and on the basis of the most recent business plan, the Company believes that it has sufficient cash to be able to continue its operations for at least the next twelve months from the date of issuance of these financial statements, and accordingly has prepared the

consolidated financial statements assuming that it will continue as a going concern. This assessment is based on forecasts and projections within management’s most recent business plan as well as the Company’s expected ability to realize cost reductions should these forecasts and projections not be met.

Covid-19 and Macroeconomic Factors

The Company does not believe that COVID-19 or the Ukraine war has an impact on the Company’s ability to continue as a going concern. The Company does not have business relationships with Russia or Ukraine. There is no direct or indirect impact of the conflict on the day-to-day business of the Company. The Company is not materially impacted by inflation, supply disruption or cyber-attacks due to the current geopolitical conflict.

With regards to climate-related matters, the Company is not impacted in a material way by extreme weather conditions.

2.4. USE OF ESTIMATES AND JUDGMENTS

Management makes certain critical accounting estimates and management judgments 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 where assumptions and estimation uncertainties in the financial statements have potentially the most significant effect in 2022, are listed below:

Business combination (see Note 3)

On August 2, 2022, the Company announced it has entered into an agreement with Genomic Health, Inc., a subsidiary of Exact Sciences Corporation ("Exact Sciences"), to acquire the Genomic Prostate Score® (GPS) test (formerly Oncotype DX GPS) from Exact Sciences. The company accounted for this acquisition under the acquisition method of accounting and treated it as a business combination in accordance with IFRS. The purchase price was allocated based on the estimated fair value of net assets acquired and liabilities assumed at the date of the acquisition. Following the closing, an additional aggregate earn-out amount of up to \$70 million is to be paid by MDxHealth to Exact Sciences upon achievement of certain revenue milestones related to fiscal years 2023 through 2025. The fair value of this contingent consideration at the acquisition date of August 2, 2022, was assessed at \$50.5 million, based on a probability-weighted estimate of the net present value expected to become payable, as further detailed in Note 3. Subsequent fair value adjustments to this contingent consideration classified as financial liability are recognized through the statement of profit or loss.

Revenue recognition (see Note 4):

As further described in Note 2.7 (paragraph “Determining the Transaction Price”), the Company analyzes historical collection data on a quarterly basis and makes adjustments to its estimates. In accordance with IFRS 15, revenue is recognized where such a variable consideration is included in the transaction price only to the extent that it is highly probable that the amount of revenue recognized will not be subject to significant future reversals as a result of subsequent re-estimation.

Deferred income tax (see Note 9)

Management estimates unused tax credits and tax losses to the extent that it is probable that taxable profit will be available against which the tax credits and tax losses can be utilized. On December 31, 2022, the Company had a consolidated net tax loss carried forward amounting to \$285.3 million (2021: \$258.5 million), implying a potential deferred tax asset of \$71.3 million (2021: \$64.6 million). No deferred tax assets have been recognized as of December 31, 2022.

**Impairment Testing (see Note 3, 10 and 11)**

The Company has recorded Goodwill of \$35.9 million as part of the GPS business combination (explained above), which is subject to annual impairment testing. The Company has performed an impairment test as of December 31, 2022, at the level of the entire company which is in line with the level at which management monitors its profitability. All the Company’s cash-generating units (CGUs) are expected to benefit from the synergies of the business combination.

The impairment testing is based on a discounted cash flow (DCF) model, with cash flows for the next five years derived from the internal budgets and a residual value that assumes a perpetual growth rate of 2%. The value in use is sensitive to the discount rate used for the DCF model as well as the expected future cash-inflows and the growth rate used for extrapolation purposes.

Key underlying estimates are considered to be estimated cashflows and the weighted-average cost of capital (WACC) and are further described in Note 10.

**Share-Based Payments (see Note 24)**

Management estimates the fair value of the equity-settled share-based payment transactions by using the Black-Scholes option valuation model:

- The dividend return is estimated by reference to the historical dividend payment of the Company; 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 10-year Belgian government bond at the grant date

**Going Concern (note 2.3)**

Management needs to make significant judgements whether the Company will have sufficient liquidity to continue operations during the next twelve months. Refer to Note 2.3 for management assessment.

**Financial liabilities (note 16)**

Other financial liabilities are accounted for at fair value through the statement of profit or loss and include the following:

- The fair value of the contingent consideration payable to Exact Sciences (for the GPS acquisition) and to NovioGendix, which are presented in the yearend statement of financial position under “other non-current financial liabilities” and “other current financial liabilities” are based on an estimated outcome of the conditional purchase price/contingent payments arising from contractual obligations (level 3 input). These are initially recognized as part of the purchase price and then subsequently measured for fair valued. Any changes to fair value are recorded through “other operating income” in the statement of profit or loss.
  - o The fair value of the contingent consideration payable with regard to the GPS acquisition is based on a probability-weighted average estimate based on multiple scenarios varying in timing and amount of earn-out payment. This probability-weighted estimate is then discounted to its net present value taking into account the expected time when the earn-out would become payable in 2024, 2025 and 2026. This contingent consideration was initially recorded along with the purchase price allocation of this business combination as detailed in Note 3. Fair value at December 31, 2022, was estimated at \$52.9 million resulting in a fair value adjustment expense of \$2.4 million. The Company used a discount rate of 14.95%.
  - o For NovioGendix, fair value adjustments gain for the year ended December 31, 2022, totaled \$632,000 and the Company used a discount rate of 12.16%.
- The fair value of the derivative financial liabilities related to the initial Kreos drawdown fee of €630,000 is based upon the

evolution of the share price of MDxHealth as well as the estimated probabilities that either payment at 150%, or conversion into shares, will be requested by Kreos. Whereas share price of MDxHealth can be considered as a level 1 input, the other variable, being the probability assessment of possible scenarios should be considered as level 3 input. The fair value of the liability for the year ended December 31, 2022, is estimated at \$891,000.

The fair value of the derivative financial liabilities related to the Innovatus derivative call option (as detailed in Note 16) was performed using a binomial pricing model which takes into account several factors including the expected evolution in price of an ADS and are considered as level 3 input. The fair value of the liability for the year ended December 31, 2022, is estimated at \$0.9 million.

**2.5. NEW STANDARDS, INTERPRETATIONS AND AMENDMENTS**

**2.5.1. New Standards, Interpretations and Amendments adopted by the Company**

The accounting policies have been consistently applied by the Company and are consistent with those used in previous years.

In the current financial year, the following amendments to standards went into effect for the financial year beginning January 1, 2022, and have been endorsed by the European Union.

- Amendments to IFRS 3 Business Combinations; IAS 16 Property, Plant and Equipment; IAS 37 Provisions, Contingent Liabilities and Contingent Assets as well as Annual Improvements (effective 1 January 2022). The package of amendments includes narrow-scope amendments to three Standards as well as the Board’s Annual Improvements, which are changes that clarify the wording or correct minor consequences, oversights or conflicts between requirements in the Standards.
  - o Amendments to IFRS 3 Business Combinations update a reference in IFRS 3 to the Conceptual Framework for Financial Reporting without changing the accounting requirements for business combinations.
  - o Amendments to IAS 16 Property, Plant and Equipment prohibit a company from deducting from the cost of property, plant and equipment amounts received from selling items produced while the company is preparing the asset for its intended use. Instead, a company will recognise such sales proceeds and related cost in profit or loss.
  - o Amendments to IAS 37 Provisions, Contingent Liabilities and Contingent Assets specify which costs a company includes when assessing whether a contract will be loss-making.
  - o Annual Improvements 2018-2020 make minor amendments to IFRS 1 First-time Adoption of International Financial Reporting Standards, IFRS 9 Financial Instruments, IAS 41 Agriculture and the Illustrative Examples accompanying IFRS 16 Leases.

This adoption has not had any material impact on the disclosures or on the amounts reported in these financial statements.

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

Certain new accounting standards and amendments to standards have been published, but were not mandatory for December 31, 2022 reporting period.

The following new standard and amendments have been issued and endorsed by the European Union, but are not mandatory for the financial year beginning January 1, 2022:

- Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2: Disclosure of Accounting policies (effective January 1, 2023). The amendments aim to improve accounting policy disclosures and to help users of the financial statements to distinguish between changes in accounting estimates and changes in accounting policies.

- The IAS 1 amendment requires companies to disclose their material accounting policy information rather than their significant accounting policies. Further, the amendment to IAS 1 clarifies that immaterial accounting policy information need not be disclosed. To support this amendment, the Board also amended IFRS Practice Statement 2, ‘Making Materiality Judgements’, to provide guidance on how to apply the concept of materiality to accounting policy disclosures. The amendments are effective for annual reporting periods beginning on or after January 1, 2023. Earlier application is permitted (subject to any local endorsement process).
- Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates (effective January 1, 2023). The amendment to IAS 8, ‘Accounting Policies, Changes in Accounting Estimates and Errors’, clarifies how companies should distinguish changes in accounting policies from changes in accounting estimates. The amendments are effective for annual reporting periods beginning on or after January 1, 2023. Earlier application is permitted (subject to any local endorsement process).
  - Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction (effective January 1, 2023). The amendments clarify how companies account for deferred tax on transactions such as leases and decommissioning obligations. The main change in the amendments is an exemption from the initial recognition exemption of IAS 12.15(b) and IAS 12.24. Accordingly, the initial recognition exemption does not apply to transactions in which equal amounts of deductible and taxable temporary differences arise on initial recognition. The amendments are effective for annual reporting periods beginning on or after January 1, 2023 and early adoption is permitted.

No amendments to standards that are issued but not yet effective are considered to materially affect the Company’s accounting policies or any of the disclosures when applied for the first time.

The following amendments have been issued, but are not mandatory for the financial year beginning January 1, 2022, and have not been endorsed by the European Union:

- Amendments to IAS 1 ‘Presentation of Financial Statements: Classification of Liabilities as current or non-current’ (effective January 1, 2024), affect only the presentation of liabilities in the statement of financial position — not the amount or timing of recognition of any asset, liability income or expenses, or the information that entities disclose about those items. The amendments:
  - o clarify that the classification of liabilities as current or non-current should be based on rights that are in existence at the end of the reporting period and align the wording in all affected paragraphs to refer to the "right" to defer settlement by at least twelve months and make explicit that only rights in place "at the end of the reporting period" should affect the classification of a liability;
  - o clarify that classification is unaffected by expectations about whether an entity will exercise its right to defer settlement of a liability; and make clear that settlement refers to the transfer to the counterparty of cash, equity instruments, other assets or services; and
  - o clarify how conditions with which an entity must comply within 12 months after the reporting period, such as covenants, affect the corresponding liability’s classification.
- Amendments to IFRS 16 Leases: Lease Liability in a Sale and Leaseback (effective January 1, 2024). The amendments explain how an entity accounts for a sale and leaseback after the date of the transaction, specifically where some or all the lease payments are variable lease payments that do not depend on an index or rate. They state that, in subsequently measuring the lease liability, the seller-lessee determines ‘lease payments’ and ‘revised lease payments’ in a way that does not result in the seller-lessee recognising any amount of the gain or loss that relates to the right of use it retains. Any gains and losses relating to the full or partial termination of a lease continue to be recognised when they occur as these relate to the right of use terminated and not the right of use retained.

The Company will make an impact analysis in view of the application of the amendment of IAS 1 on its consolidated financial statements.

2.6. FOREIGN CURRENCY TRANSLATION

Functional and presentation currency

Items included in the financial statements of each of the Company’s entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The Company’s functional and presentation currency is the U.S. dollar based on the continuing development of the commercial activities in the U.S. market.

Foreign currency transactions are translated into the functional currency using the exchange rates at the date of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are generally recognized in profit or loss.

The results and financial positions of foreign operations that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- Assets and liabilities for each statement of financial position presented are translated at the closing rate at the date of that balance sheet
- Income and expenses for each statement of profit or loss and statement of comprehensive income are translated at average exchange rates
- All resulting exchange differences are recognized in other comprehensive income

2.7. REVENUE RECOGNITION

Performance obligations and timing of revenue recognition

The majority of the Company’s revenue is derived from laboratory services with revenue recognized at a point in time when control of the services has transferred to the customer. This is generally when the test results are delivered to the customer.

Minor other Company’s revenue is derived from license fees and royalties:

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

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. 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.

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.

Determining the transaction price

A large portion of the Company’s revenues are derived from Medicare, which reimburses the Company for tests performed on its insured patients. Medicare has set a fixed price (via a Local Coverage Determination or “LCD”) for the Company’s Confirm mdx and GPS tests. Therefore, the amount of revenue recognized from Medicare for these tests is determined by reference to the LCD pricing.

For other patients insured by commercial insurance companies where there is no certainty of the amount that will be paid for services rendered, the Company uses historical collection data – on an individual payor basis – to estimate its future collection and corresponding revenues that should be recognized for each type of test. The Company analyzes historical collection data on a monthly basis and makes monthly adjustments to its estimates. In accordance with IFRS 15, revenue is recognized where such a variable consideration is included in the transaction price only to the extent that it is highly probable that the amount of revenue recognized will not be subject to significant future reversals as a result of subsequent re-estimation.

When historical collection data is insufficient to estimate future collections, the Company defaults to cash basis, meaning that revenues will not be recognized until actual cash payment is received from the payor.

Total revenue in any given year includes amounts related to tests performed in previous years that relate to:

- revenue from transactions in previous years that did not previously meet the revenue recognition criteria;
- differences between the revenue recognized in previous years and the actual amount received; and
- reversals of revenue relating to balances that are outstanding for more than 9 months.

2.8. SEGMENT INFORMATION

Information for the Company’s operating segments has been determined by reference to the information used by the chief operating decision maker (“CODM”) of the Company to review the performance of the Company and in making decisions on allocation of resources, the nature of the activities and the management structure and accountabilities. The Company’s CEO has been identified as the chief operating decision maker in accordance with his designated responsibility for the allocation of resources to operating segments and assessing their performance through periodic reporting. The CODM periodically reviews the Company’s performance based on information at a company level.

The Company monitors the profitability of the group as a whole given revenues are generated from clinical laboratory service testing and does accordingly not distinguish different business segments.

2.9. INTANGIBLE ASSETS

Initial measurement:

Externally acquired

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.

Intangible assets are recognized on the business combinations of NovioGendix in 2015 (Select mdx) and GPS in 2022 and include:

- Externally acquired intellectual property, including patents, technology and related IP; and
- Customers

All were valued through application of the relief from royalty method, except for the customers which were valued on the basis of multi-period excess earnings method.

Externally acquired intangible assets also include patents and software licenses which are initially recognized at cost.

Internally generated intangible assets (development costs)

Development costs are capitalized when the following can be demonstrated:

- 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 relate to Confirm mdx, Select mdx, Resolve mdx and GPS.

Subsequent measurement

Intangible assets are carried at their cost less any accumulated amortization and any accumulated impairment losses amortized on a straight-line basis over their estimated useful lives on the following basis:

- Patents & software: shorter of (a) 5 years; or (b) the software license period / patent life
- Intellectual property: 10-15 years
- Customers: 6.5 years
- Capitalized development costs: 5 years

Amortization over the asset’s useful life shall begin when the asset is available for use.

2.10. 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 non-cancellable lease period of the related lease

2.11. RIGHT-OF-USE ASSETS AND LIABILITIES

Right-of-use assets:

The Company recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Unless the Company is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognized right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term. Depreciation periods range between 3 and 6 years. Right-of-use assets are subject to impairment.

Lease liabilities:

At the commencement date of the lease, the Company recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Company and payments of penalties for terminating a lease, if the lease term reflects the Company exercising the option to terminate. The variable lease payments that do not depend on an index or a rate are recognized as expense in the period on which the event or condition that triggers the payment occurs. In calculating the present value of lease payments, the Company uses the incremental borrowing rate at the lease commencement date which is in the following ranges:

- Buildings: 10% and 11%
- Vehicles: 2.5% and 3.75%
- Materials: 5% and 6%

After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the in-substance fixed lease payments or a change in the assessment to purchase the underlying asset.

Short-term leases and leases of low-value assets:

The Company applies the short-term lease recognition exemption to its short-term leases of machinery and equipment (i.e., those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered of low value (i.e., below \$5,000). Lease payments on short-term leases and low-value assets are recognized in the consolidated statement of profit or loss as incurred.

2.12. IMPAIRMENT OF ASSETS

Goodwill and intangible assets that have an indefinite useful life are not subject to amortization and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Other assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. The Company monitors its Goodwill at consolidated Company level which is the level of the Company of cash-generating units (CGUs) benefiting from the synergies. Non-financial assets other than Goodwill that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

2.13. 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.

2.14. GOVERNMENT GRANTS

A government grant is only recorded as a 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.

Government grants are recognized as other operating income over the life of the grant as the required or planned activities are performed and the related costs are incurred, and when there is reasonable assurance that the Company will comply with the conditions of the grant.

2.15. CASH AND CASH EQUIVALENTS

Cash and cash equivalents are carried on the consolidated statement of financial position 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.

2.16. 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.

2.17. SHARE CAPITAL

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

2.18. FINANCIAL ASSETS

The financial assets consist mainly of trade receivables and other current assets (deposits).

Classification and measurement on initial recognition

The classification of financial assets at initial recognition depends on the financial asset’s contractual cash flow characteristics and the Company’s business model for managing them.

The company initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs.

For both trade receivables that do not contain a significant financing component, and trade receivables for which the collection is expected in less than one year, the Company has applied the simplified approach to providing for expected credit losses (ECL) prescribed by IFRS 9, which requires the use of the lifetime expected loss provision for all trade receivables.

Trade receivables do not carry any interest and are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method, less provision for impairment based on expected credit losses, where applicable.

Subsequent measurement

After initial recognition, trade receivables and some other current assets as listed in Note 14 are measured at amortized cost using the effective interest method, less provision for impairment based on expected credit losses.

2.19. FINANCIAL LIABILITIES

The financial liabilities consist mainly of loans and borrowings, lease liabilities, trade and other payables and other financial liabilities that include derivative financial liabilities and contingent consideration related to business combinations.

Measurement on initial recognition

At initial recognition, financial liabilities are measured at fair value less transaction costs unless the financial liability is carried at fair value through the statement of profit or loss, in which case the transaction costs are immediately recognized in the statement of profit or loss. The best estimate of the fair value at initial recognition is usually the transaction price, represented by the fair value of the consideration given or received in exchange for the financial instrument. Any difference between the fair value estimated by the entity and the transaction price (“day one gain or loss”) is recognized:

- in the statement of profit or loss if the estimate is evidenced by a quoted price in an active market; and
- deferred as an adjustment to the carrying amount of the financial instrument in all other cases.

The fair value of the contingent consideration payable at the date of acquisition is computed as the sum of the probability-weighted fair values of the purchase prices, as follows:

- GPS: the liability recognized reflects a probability-weighted estimate at the current net present value at the date of acquisition, which is expected to become payable.
- Noviogendix: each of the potential product development paths. The fair value of each path is in turn computed as the sum of the survival probability discounted to present values of the contingent payments in each such path, including the milestone and commercialization payments. Any other financial liability included in the consideration payable for a business combination is recorded at fair value at the date of acquisition.

The derivative financial instrument related to the Innovatus debt facility option to convert up to 15% of the outstanding aggregate principal amount into ordinary shares of the Company for a period up to August 2, 2025, is accounted for at fair value with a portion of the transaction costs allocated to the embedded derivative being expensed as incurred. The embedded derivative will be measured as an American call option using a binomial tree option pricing model with changes to fair value being recorded in the statement of profit or loss under Financial expenses, net, as described further in Note 16.

The derivative financial instrument related to the initial drawdown fee of the Kreos debt facility, which is either convertible into shares of the Company or repayable in cash at 150% at the discretion of Kreos through 2029, is computed as the sum of the probability-weighted values of the fair values associated with each of the possible outcomes further described in Note 16.

Subsequent measurement

After initial recognition, loans and borrowings, lease liabilities, trade and other payables, are measured at amortized cost using the effective interest method. Contingent considerations and derivative financial liabilities are measured at fair value are reviewed at each reporting period, with any changes in fair value recorded in the statement of profit and loss.

2.20. RETIREMENT BENEFIT PLANS AND EMPLOYEE SAVINGS PLANS

Payments to defined contribution employee savings plans are charged as an expense as they fall due. The Company does not offer nor operate any material defined benefit plans for its employees. With respect to Belgian pension plans and as explained in Note 23, the Company has considered the potential impact of the employer’s legal obligation to guarantee a minimum return on the Belgian pension plans and that this was assessed not to be significant.

2.21. 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 statement of profit or loss. 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

Acquisition of Genomic Prostate Score® (GPS) test (formerly Oncotype DX GPS) from Exact Sciences

On August 2, 2022, the Company announced it has entered into an agreement with Genomic Health, Inc., a subsidiary of Exact Sciences Corporation ("Exact Sciences"), to acquire the GPS test from Exact Sciences. MDxHealth acquired GPS in order to expand its menu of tests targeted into urology and prostate cancer and in order to position the Company as one of the leaders in the urology and prostate cancer space with one of the most comprehensive menus of precision diagnostics.

Under the terms of the agreement, the Company acquired the GPS prostate cancer business of Exact Sciences for an aggregate purchase price of up to \$100 million, of which an amount of \$25 million was paid in cash and an amount of \$5 million was settled through the delivery of 691,171 American Depositary Shares ("ADSs") of the Company, at a price per ADS of \$7.23. Following the closing, which took place on August 2, 2022, an additional aggregate earn-out amount of up to \$70 million is to be paid by the Company to Exact Sciences over a three year period, commencing in 2024, in tranches equal to a portion of the annual revenues attributable to the GPS prostate cancer business for the preceding fiscal year; provided, in each instance, that such revenues exceed certain minimum revenue milestones for such fiscal year.

At the option of MDxHealth, the earn-out amounts can be settled in cash or through the issuance of additional ADSs of the Company (valued in function of a volume weighted average trading price of the Company's shares at the end of the relevant earn-out period) to Exact Sciences, provided that the aggregate number of shares representing the ADSs held by Exact Sciences shall not exceed more than 5% of the outstanding shares of the MDxHealth.

The Acquisition was accounted for under the acquisition method of accounting and is being treated as a business combination in accordance with IFRS given that there are inputs from the intellectual property and customers acquired, a substantive process, consisting of a workforce that was hired from Exact Sciences, which allows the Company to generate outputs as from day 1 of the acquisition. The purchase price was allocated based on the estimated fair value of net assets acquired and liabilities assumed at the date of the acquisition.

The acquisition consideration was comprised of (in thousands USD):

Cash	\$	25,000
Stock		5,000
GPS Contingent consideration		50,483
<b>Total acquisition consideration</b>	<b>\$</b>	<b>80,483</b>

The purchase price in excess of the fair value of net assets acquired, has been considered as residual Goodwill for an amount of \$35.9 million.

The fair value of the identifiable assets at the date of acquisition were:

Thousands of \$ As of December 31, 2022	Carrying value at acquisition date	Fair value adjustments	Fair value at acquisition date
Intangible assets IP / Brand	-	36,550	36,550
Intangible assets Customer relationships	-	8,007	8,007
<b>Total identified assets</b>	<b>-</b>	<b>44,557</b>	<b>44,557</b>
Goodwill	-	35,926	35,926
<b>Acquisition price</b>	<b>-</b>	<b>-</b>	<b>80,483</b>

We have performed a fair value analysis of the business combination, with corresponding adjustments to the intangible assets.

The accounting for the business combination resulted in fair values at date of acquisition of \$44.6 million for the IP/brand and customer relationships, based on the relief-from-royalty valuation method, with a royalty rate of 9.56% and a remaining useful life of 15 years for the IP/Brand and a useful life of 6.5 years for the customer relationships. The discount rate (post-tax WACC) used for the valuation was set at 14.95%. The goodwill recognized is primarily attributable to the trained and knowledgeable workforce and to the expected synergies that will be realized at level of operations, existing customer base, and sales & marketing.

Following the closing, an additional aggregate earn-out amount of up to \$70 million is to be paid by MDxHealth to Exact Sciences upon achievement of certain revenue milestones related to fiscal years 2023 through 2025. The contingent consideration has been assessed at \$52.9 million for the year ended December 31, 2022. The liability recognized reflects a probability-weighted estimate at the current net present value at the date of acquisition, which is expected to become payable, as further detailed in Note 16. Future fair value adjustments to this contingent consideration will be recognized in the statement of profit or loss.

The net deferred tax asset resulting from this purchase price allocation was not recognized given insufficient future taxable profits. The recognized goodwill is expected to be fully tax deductible upon actual payment of the contingent consideration.

The total acquisition-related costs recognized as an expense in General & administrative expenses were \$3.7 million.

The GPS acquisition has contributed \$9.3 million to the Company’s consolidated revenues for the period ended December 31, 2022. Per the unaudited special purpose financial statements for the GPS business filed as exhibit 99.1 to Form 6-K on December 19, 2022, the GPS business generated revenues of \$18.5 million for the six-month period ended June 30, 2022. Revenue information for the month of July 2022 is not available and the Company does segregate the net result of the GPS stand-alone business.

The Company financed the acquisition in part through a \$35 million loan and security agreement with an affiliate of Innovatus Capital Partners, LLC (“Innovatus”), which replaced the Company’s existing €9 million debt facility with Kreos Capital (“Kreos”). Refer to note 16 for further details.

NOTE 4: Revenue and Cost of goods & services sold

REVENUE

Thousands of \$ For the years ended December 31	2022	2021
Services	36,965	21,937
Licenses	25	250
Royalties and other revenues	64	52
<b>Total revenue</b>	<b>37,054</b>	<b>22,239</b>

Revenues related to services are recognized at a point in time while licenses, royalties and other revenues are generally recognized over time as described in Note 2.7.

The Company did not recognize any contract assets or contracts liabilities.

Total revenue for 2022 was \$37.1 million, an increase of 67% as compared to total revenue of \$22.2 million for 2021. Excluding revenues from the recently acquired GPS test, total revenue for 2022 was \$27.7 million, an increase of 25% versus 2021. Revenues from sales of Confirm mdx accounted for 59% and 91% of total revenues in 2022 and 2021, respectively. 2022 revenues were comprised of \$21.8 million from Confirm mdx, \$9.3 million from GPS, \$4.9 million from Resolve mdx, with the remaining revenues from Select mdx and other.

Medicare

Reimbursement for diagnostic tests furnished to Medicare beneficiaries (typically patients aged 65 or older) is usually based on a fee schedule set by the U.S. Centers for Medicare & Medicaid Services ("CMS"), a division of the U.S. Department of Health and Human Services ("HHS"). As a Medicare-enrolled service provider, the Company bills the regional Medicare Administrative Contractor ("MAC") for CMS that covers the region where the testing service is performed by the Company. The Confirm mdx test obtained a positive Medicare local coverage determination ("LCD") in 2014, and the GPS test obtained a positive Medicare coverage LCD in 2015, each of which provides coverage for Medicare patients throughout the United States.

In July 2022, a foundational LCD covering the indication for the Select mdx test became effective under the Molecular Diagnostic Services Program ("MoIDX"), administered by Palmetto GBA, which handles technical assessments for U.S. laboratories that perform molecular diagnostic testing. Under the foundational LCD process recently implemented by MoIDX, all tests within an LCD-covered indication must submit a technical assessment ("TA") for review and consideration. A technical assessment requesting coverage for Select mdx has been submitted and the Company is engaged in an interactive review process with MoIDX. Based on the Company’s most recent communications with MoIDX, a final coverage decision is not expected until mid-year 2023. A final determination with respect to Medicare coverage and reimbursement of the Select mdx test therefore remains pending, and there can be no assurance that such coverage and reimbursement will be granted or, if granted, that it will be maintained.

In 2022, Medicare represented the only payer generating over 10% of the Company’s revenues, for a total of \$15.8 million (2021: \$8.5 million).

At the end of 2022, the Company had concluded agreements with 129 commercial payors for Confirm mdx (2021: 119) and 62 commercial payors for Select mdx (2021: 54).

Segment revenue

The Company does not distinguish different business 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. However, the Company does distinguish different geographical operating segments based on revenue since the revenues are generated both in United States of America and Europe.

In 2022, the Company earned 99.8% (2021: 98.6%) of its revenue from external customers from its clinical laboratory testing services and out-licensing of intellectual property. In 2022, the clinical laboratory testing in the U.S. CLIA laboratory represented 99% of the Company’s revenue (2021: 97%), while the out-licensing of intellectual property revenue in Europe represented less than 1% (2021: 1.5%).

The amount of its revenue from external customers broken down by location is shown in the table below:

Thousands of \$ For the years ended December 31	2022	2021
United States of America	36,768	21,785
Europe	277	441
Rest of the world	9	13
<b>Total segment revenue</b>	<b>37,054</b>	<b>22,239</b>

At the end of 2022, 93% of the non-current assets were located in the US (2021: 38%) and the remaining 7% in Europe (2021: 62%). The increase in non-current assets located in the U.S. is mainly due to acquired intangible assets in the GPS business combination as detailed in Note 3.

COST OF GOODS & SERVICES SOLD

Thousands of \$ For the years ended December 31	Notes	2022	2021
Cost of goods & services sold		17,835	11,675
<b>Total cost of goods &amp; services sold</b>		<b>17,835</b>	<b>11,675</b>

The costs of goods & services sold include the costs associated with providing testing services to third parties and include the cost of materials, labor (including salaries, bonuses, and benefits), transportation, collection kits, and allocated overhead costs associated with processing samples. Allocated overhead costs include depreciation of laboratory equipment, facility occupancy and information technology costs. Costs associated with processing samples are expensed when incurred, regardless of the timing of revenue recognition.

NOTE 5: Nature of expenses

RESEARCH AND DEVELOPMENT EXPENSES

Thousands of \$ For the years ended December 31	Notes	2022	2021
Personnel costs	6	2,453	1,949
Depreciation and amortization	11/12	2,272	1,360
Impairment	11	44	0
Lab consumables		713	793
Patent expenses		430	577
External collaborator fees		783	1,020
Clinical validation		584	842
Other expenses		278	132
<b>Total research and development expenses</b>		<b>7,557</b>	<b>6,673</b>

Research and development expenses consist of costs incurred for the development and improvement of our products. These expenses consist primarily of labor costs (including salaries, bonuses, benefits, and stock-based compensation), reagents and supplies, clinical studies, outside services, patent expenses, depreciation of laboratory equipment, facility occupancy and information technology costs. Research and development expenses also include costs associated with assay improvements and automation workflow for our current suite of products. The Company expenses its research and development expenses in the period in which they are incurred, except for those development expenses that qualify for capitalization (refer to Note 11).

Total research and development expenses increased by 13% over 2021, primarily due to the amortization expenses related to the acquired IP and brand for the GPS business, as well as an increase in lab consumables, partially offset by savings in patent expenses, clinical validation, and external collaborator fees.

SELLING AND MARKETING EXPENSES

Thousands of \$ For the years ended December 31	Notes	2022	2021
Personnel costs	6	19,070	13,402
Depreciation and amortization	11/12	1,628	796
Professional fees		1,259	523
Marketing expenses		2,843	1,761
Travel expenses		789	340
Offices & facilities expenses		356	436
Other expenses		637	486
<b>Total selling and marketing expenses</b>		<b>26,582</b>	<b>17,744</b>

The Company’s sales and marketing expenses are expensed as incurred and include costs associated with its sales organization, including its direct clinical sales force and sales management, medical affairs, client services, marketing and managed care, as well as technical lab support and administration. These expenses consist primarily of labor costs (including salaries, bonuses, benefits, and stock-based compensation), customer education and promotional expenses, market analysis expenses, conference fees, travel expenses and allocated overhead costs.

For the year ended December 31, 2022, selling and marketing expenses increased by \$8.8 million, or 50%, compared to 2021, primarily due to an increase in personnel costs and marketing expenses related to the Company’s acquisition of the GPS business as well as an increase in amortization expense related to customer lists as part of the GPS intangible asset.

GENERAL AND ADMINISTRATIVE EXPENSES

Thousands of \$ For the years ended December 31	Notes	2022	2021
Personnel costs	6	8,995	9,009
Depreciation and amortization	11/12	965	880
Professional fees		7,762	1,678
Public company expenses		4,025	1,108
Offices & facilities expenses		1,142	845
Royalties to third parties		47	152
Other expenses		603	477
<b>Total general and administrative expenses</b>		<b>23,539</b>	<b>14,149</b>

General and administrative expenses include costs for certain executives, accounting and finance, legal, revenue cycle management, information technology, human resources, and administrative functions. These expenses consist primarily of labor costs (including salaries, bonuses, benefits, and stock-based compensation), professional service fees such as consulting, accounting, legal, general corporate costs, and public-company costs associated with the Company’s listing, as well as allocated overhead costs (rent, utilities, insurance, etc.).

General and administrative expenses increased in 2022 by \$9.4 million, of which \$3.7 million were one-time expenses related to the GPS acquisition (included in Professional fees), with the remaining \$5.7 million increase primarily related to higher insurance, professional fees and public company expenses.

NOTE 6: Personnel costs

Thousands of \$ For the years ended December 31	2022	2021
The number of employees at the end of the year was:		
Laboratory operations	67	42
R&D staff	19	14
S&M staff	101	71
G&A staff	71	64
<b>Total number of employees</b>	<b>258</b>	<b>191</b>
<b>Their aggregate remuneration comprised:</b>		
Wages and salaries	23,066	18,150
Social security costs	1,684	1,257
Pension costs	724	594
Health insurance expenses	3,167	2,324
Share-based compensation	867	1,222
Other costs	1,010	813
<b>Total personnel costs</b>	<b>30,518</b>	<b>24,360</b>

The personnel numbers in the table reflect year-end numbers, with 42 sales and marketing employees hired in August 2022 as part of the GPS acquisition.

NOTE 7: Other operating income, net

Thousands of \$ For the years ended December 31	2022	2021
Grant subsidies – The Netherlands	5	382
Grant subsidies – USA	0	659
Fair value adjustments	515	176
Other operating income	39	53
Other operating expenses	0	(109)
<b>Total other operating income, net</b>	<b>559</b>	<b>1,161</b>

Other operating income for the year ended December 31, 2022, primarily consisted of a positive fair value adjustment of \$632,000 of the contingent consideration related to the acquisition of NovioGendix in 2015, partially offset by a negative fair value adjustment of \$117,000 related to the initial Kreos drawdown derivative financial instrument. Other operating income, net, decreased \$602,000 for 2022 compared to 2021, primarily due to reductions in grant income, partially offset by the above-mentioned fair-value adjustments.

NOTE 8: Finance expenses, net

Thousands of \$ For the years ended December 31	2022	2021
Interest income	125	11
Interest on Kreos loan	(660)	(1,566)
Interest on Innovatus loan	(1,615)	0
Interest on other loans and leases	(361)	(309)
Fair value adjustments	(2,479)	(290)
Kreos loan extinguishment	(1,047)	0
Other financial expenses	(107)	(7)
<b>Financial expenses, net</b>	<b>(6,144)</b>	<b>(2,161)</b>

For the year ended December 31, 2022, financial expenses, net, were primarily comprised of fair value adjustments for the GPS contingent consideration of \$2.4 million resulting from changes in net present value, interest charges and extinguishment expenses of \$1.6 million for the loan facility with Kreos Capital (as further detailed in Note 16), and interest charges of \$1.6 million related to the Innovatus debt facility.

Other financial expenses relate to bank costs incurred during the year.

NOTE 9: Income Tax

No income taxes were payable in view of the losses incurred by the Company. On December 31, 2022, the Company had a consolidated net tax loss carried forward amounting to \$285.3 million (2021: \$258.5 million), implying a potential deferred tax asset of \$71.3 million (2021: \$64.6 million) at a tax rate of 25%.

The tax losses related to MDxHealth SA in Belgium are available for carry forward. Until 2021, tax losses related to MDxHealth BV in the Netherlands are available for carry forward to a period of 6 years. As of 2022, tax losses related to MDxHealth BV in the Netherlands are available for carry forward indefinitely. The tax losses of MDxHealth Inc., related to the years beginning on or after January 1, 2018, are available for carry forward indefinitely. Tax losses related to the years before January 1, 2018, can be carried forward to a period of 20 years.

The Company has no notional interest deduction to offset future taxable profits in 2022 and 2021.

Tax credits (investment deductions) amounted to \$402,000 in 2022 and \$372,000 in 2021.

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 2022 and 2021. The tax reconciliation and the impact of the unrecognized deferred tax assets is as follows:

Thousands of \$ For the years ended December 31	2022	2021
Loss for the year	(44,044)	(29,002)
Income tax expense	0	0
Loss before income tax	(44,044)	(29,002)
Tax using the MDxHealth's domestic tax rate (25.00% in 2022 and 2021)	11,011	7,251
Effect of unused tax losses not recognized as deferred tax assets	(11,011)	(7,251)

NOTE 10: Goodwill

On August 2, 2022, the Company acquired the GPS test from Exact Sciences (refer to Note 3 for further details). The purchase price in excess of the fair value of the net assets acquired has been considered as residual goodwill for an amount of \$35.9 million.

The Company is required to test Goodwill for impairment on an annual basis. The recoverable amount is determined based on a value-in-use calculations. The use of this method requires the estimation of future cash flows and the determination of a discount rate in order to calculate the present value of the cash flows.

The company monitors its Goodwill at the consolidated company level, which is the level of cash generating units (CGUs) benefiting from the synergies. The recoverable amount of the CGU has been determined from the value-in-use calculation based on the Company's cash flow projections covering a period of 5 years through December 31, 2027.

The amount by which the CGU's recoverable value exceeds its carrying value is \$39.8 million.

The changes in the carrying value of Goodwill at December 31, 2022 and 2021 can be presented as follows:

Thousands of \$	Goodwill
<b>At January 1, 2021</b>	-
Additions through business combination	-
Impairment	-
Currency translation adjustments	-
<b>Carrying value at December 31, 2021</b>	-
<b>At January 1, 2022</b>	-
Additions through business combination	35,926
Impairment	-
Currency translation adjustments	-
<b>Carrying value at December 31, 2022</b>	<b>35,926</b>

The assumptions used are as follows:

Assumptions used	December 31, 2022
Discount rate (post-tax)	14.95%
Terminal growth rate	2%

The discount rate is based on comparable companies in the industry together with company-specific risks. Terminal growth rate is based on management estimates and industry data.

The Company's impairment review is sensitive to changes in the assumptions used, most notably the discount rate and the terminal growth rate.

An increase of 1% in the discount rate would cause the value-in-use of the CGU to reduce by \$12.5 million but would not give rise to an impairment. A 1% reduction in perpetuity growth rate would cause the value-in-use of the CGU to decrease by \$8.6 million but would not give rise to an impairment. Based on sensitivity analysis performed at December 31, 2022 , an increase of the post-tax discount rate by 3.86% up to 18.81% would result in the carrying amount exceeding the recoverable amount.

Based on the above information, management concluded that there is no Goodwill impairment in 2022.

**NOTE 11: Intangible assets**

Thousands of \$	Patents and software licenses	Internally developed intangible assets	Externally acquired intellectual property	Customers	Total
<b>Gross value</b>					
At January 1, 2021	5,134	9,323	4,500	-	18,957
Gross value at December 31, 2021	5,134	9,323	4,500	-	18,957
<b>Accumulated amortization and impairment</b>					
At January 1, 2021	(4,676)	(6,810)	(2,413)	-	(13,899)
Additions	(234)	(926)	(450)		(1,610)
Accumulated amortization and impairment at December 31, 2021	(4,910)	(7,736)	(2,863)	-	(15,509)
Net value at December 31, 2021	224	1,587	1,637	-	3,448
<b>Gross value</b>					
At January 1, 2022	5,134	9,323	4,500	-	18,957
Additions		1,049	325		1,374
Additions through business combination (Note 3)			36,550	8,007	44,557
Currency translation adjustments					
Gross value at December 31, 2022	5,134	10,372	41,375	8,007	64,888
<b>Accumulated amortization and impairment</b>					
At January 1, 2022	(4,910)	(7,736)	(2,863)	-	(15,509)
Additions	(224)	(942)	(1,490)	(513)	(3,169)
Impairment		(44)			(44)
Currency translation adjustments					
Accumulated amortization and impairment at December 31, 2022	(5,134)	(8,722)	(4,353)	(513)	(18,722)
Net value at December 31, 2022	0	1,650	37,022	7,494	46,166

Amortization of intangible assets is included in research & development expenses and in selling and marketing expenses in the statement of profit and loss.

The externally acquired intangible asset includes technology acquired in the business combination with NovioGendix in 2015 and with the acquisition of the GPS test in August 2022, and increased by \$36.6 million in 2022 due to the GPS acquisition. The estimated remaining amortization period amounts to 2.6 years for the NovioGendix IP and to 14.6 years for the GPS IP.

Customer relationships includes customers acquired in the GPS acquisition, resulting in the fair value at acquisition date of \$8.0 million. The GPS Customer relationships are amortized over 6.5 years, the estimated remaining amortization period amounts to 6 years.

The internally-developed intangible assets relate to the capitalized development expenses for Confirm mdx and Select mdx over the past years as well as for the development of the GPS assay in-house and our Resolve mdx assay. The estimated remaining amortization period amounts to 1.2 years for Confirm mdx and Select mdx and 5 years for GPS and 4.3 years for Resolve mdx. In 2022, the Company capitalized \$1.0 million (2021: \$0) in GPS and Resolve mdx development expenses.

**NOTE 12: Property, plant and equipment and right of-use assets****Property, plant and equipment**

Thousands of \$	Laboratory equipment	Furniture	IT equipment	Leasehold improvements	Total
<b>Gross value</b>					
At January 1, 2021	5,359	434	504	666	6,963
Additions	255	131	158	675	1,219
Disposals			(2)		(2)
Exchange rate difference arising	(329)	4	13		(312)
Gross value at December 31, 2021	5,285	569	673	1,341	7,868
<b>Accumulated depreciation</b>					
At January 1, 2021	(4,874)	(244)	(343)	(529)	(5,990)
Additions	(277)	(64)	(103)	(77)	(521)
Disposals			2		2
Exchange rate difference arising	334	(7)	(15)		312
Accumulated depreciation at December 31, 2021	(4,817)	(315)	(459)	(606)	(6,197)
Net value at December 31, 2021	468	254	214	735	1,671
<b>Gross value</b>					
At January 1, 2022	5,285	569	673	1,341	7,868
Additions	1,695	104	277	713	2,789
Disposals			(258)		(258)
Exchange rate difference arising	88	(4)	(5)	4	83
Gross value at December 31, 2022	7,068	669	687	2,058	10,482
<b>Accumulated depreciation</b>					
At January 1, 2022	(4,817)	(315)	(459)	(606)	(6,197)
Additions	(276)	(72)	(159)	(166)	(673)
Disposals			258		258
Exchange rate difference arising	(91)	7	3	2	(79)
Accumulated depreciation at December 31, 2022	(5,184)	(380)	(357)	(770)	(6,691)
Net value at December 31, 2022	1,884	289	330	1,288	3,791

During 2022, the Company acquired \$1.7 million of laboratory equipment and \$713,000 of leasehold improvements. In 2021, the company also acquired \$255,000 of laboratory equipment and \$675,000 of leasehold improvements. The primary purpose of these acquisitions was to add testing capacity for its new GPS and Resolve assays.

Right of-use assets

Thousands of \$	Buildings	Vehicles	Materials	Total
<b>Gross value</b>				
<b>Balance at January 1, 2021</b>	<b>3,612</b>	<b>218</b>	<b>897</b>	<b>4,727</b>
Additions	1,518			1,518
Disposals				
<b>Gross value at December 31, 2021</b>	<b>5,130</b>	<b>218</b>	<b>897</b>	<b>6,245</b>
<b>Accumulated depreciation</b>				
<b>Balance at January 1, 2021</b>	<b>(1,177)</b>	<b>(87)</b>	<b>(729)</b>	<b>(1,993)</b>
Additions	(752)	(42)	(111)	(905)
<b>Accumulated amortization on December 31, 2021</b>	<b>(1,929)</b>	<b>(129)</b>	<b>(840)</b>	<b>(2,898)</b>
<b>Net value at December 31, 2021</b>	<b>3,201</b>	<b>89</b>	<b>57</b>	<b>3,347</b>
<b>Gross value</b>				
<b>Balance at January 1, 2022</b>	<b>5,130</b>	<b>218</b>	<b>897</b>	<b>6,245</b>
Additions	1,435	58	334	1,827
Exchange rate differences			(1)	(1)
<b>Gross value on December 31, 2022</b>	<b>6,565</b>	<b>276</b>	<b>1,230</b>	<b>8,071</b>
<b>Accumulated depreciation</b>				
			(1)	(1)
<b>Balance at January 1, 2022</b>	<b>(1,929)</b>	<b>(129)</b>	<b>(840)</b>	<b>(2,898)</b>
Additions	(945)	(51)	(71)	(1,067)
Exchange rate differences			(3)	(3)
<b>Accumulated amortization on December 31, 2022</b>	<b>(2,874)</b>	<b>(180)</b>	<b>(914)</b>	<b>(3,968)</b>
<b>Net value at December 31, 2022</b>	<b>3,691</b>	<b>96</b>	<b>316</b>	<b>4,103</b>

In December 2019, the Company entered into a lease agreement (the “Alton lease”) for approximately 11,000 square feet of office space in Irvine, California. In April 2020, the company amended the Alton Lease to add approx. 8,000 additional square feet of adjacent office space. The term of both the Alton lease and the first amendment is for a period of 6 years, and both commenced in September 2020. In March 2021, the Company amended the Alton lease for a second time, in order to renew for an additional 5 years its existing 13,000 square foot laboratory space which was previously part of a separate lease. The commencement date for the second Alton lease amendment was October 2021. Under the terms of the Alton Lease Agreement, the Company has an option to extend the Alton Lease for a period of 5 years. In October of 2021, the company entered into a 35-month lease agreement for 6,000 additional office space adjacent to the laboratory. In June 2022, the company entered into a 36-month lease agreement (the “Plano lease”) for approximately 3,000 square feet of lab space in Plano, Texas with an effective date of June 2022. The Plano lease was amended in November 2022 to add approximately 1,500 square feet of office space. Under the terms of the Plano lease, the lease will automatically renew for successive 12-month periods after the end of the original term of the agreement. Under the terms of the lease agreements mentioned, the rental payments escalate through the term of each agreement and the Company is subject to additional charges for common area maintenance and other costs.

In October 2022, the company renewed its lease agreement for a term of 60 months for its facilities in Nijmegen, The Netherlands.

The new lease agreements from 2022 represent an additional right of use assets of a total value of \$1.8 million.

The following amounts related to leases are recognized in the statement of profit or loss:

Thousands of \$	2022	2021
Depreciation expense	1,067	905
Interest expense on lease liabilities	314	229

**NOTE 13: Inventories**

Thousands of \$ For the years ended December 31	2022	2021
Raw materials and consumables	2,327	1,911
<b>Total Inventories</b>	<b>2,327</b>	<b>1,911</b>

Inventories are recognized at the lower of cost or net realizable value. Inventories recognized as an expense during the year ended December 31, 2022, amounted to \$3.6 million (2021: \$3.2 million). These were included in cost of sales and services.

**NOTE 14: Trade and other receivables****TRADE RECEIVABLES**

Thousands of \$ For the years ended December 31	2022	2021
Trade receivables	9,357	4,582
<b>Total trade receivables</b>	<b>9,357</b>	<b>4,582</b>

Trade receivables mainly consist of claims due from our patients' insurance companies related to our diagnostic tests.

Considering the Company's revenue recognition methodology further described in Note 2.7, total accounts receivable balance could be presented in relation with the claim date of each sample, as follows:

A/R by claim date Thousands of \$ For the years ended December 31, 2022	Months				
	1-3 months	4-6 months	7-12 months	Not due	Total
Confirm mdx	1,865	821	765		<b>3,451</b>
Select mdx	134	101	78	25	<b>338</b>
Resolve mdx	1,966	458	158		<b>2,582</b>
GPS	1,907	895			<b>2,802</b>
Other	163			21	<b>184</b>
<b>Total Trade Receivables</b>	<b>6,035</b>	<b>2,275</b>	<b>1,001</b>	<b>46</b>	<b>9,357</b>

A/R by claim date Thousands of \$ For the years ended December 31, 2021	Months				
	1-3 months	4-6 months	7-12 months	Not due	Total
Confirm mdx	1,644	746	1,256		<b>3,646</b>
Select mdx	151	203	206	33	<b>593</b>
Other	321			22	<b>343</b>
<b>Total Trade Receivables</b>	<b>2,116</b>	<b>949</b>	<b>1,462</b>	<b>55</b>	<b>4,582</b>

**PREPAID EXPENSES AND OTHER CURRENT ASSETS**

Thousands of \$ For the years ended December 31	2022	2021
Prepayments	1,710	1,022
Deposits	101	89
Recoverable VAT	97	246
Grants to be received	54	235
Other	0	23
<b>Total prepaid expenses and other current assets</b>	<b>1,962</b>	<b>1,615</b>

Prepaid expenses mainly consist of prepaid insurance premiums and prepaid maintenance contracts.

All financial assets carried at amortized cost are shown net of expected credit losses.

NOTE 15: Cash and cash equivalents

Thousands of \$ For the years ended December 31	2022	2021
Cash and cash equivalents	15,503	58,498
<b>Total cash and cash equivalents</b>	<b>15,503</b>	<b>58,498</b>

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 had no restricted cash in 2022 and 2021.

NOTE 16: Loans, Borrowings, Leases obligations and other financial liabilities

Loans, Borrowings & Lease liabilities

Thousands of \$ For the years ended December 31	2022	2021
<b>Non-current loans and borrowings</b>		
Loans	34,914	7,651
Lease liabilities (*)	3,091	2,624
<b>Total non-current loans and borrowings</b>	<b>38,005</b>	<b>10,275</b>

Thousands of \$ For the years ended December 31	2022	2021
<b>Current loans and borrowings</b>		
Loans	616	4,441
Lease liabilities	1,172	840
<b>Total current loans and borrowings</b>	<b>1,788</b>	<b>5,281</b>

(\*) the evolution in the right of use assets is further disclosed in note 12.

Innovatus debt facility

On August 2, 2022, the Company entered into a \$70 million loan and security agreement with Innovatus Life Sciences Lending Fund I, LP ("Innovatus"), which loan also replaced the Company's €9 million debt facility with Kreos Capital. At closing, an amount of \$35 million was drawn, with an additional \$35 million remaining available as a \$20 million term B loan and a \$15 million term C loan that can be drawn in 2024 and 2025 respectively, subject to certain conditions. The loans are secured by assets of the Group including intellectual property rights. Remaining proceeds of the loans will be used for working capital purposes and to fund general business requirements.

The loans accrue interest at a floating per annum rate equal to the sum of (a) the greater of (i) the prime rate published in The Wall Street Journal in the "Money Rates" section or (ii) 4.00%, plus (b) 4.25%, and require interest-only payments for the initial four years. As contractually agreed, and at the election of the Company, a portion of the interest becomes payable in-kind by adding an amount equal to 2.25% of the outstanding principal amount to the then outstanding principal balance on a monthly basis until August 2, 2025. The loans mature on August 2, 2027. The lenders shall have the right to convert, prior to August 2, 2025, up to 15% of the outstanding principal amount of the loans into ADSs of the Company at a price per ADS equal to \$11.21, reflecting a substantial premium to the trading price prior to the announcement of the acquisition. Amounts converted into ADSs of the Company will be reduced from the principal amount outstanding under the loan. Notable fees payable to Innovatus consist of a facility fee equal to 1% of the total loan commitment, due on the funding date of the relevant loans, and an end-of-loan fee equal to 5% of the amount drawn, payable upon final repayment of the relevant loans.

Security has been granted over all assets (including IP rights) owned by the Company and MDxHealth, Inc. The loan agreement contains customary financial covenants and general affirmative and negative covenants, including limitations on our ability to transfer or dispose of assets, change our business, merge with or acquire other companies, incur additional indebtedness and liens, make investments, pay dividends and conduct transactions with affiliates.

The Innovatus debt facility has been accounted for as a hybrid financial instrument which includes a host financial liability as well as an embedded derivative financial instrument being an equity conversion call option at a fixed rate of up to 15% of the aggregate outstanding principal amount through August 2, 2025.

The embedded derivative is not considered to be closely related to the host financial liability given the differences in economics and risks, and as such both are accounted for separately:

- The host financial liability is recognized at amortized cost applying the effective interest rate method and has been accounted for as non-current loans and borrowings;
- The embedded derivative convertible (American) call option is recognized at fair value using a binomial tree option pricing model whereby the fair value is based on the actual stock price and the estimated volatility of the Company’s ADS on Nasdaq since the Company’s IPO on November 4, 2021, and through the valuation date. The volatility measured on August 2, 2022, which was the closing date of the Innovatus debt facility, was 62.85% and at December 31, 2022 was 64.82%. Any changes to the fair value of the embedded derivative will be recognized through the statement of profit or loss. The derivative financial instrument has been accounted for as other current financial liabilities.

Kreos debt facility

As part of the new debt facility with Innovatus, the Company’s debt facility with Kreos for an outstanding principal amount of €9 million has been fully repaid in cash during September 2022, for a total amount of \$10.8 million. This repayment included the two convertible loans of €180,000 (\$185,364) and €202,500 (\$208,535) that were not converted by Kreos and that were entered into as part of amendments to the original Kreos debt facility.

The repayment did not include the derivative financial liability for the initial Kreos drawdown fee which had an estimated fair value on December 31, 2022, of \$891,000 and is included in Other financial liabilities as a separate financial instrument valued at fair-value through statement of profit or loss. This financial liability is payable upon demand in cash, or convertible into the Company’s common stock, upon election by Kreos.

The financial results largely related to the interest charges for the loan facility with Kreos Capital for a total of \$206,000. The amortized cost is calculated using the effective interest method, which allocates interests and expenses at a constant rate over the term of the instrument. The debt extinguishment costs incurred amounted to \$1.8 million and are included in the statement of profit or loss under Financial expenses.

During 2019, the Company entered into a loan facility with Kreos Capital in the amount of €9.0 million, or approximately \$10.2 million. The loan had a term of four years with the first 12 months of interest-only payments followed by 36 months of principal and interest payments. On October 20, 2020, MDxHealth and Kreos Capital executed an amendment to the 2019 loan facility, extending the interest-only period from 12 months to 18 months. As a result of this amendment, repayment of principal was extended by 6 months, from November 2020 to May 2021. As part of the amendment, the Company agreed to increase the end-of-loan fee by €67,500 (approx. \$80,000) as well as to provide for €180,000 of the €9 million loan to be convertible into shares of MDxHealth at a 25% premium to the 30-day volume weighted average price immediately prior to signing the amendment. If exercised, this amount was to be reduced from the principal amount due under the loan agreement.

In April 2021, MDxHealth and Kreos Capital executed a second amendment to the loan facility, extending the interest-only period from 18 months to 27 months. As a result of this amendment, repayment of principal was extended from May 2021 to February 2022. As part of the amendment, the Company agreed to increase the end-of-loan fee by an additional €67,500

(approx. \$80,000) as well as to provide for an additional €202,500 of the €9 million loan to be convertible into shares of MDxHealth at a 25% premium to the 30-day volume weighted average price 10 days prior to signing the amendment.

The convertible part of the loan, representing the first discretionary convertible loan of €180,000 (\$203,868) and the second discretionary convertible loan of €202,500 (\$229,352) were recognized at their amortized cost. In addition, the second amendment provided for a further six-month extension of the interest-only period if the Company would receive gross proceeds for a minimum amount of \$30 million in new equity financing. Following the completion of the Company’s Initial Public Offering of ADSs in the United States on November 8, 2021, whereby the Company received gross proceeds of \$45 million in new equity financing, Kreos granted a six-month extension of the interest-only period through July 2022.

In addition, as the loan facility is contracted in Euro, the foreign exchange rate impacts the carrying amount. The amortized cost is calculated using the effective interest method, which allocates interests and expenses at a constant rate over the term of the instrument.

On April 20, 2020, the Company, through its U.S. subsidiary, MDxHealth Inc., has entered into a “Paycheck Protection Program” (PPP) loan with the U.S. Small Business Administration (SBA) in the amount of \$2,316,000 as part of the U.S Coronavirus Aid, Relief, and Economic Security (CARES) Act. The loan has a term of five years and carries an interest rate of 1.0% per year. Payments on the loan are deferred for the first eighteen months following disbursement of the loan, with principal and interest payments beginning on the nineteenth month. Interest on the loan continues to accrue during the eighteen-month deferment period. Cash proceeds from the loan were received in July 2020. As of December 31, 2022, the outstanding amount on the PPP loan was \$1.6 million.

In addition to the contracted loans, the Company has several lease obligations. The leases have terms of 3 to 5 years.

Maturity of loans and borrowings are as follows at the balance sheet date:

Thousands of \$ For the years ended December 31	2022	2021
<b>Loans</b>		
Within one year	630	4,780
Years two to five	38,439	9,283
<b>Leases</b>		
Within one year	1,551	1,127
Years two to five	2,330	3,094

*Note: all figures shown in this table are undiscounted and reflect future cash payments (capital and interests)*

Other financial liabilities

Thousands of \$ For the years ended December 31	2022	2021
<b>Other financial liabilities</b>		
Other non-current financial liabilities	53,537	1,466
Other current financial liabilities	2,327	961
<b>Total other financial liabilities</b>	<b>55,864</b>	<b>2,427</b>

GPS Contingent consideration

As part of the acquisition of the GPS business from Exact Sciences in August 2022, an aggregate earn-out amount of up to \$70 million is to be paid by MDxHealth to Exact Sciences upon achievement of certain revenue milestones related to fiscal years 2023 through 2025, with the maximum earn-out payable in relation to 2023 and 2024 not to exceed \$30 million and \$40 million, respectively. The liability recognized reflects a probability-weighted estimate at the current net present value which is expected to become payable. Future fair value adjustments to this contingent consideration will be recognized in the statement of profit or loss. The value of the contingent liability for GPS including the fair value adjustment accounted for under other non-current financial liabilities is \$52.9 million as of December 31, 2022.

Innovatus embedded derivative convertible call option

The embedded derivative convertible (American) call option is recognized at fair value within the other non-current financial liabilities and amounts to \$910,000 as at December 31, 2022.

Kreos derivative financial instrument (“initial drawdown fee”)

As of December 31, 2022, the derivative financial liability of the convertible initial drawdown fee payable to Kreos remains outstanding as follows:

- a drawdown fee of €630,000 (\$713,538) is due to Kreos Capital which was not payable in cash but remained outstanding as a "convertible loan" (the "Initial Convertible Loan").
- Upon the Expiration Date, the convertible loan will convert automatically into ordinary shares at €0.85 per share.
- In lieu of converting the Initial Convertible Loan, Kreos Capital may instead cancel the convertible loan at any time (but before the Expiration Date) after the earlier to occur of (i) a repayment or prepayment in full of the loan, and (ii) sale of the entire issued share capital of MDxHealth. In such case, Kreos Capital will be paid an amount equal to 150% of the principal amount of the Initial Convertible Loan.

The fair value of the financial derivative related to the initial drawdown fee of the Kreos loan is computed as the sum of the probability-weighted values of the fair values associated with each of the possible outcomes and amounts to \$891,000 as of December 31, 2022. The derivative financial instrument is accounted for within other current financial liabilities.

Other financial liabilities

Other financial liabilities include the contingent consideration related to the acquisition of NovioGendix in 2015 and amounts to \$1.2 million of which \$526,000 was considered as current. The contingent consideration is valued at fair value through the statement of profit or loss. The fair value of this contingent consideration is reviewed on a periodic basis. The fair value is based on a risk-adjusted future cash flows of different scenarios discounted using an interest rate of 12.16%. The structure of the possible scenarios and the probability assigned to each scenario is reassessed by management at every reporting period and requires judgement from management about the outcome and probability of the different scenarios (refer to Note 26 for further details).

A reconciliation of cash and non-cash movements of loans and borrowings, lease liabilities and other financial liabilities is presented below:

Thousands of \$ For the years ended December 31	Loans and borrowings		Other financial liabilities	
	2022	2021	2022	2021
Beginning balance	12,092	13,097	2,427	1,599
Cash movements				
Loans and borrowings repaid <sup>1</sup> (Kreos / PPP)	(10,805)			
Loans and borrowings received (Innovatus)	34,291			
Non-cash movements				
GPS Contingent Consideration			50,483	
Reclassification <sup>2</sup>		(773)		773
Recognition of Innovatus embedded derivative convertible call option	(1,026)		1,026	
Kreos effective interest rate adjustment and extinguishment costs	1,328	536		194
Innovatus - effective interest rate adjustment	660			
Foreign exchange rate impact / other	(1,010)	(768)	(35)	(59)
Fair value changes through profit and loss			1,963	(80)
Ending balance	35,530	12,092	55,864	2,427

<sup>1)</sup> The amount includes interest paid on loans and borrowings

<sup>2)</sup> Reclassification of the fair value of the derivative financial liability of the initial drawdown fee to be presented separately

Fair value adjustments recognized during 2022 for other financial liabilities relate to:

Thousands of \$ For the years ended December 31	2022
Decrease of contingent consideration NovioGendix	(632)
Increase of Kreos derivative financial instrument (“initial drawdown fee”)	116
Increase of GPS contingent consideration	2,398
Decrease of Innovatus embedded derivative convertible call option	(116)
Total fair value adjustment	1,766

Thousands of \$ For the years ended December 31	Lease liabilities	
	2022	2021
Opening balance	3,464	2,774
Cash movements		
Repayment of lease liabilities	(1,358)	(1,057)
Non-cash movements		
Interest accretion	314	229
New leases	1,843	1,518
Closing balance	4,263	3,464

NOTE 17: Contractual obligations

Thousands of \$ For the years ended December 31	2022	2021
Outstanding commitments for future minimum rent payments, which fall due as follows:		
Less than one year	156	215
Years 2-5	60	39
Total contractual obligations	216	254

For 2022 and 2021, we refer to note 12 and 16 for the lease liabilities subsequent adoption and application of IFRS 16.

Outstanding commitments for future minimum rent payments include rental fees related to leased facilities, and equipment for assets with a value below \$5,000 or with short-term duration. 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 18: Trade and other payables

Thousands of \$ For the years ended December 31	2022	2021
Trade accounts payable	5,061	3,192
Accruals for invoices to be received	5,117	4,263
Total trade accounts payable	10,178	7,455

OTHER CURRENT LIABILITIES

Thousands of \$ For the years ended December 31	2022	2021
Payroll	3,932	2,703
Other accruals	53	32
Total other current liabilities	3,985	2,735

## NOTE 19: Financial instruments and fair value

The table shows the Company'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 and derivative financial instruments 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.

Thousands of \$ For the years ended December 31	2022	2021	Fair value hierarchy
<b>Assets</b>			
<b>At amortized cost</b>			
Trade receivables	9,357	4,582	
Cash and cash equivalents	15,503	58,498	
<b>Total financial assets</b>	<b>24,860</b>	<b>63,080</b>	
<b>Liabilities</b>			
<b>At fair value:</b>			
Other financial liabilities			
- <i>GPS contingent consideration</i>	52,881		Level 3
- <i>NovioGendix contingent consideration</i>	1,182	1,617	Level 3
- <i>Innovatus derivative instrument</i>	910		Level 3
- <i>Kreos derivative instrument</i>	891	810	Level 3
<b>Subtotal financial liabilities at fair value</b>	<b>55,864</b>	<b>2,427</b>	
<b>At amortized cost:</b>			
Loans and borrowings	35,530	12,092	Level 2
Lease liabilities	4,263	3,464	
Trade payables	10,178	7,455	
<b>Subtotal financial liabilities at amortized cost</b>	<b>49,971</b>	<b>23,011</b>	
<b>Total financial liabilities</b>	<b>105,835</b>	<b>25,438</b>	

### Recognized fair value measurements – valuation technique and principal inputs

The fair 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, other current assets and the trade payables approximate their fair value due to their short-term character;
- The fair value of loans and borrowings applying the Effective Interest Rate method approximates their carrying value (level 2).
  - Innovatus debt facility:** the host financial liability was obtained with a variable interest rate based upon the Prime Rate (with a floor of 4% and a margin of 4.25%)
  - Paycheck Protection Program (PPP):** applying a market rate would not result in a materially different fair value which carries an interest rate of 1% and was obtained as part of the U.S Coronavirus Aid, Relief, and Economic Security (CARES) Act.

- Kreos debt facility:** the Kreos loan was obtained at the end of 2019 with a nominal fixed interest rate of 9.5%, however, the carrying value is considered to approximate their fair value considering:
  - Additional contractually agreed advance and post payments agreed upon with Kreos that have been integrated in the effective interest rate method;
  - During 2020 and 2021, the Company and Kreos negotiated modification to the original agreement resulting in additional consecutive interest-only periods. As compensation for these modifications, part of the loan amounts became convertible as described in Note 16, however the Company and Kreos agreed to maintain nominal fixed interest rate in line with the initial agreement.
  - Given repayment of the Kreos facility during 2022, no fair value assessment was performed as of December 31, 2022

- Leases are measured at the present value of the remaining lease payments, using a discount rate based on the incremental borrowing rate at the commencement date of these leases. Their fair value approximates their carrying value.
- The fair value of contingent consideration payable to NovioGendix (presented in the yearend statement of financial position under “other non-current financial liabilities” and “other current financial liabilities”) and Exact Sciences is based on an estimated outcome of the conditional purchase price/contingent payments arising from contractual obligations (level 3). This is initially recognized as part of the purchase price and subsequently fair valued with changes recorded through other operating income in the statement of profit or loss.
  - NovioGendix:** the Company used a discount rate of 12.16%. A net positive fair value measurement of \$435,000 was recognized in the 2022 consolidated financial statements of which \$632,000 in operating income and \$197,000 in financial expense.
  - GPS:** The fair value of the contingent consideration payable to Exact Sciences is based on a probability-weighted average estimate based on multiple scenarios varying in timing and amount of earn-out payment. This probably-weighted estimate is then discounted to its net present value taking into account expected time when earn-out would become payable in 2024, 2025 and 2026. This contingent consideration was initially recorded along with the purchase price allocation of this business combination as explained in Note 3. A fair-value adjustments resulting in a financial charge of \$ 2.4 million has been recorded as of December 31, 2022. The Company used a discount rate of 14.95%
- The fair value of the derivative financial liabilities related to the initial Kreos drawdown fee of €630,000 (\$672,000) is based upon the evolution of the share price of MDxHealth as well as the estimated probabilities that either payment at 150% or conversion will be requested by Kreos. Whereas share price of MDxHealth can be considered as a level 1 input, the other variable, being the probability assessment of possible scenarios should be considered as level 3 input. The fair value of the liability is estimated at \$891,000 for the year ended December 31, 2022.
- The fair value of the derivative financial liabilities related to the Innovatus derivative call option (as detailed in Note 16) was performed using a binomial pricing model which takes into account several factors including the expected evolution in price of an ADS and are considered as level 3 input. The fair value of the liability is estimated at \$910,000 for the year ended December 31, 2022.
- Financial instruments are evaluated based on the mark-to-market report and the unrealized gains (loss) are recognized through the statement of profit or loss.

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.

A reconciliation of cash and non-cash movements of level 3 financial liabilities is presented below:

Thousands of \$ For the years ended December 31	Financial derivative instruments (Kreos and Innovatus)		Contingent consideration (NovioGendix and GPS)	
	2022	2021	2022	2021
<b>Beginning balance</b>	<b>810</b>	<b>0</b>	<b>1,617</b>	<b>1,599</b>
<b>Cash movements</b>				
Loans and borrowings repaid				
<b>Non-cash movements</b>				
GPS contingent consideration			50,483	
Innovatus embedded derivative convertible call option	1,026			
Reclassification <sup>1)</sup>		773		
Effective interest rate adjustment				
Foreign exchange rate impact / other movements	(35)	(59)		
Fair value changes through profit and loss		96	1,963	18
<b>Ending balance</b>	<b>1,801</b>	<b>810</b>	<b>54,063</b>	<b>1,617</b>

<sup>1)</sup> Reclassification of the fair value of the derivative financial liability of the initial drawdown fee to be presented separately

NOTE 20: Loss per share

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.

Years ended December 31	2022	2021
Loss for the year, in thousands of \$	(44,044)	(29,002)
Basic and diluted loss per share, in \$	(0.28)	(0.24)

Weighted average number of shares	2022	2021
Weighted average number of shares for basic and diluted loss per share	158,658,165	121,935,741

At December 31, 2022 and 2021, the Company had potential dilutive shares in the form of warrants, contingent considerations and convertible loans (see Note 16 for further details). Diluted loss per share considers the impact of potentially dilutive securities except in periods in which there is a loss because the inclusion of the potential common shares would have an anti-dilutive effect.

NOTE 21: Financial Risk Management

CAPITAL MANAGEMENT

Capital is comprised of equity attributable to shareholders, borrowings, and cash and cash equivalents. The Company aims to maintain a strong capital base in order to maintain investor and creditor confidence and to sustain the future development of the business. The Company’s objectives when managing capital are to maintain sufficient liquidity to meet its working capital requirements, fund capital investment and purchases, and safeguard its ability to continue operating as a going concern. The Company monitors capital regularly to ensure that the statutory capital requirements are met and may propose capital increases at shareholders’ meetings to ensure the necessary capital remains intact.

CREDIT RISK

Credit risk arises from cash and cash equivalents, short-term bank deposits, as well as credit exposure to collaboration partners. Credit risk refers to the risks that counterparty will default on its contractual obligations resulting in financial loss to the Company.

At the end of 2022, the Company operated with more than 1,000 different customers, systematically reducing credit risk compared to prior periods.

In the U.S. 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. For example, for tests that fall under the Clinical Laboratory Fee Schedule, 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 \$9.4 million as of December 31, 2022, and no allowance for expected credit loss was recorded. No ECL has been recorded for other financial assets carried at amortized cost as there is no related credit risk.

The credit risk on cash and cash equivalents of \$15.5 million is limited given that the counterparties are banks with high credit scores attributed by international rating agencies. The Company had no exposure to Silicon Valley Bank, Silvergate Bank, or Credit Suisse.

INTEREST RISK

During 2022, the Company entered into a 60-month loan with Innovatus for a total amount of \$35 million (refer to Note 16 for further details). The loan accrues interest at a floating per annum rate equal to the sum of (a) the greater of (i) the Prime rate published in The Wall Street Journal in the “Money Rates” section or (ii) 4.00%, plus (b) 4.25%, and require interest-only

payments for the initial four years. For every increase of 0.25% in the Prime rate, the Company’s interest expense increases by approximately \$90,000 per year.

In addition, on April 20, 2020, the Company, through its U.S. subsidiary, MDxHealth Inc., has entered into a “Paycheck Protection Program” (PPP) loan with the U.S. Small Business Administration (SBA) in the amount of \$2,316,000 as part of the U.S Coronavirus Aid, Relief, and Economic Security (CARES) Act. The amortized cost is calculated using the effective interest method, which allocates interests and expenses at a constant rate over the term of the instrument; the effective interest rate for the loan is 1.00%. Considering the fixed interest rate, the Company is not exposed to interest risk, thus did not perform any sensitivity analysis.

CURRENCY RISK

The functional currency changed from the EURO to the U.S. Dollar as of July 1, 2014. Consequently, the currency risk is concentrated on European operations.

As of December 31, 2022, cash deposits in EURO amounted to €1.1 million.

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 immaterial given the limited size of the European operations and contribution to revenues versus the Company as a whole.

LIQUIDITY RISK

The Company 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. At the date of this report, the Company has 2 loan agreements with banks and state institutions, and 11 leases (see Notes 12 and 16).

For the years ended December 31, 2022 Thousands of \$	Less than 1 year	Between 1 and 2 years	Between 3 and 5 years	Total contract ual cash flows	Carrying amount
<b>Non derivatives</b>					
Trade payables	10,178		1,256	10,178	10,178
Loans	630	630	37,809	39,069	35,530
Lease liabilities	1,324	915	2,179	4,418	4,263
<b>Total</b>	<b>12,132</b>	<b>1,545</b>	<b>39,988</b>	<b>53,665</b>	<b>49,971</b>

For the years ended December 31, 2021 Thousands of \$	Less than 1 year	Between 1 and 2 years	Between 3 and 5 years	Total contract ual cash flows	Carrying amount
<b>Non derivatives</b>					
Trade payables	7,455			7,455	7,455
Loans	4,780	8,200	1,083	14,063	12,092
Lease liabilities	1,127	915	2,179	4,221	3,464
<b>Total</b>	<b>13,362</b>	<b>9,115</b>	<b>3,262</b>	<b>25,739</b>	<b>23,011</b>

Note: Except for carrying amount, all figures shown in this table are undiscounted and reflect future cash payments

The Company is also committed to a potential additional cash out of:

- €945,000 (\$1.0 million) if Kreos requests payment in cash of the derivative financial liabilities related to the initial Kreos drawdown fee (see Note 16).
- an aggregate earn-out amount of up to \$70 million that could become payable in cash by MDxHealth to Exact Sciences upon achievement of certain revenue milestones related to fiscal years 2023 through 2025 and payable during 2024 through 2026.

OTHER RISKS

The Company subscribes to certain insurance policies to cover matters such as (i) fire, theft, and other damage to its assets, (ii) product and liability insurance and clinical trial insurance, and (iii) D&O insurance. To date, no significant 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.

NOTE 22: Share capital and reserves

At December 31, 2022, 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.

For the years ended december 31	2022	2021
Common shares	162,880,936	155,969,226
<b>Total outstanding shares</b>	<b>162,880,936</b>	<b>155,969,226</b>

On January 21, 2021, the company announced the successful pricing of its capital increase with the offering of new ordinary shares. The Company raised €25.0 million (\$30.4 million) in gross proceeds by means of a private placement of 27,777,777 new shares at an issue price of €0.90 per share through an accelerated bookbuild offering. As a result of the issuance of new shares, the Company's share capital increased from €68,998,734.95 to €90,132,067.69 and its issued and outstanding shares increased from 90,691,449 to 118,469,226 ordinary shares.

On November 8, 2021, the Company announced that completion of a capital increase by means of an initial public offering in the United States of 3,750,000 ADSs at an issue price of \$12 per ADS, resulting in gross proceeds of \$45.0 million. As a result of this capital increase, its share capital has increased from €90,132,067.69 to €118,662,067.69 and the number of issued and outstanding shares has increased from 118,469,226 to 155,969,226 ordinary shares, through the issuance of a total of 37,500,000 new shares.

On August 11, 2022, to settle a portion of the purchase price for the acquisition by the Company of the GPS test from Genomic Health, Inc. (a subsidiary of Exact Sciences Corporation) announced on August 2, 2022, the Company issued 691,171 American Depositary Shares, or “ADSs” (each representing 10 ordinary shares of the Company with no nominal value per share), at a price per ADS of \$7.23, totaling \$5 million. As a result, the Company's share capital has increased from €118,662,067.69 to €123,539,165.19 and the number of issued and outstanding shares has increased from 155,969,226 to 162,880,936 ordinary shares.

For the years ended december 31	Thousands of \$		thousands of €	
	Share Capital	Issuance Premium	Share Capital	Issuance Premium
As of January 1, 2021	76,716	136,349	62,214	112,078
January 2021 – Issuance of 27,777,777 shares (*)	23,632	4,693	19,473	3,867
November 2021 – Issuance of 37,500,000 shares (*)	28,106	12,135	24,412	10,536
<b>As of December 31, 2021</b>	<b>128,454</b>	<b>153,177</b>	<b>106,099</b>	<b>126,481</b>
August 2022 – Issuance of 6,911,710 shares (*)	5,000		4,876	
<b>As of December 31, 2022</b>	<b>133,454</b>	<b>153,177</b>	<b>110,975</b>	<b>126,481</b>

(\*) net of expenses

The capital stock and the issuance premium amounted to the following:

For the years ended December 31	Thousands of \$		Thousands of €	
	2022	2021	2022	2021
Share Capital as per statutory accounts	148,419	143,419	123,539	118,662
Capital increase costs	(14,965)	(14,965)	(12,564)	(12,564)
Share capital under IFRS	133,454	128,454	110,975	106,098
Issuance premium	153,177	153,177	126,481	126,481
Share capital and issuance premium	286,631	281,631	237,456	232,579

The history of the Share Capital can be found in “General Information; Capital and Shares”.

By virtue of the resolution of the extraordinary general shareholders' meeting of the Company held on May 27, 2021, which entered into force on June 1, 2021, the board of directors of the Company has been granted certain powers to increase the Company's share capital in the framework of the authorised capital. The powers under the authorised capital have been set out in article 6 of the Company's articles of association.

Pursuant to the authorisation granted by the extraordinary general shareholders' meeting, the board of directors was authorised to increase the share capital of the Company on one or several occasions by a maximum aggregate amount of EUR 90,132,067.69 (excluding issue premium, as the case may be) for a period of 5 years as from June 1, 2021.

The board of directors has used its powers under the authorised capital on (i) November 8, 2021, by issuing 37,500,000 new shares (3,750,000 ADSs) for an aggregate amount of €28,530,000.00 (excluding issue premium), and (ii) August 11, 2022, by issuing 6,911,710 new shares (691,171 ADSs) for an aggregate amount of €4,877,097.50. Moreover, subsequent to the balance sheet date (and as described further in Note 27), the board of directors has used its powers under the authorised capital at the occasion of the February 2023 capital increase. As a result, the board of directors therefore still has the authority under the authorised capital to increase the Company's share capital with an aggregate amount of €16,792,505.80 (excluding issue premium, as the case may be).

In addition to the outstanding shares of the Company:

- a total of 13,895,280 subscription rights of the Company have been created, of which 12,257,780 subscription rights have been granted as of December 31, 2022, which entitles their holders (assuming all subscription rights are granted and exercised) to subscribe to a total of 12,257,780 new shares with voting rights (see Note 24 for further details). The remaining 1,637,500 subscription rights have not yet been granted and are currently still managed by the Company’s board of directors;
- under the loan agreement entered into by the Company and Kreos Capital in July 2021, a drawdown fee equal to 7% of the amounts drawn down under the loan agreement (being EUR 630,000 in aggregate) remains outstanding as a payable due by the Company (without accruing interest), and is convertible into ordinary shares with voting rights by means of a contribution in kind of the payable by Kreos Capital to the share capital of the Company at a price of €0.85 per share (see Note 24 for further details);  
and,
- under the loan and security agreement entered into by the Company and Innovatus Capital Partners in August 2022, Innovatus has the right to convert, prior to August 2, 2025, up to 15% of the outstanding principal amount of the loans (by means of a contribution in kind of the relevant payables due by the Company under the loans) into American Depositary Shares (“ADSs”) of the Company (each representing 10 ordinary shares of the Company) at a conversion price per ADS equal to \$11.21 (i.e., \$1.121 per share on the basis of the ratio of 1 ADS per 10 shares) (see note 16 for further details).

NOTE 23: Retirement benefit plans

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

A total cost of \$724,000 in 2022 (2021: \$594,000) represents contributions payable to these plans 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 plan operated by the government (i.e., legal pension) and are members of a bank-operated private pension plan. The Company is required to contribute a specified percentage of payroll costs to the retirement benefit plan to fund the benefits. The obligation of the Company with respect to the retirement benefit plan 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.

NOTE 24: Share-based payments

This section provides an overview of the outstanding warrants as of December 31, 2022. 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 March 15, 2012 (195,000), June 15, 2012 (700,000), June 23, 2014 (1,500,000), June 19, 2017 (2,500,000), June 21, 2019 (3,000,000), May 27, 2021 (3,600,000) and May 25, 2022 (5,000,000). In aggregate 17,310,800 warrants were issued, subject to warrants being granted to and accepted by the beneficiaries. 18,150 of these warrants never allocated have become null and void, resulting in a remaining and outstanding 17,296,650 warrants, (i) 2,840,397 warrants were terminated or lapsed, (ii) 577,123 warrants were exercised, (iii) 12,257,780 warrants were granted but not yet exercised, and (iv) 1,637,500 warrants were not yet granted by the Company. For the year 2022, 590,345 warrants (2021: 304,968) were terminated or lapsed, no warrants were exercised, and 2,127,021 warrants (2021: 795,250) were vested. As a result, as at December 31, 2022, there are 12,257,780 warrants outstanding, entitling their holders to subscribe to 12,257,780 shares of the Company.

Number of potential shares from outstanding warrants	2022	2021
As of January 1	8,917,625	5,766,093
Number of warrants cancelled/forfeited during the year	(590,345)	(304,968)
Number of warrants granted during the year	3,930,500	3,456,500
As of December 31	12,257,780	8,917,625

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 warrants granted 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 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 warrants granted under the June 21, 2019 Stock Option Plan, the May 27, 2021 Stock Option Plan and under the May 25, 2022 Stock Option Plan to specific beneficiaries (Directors and Management Team) may adopt a manual vesting procedure under certain conditions or a particular vesting period over 3 years.

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 2021	3,456,500	1.37	3,456,500	1.37
Outstanding 31 December 2021	8,917,625	1.53	8,917,625	1.53
Granted in 2022	3,930,500	0.68	3,930,500	0.68
Outstanding 31 December 2022	12,257,780	1.23	12,257,780	1.23
Exercisable at 31 December 2022	5,220,520	1.63	5,220,520	1.63

The following table provides an overview of the outstanding potential shares from warrants per personnel category at December 31, 2022 and 2021:

Category	2022	2021
Executive Director	3,950,000	2,950,000
Non-Executive Directors	248,000	272,000
Management team (excluding the Executive Director)	4,083,000	2,938,000
Other employees, consultants, and former service providers	3,976,780	2,757,625
Total outstanding at December 31	12,257,780	8,917,625

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	2022	2021
Share-based compensation	867	1,222
Cumulated Share-based compensation	11,474	10,607

The Cumulated Share-based compensation amount is part of the Total Shareholders' Equity on the Consolidated statement of financial position. This amount is presented on the Consolidated statement of financial position 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 €1.23 or \$1.32 at December 31, 2022 (€1.53 or \$1.73 at December 31, 2021). The weighted average remaining contractual life of all outstanding warrants at the end of 2022 is 7.31 years (2021: 7.18 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.
23-Jun-14	12,000	12,000	€ 4.13	-	48.12%	1.78%	75.32	63.29
9-Feb-15	60,000	95,000	€ 4.49	-	46.75%	0.62%	79.73	61.71
29-May-15	20,000	30,000	€ 4.91	-	46.52%	0.81%	64.14	52.11
1-Oct-15	-	83,000	€ 4.20	-	48.99%	0.90%	72.03	54.02
1-Dec-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
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
1-Jan-17	-	19,000	€ 4.56	-	53.84%	0.73%	56.98	50.96
1-Apr-17	-	18,000	€ 5.41	-	51.80%	0.81%	54.02	48.00
11-Apr-17	20,000	200,000	€ 5.35	-	51.83%	0.72%	65.68	47.67
29-Jul-17	-	10,000	€ 4.72	-	50.95%	0.87%	50.10	44.05
1-Sep-17	-	34,000	€ 4.92	-	48.08%	0.71%	60.99	42.97
2-Nov-17	-	99,000	€ 4.61	-	45.23%	0.66%	52.93	40.90
20-Jun-17	30,000	30,000	€ 4.97	-	51.57%	0.59%	81.40	63.39
01-Apr-18	-	42,000	€ 3,77	-	46.08%	0.76%	54.02	42.02
01-Jun-18	50,000	30,000	€ 4,97	-	46.15%	0.77%	52.01	40.01
05-Dec-18	-	20,000	€1,73	-	57.56%	0.79%	45.86	33.86
24-Jan-19	-	191,000	€ 1,64	-	67.56%	0.77%	62.24	50.20
16-May-19	-	1,508,000	€ 1,49	-	75.78%	0.38%	58.55	46.52
01-Nov-19	-	8,000	€ 1,01	-	82.15%	0.00%	64.99	46.98
01-Dec-19	-	12,000	€ 1,02	-	81.95%	0.00%	64.01	45.99
01-Feb-20	-	2,000	€ 0,98	-	80.26%	0.00%	61.97	49.67
01-Jun-20	-	6,000	€ 0,85	-	86.64%	0.00%	57.99	45.99
01-Oct-20	-	2,000	€ 0,80	-	85.20%	0.00%	53.95	35.97
15-Jul-20	-	225,000	€ 0,80	-	85.89%	0.00%	56.51	38.53
01-Jul-19	60,000	20,000	€ 1,28	-	78.70%	0.07%	69.01	51.02
24-Jul-19	-	980,000	€ 1,24	-	78.64%	0.00%	68.25	50.27
15-Jul-20	-	1,598,000	€ 0,80	-	85.89%	0.00%	56.52	38.53
30-Jul-20	20,000	-	€ 1,28	-	87.02%	0.00%	56.02	38.04
01-Oct-20	-	10,000	€ 1,28	-	85.20%	0.00%	53.95	35.97
01-Mar-21	-	2,000	€ 1.08	-	65.06%	0.00%	48.99	31.00
03-May-21	-	8,000	€ 1.16	-	64.59%	0.01%	46.92	28.93
01-Jun-21	-	4,000	€ 1.18	-	65.82%	0.01%	45.96	27.98
27-Jul-21	-	30,000	€ 1.36	-	63.36%	0.00%	44.12	26.14
27-Jul-21	-	202,500	€ 1.36	-	63.36%	0.00%	44.12	26.14

24-Nov-21	-	40,000	€ 1.05	-	60.78%	0.14%	49.25	37.25
03-Jul-21	-	2,570,000	€ 1.38	-	63.10%	0.04%	44.91	26.93
07-Jul-21	-	600,000	€ 1.39	-	63.11%	0.00%	44.78	26.79
06-May-22	-	5,000	€ 0.75	-	53.16%	1.64%	58.85	52.87
04-Aug-22	-	38,000	€ 0.80	-	55.63%	1.41%	55.89	49.91
03-Aug-22	-	425,000	€ 0.68	-	57.05%	1.50%	67.96	55.92
03-Aug-22	-	3,125,000	€ 0.68	-	57.05%	1.50%	73.97	61.94
04-Aug-22	-	10,000	€ 0.80	-	55.63%	1.41%	73.94	61.91
01-Oct-22	-	312,500	€ 0.74	-	57.26%	2.77%	72.03	60.00
12-Dec-22	-	15,000	€ 0.74	-	58.30%	2.40%	69.67	63.65

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 Company. 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 25: Related parties

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, 2022, the executive management team included four members:

- 1. Chief Executive Officer, Mr. Michael McGarrity
- 2. Executive Vice President of Corporate Development & General Counsel, Mr. Joseph Sollee
- 3. Chief Financial Officer, Mr. Ron Kalfus
- 4. Chief Commercial Officer, Mr. John Bellano

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

Thousands of \$ except per personnel, warrants & share amounts For the years ended December 31	2022	2021
Number of management members and Executive Directors	4	4
Short-term employee benefits	1,550	1,545
Post-employment benefits	54	52
Other employment costs	219	207
<b>Total benefits</b>	<b>1,822</b>	<b>1,804</b>
IFRS share-based compensation expense	863	982
Number of warrants offered	2,200,000	2,200,000
<b>Cumulative outstanding warrants</b>	<b>8,088,000</b>	<b>5,888,000</b>
Exercisable warrants	3,618,642	1,282,238

In 2022, in aggregate for the four members of the executive management team, no warrants were exercised, and 2,200,000 new warrants were granted and accepted. The annualized IFRS cost for existing warrants was \$863,000.

In 2021, in aggregate for the four members of the executive management team, no warrants were exercised, and 2,200,000 new warrants were granted and accepted. The annualized IFRS cost for existing warrants was \$982,000.

No loans, quasi-loans or other guarantees are outstanding with members of the executive management team.

REMUNERATION OF THE BOARD

The total remuneration of the Board of Directors (including the Executive Director) in 2022 and 2021 was \$876,000, and \$863,000, 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.

TRANSACTIONS WITH NON-EXECUTIVE DIRECTORS

Since 2012, the Non-Independent Directors do not receive a fee payment for attending and preparing for Board meetings or for assisting the Company with Board matters. They receive reimbursement for expenses directly related to the Board meetings, totaling less than \$23,000 in 2022.

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 2022 and 2021, fees and expense reimbursement in the amount of \$314,000 and \$302,000, respectively, were paid to independent members of the Board of Directors.

No warrants were granted to Non-Executive Directors in 2022 and no warrants were exercised in 2022.

## NOTE 26: Significant agreements, commitments and contingencies

### FAIR VALUE OF OTHER FINANCIAL LIABILITIES

On September 18, 2015, MDxHealth acquired MDxHealth BV (former 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 €250,000 was paid. On top of the acquisition price, MDxHealth is committed to pay future milestone fees. The Company paid €1.0 million, being \$1 million regarding these milestone fees in 2017. The Company is contractually required to pay at maturity to the holder of the obligation the amount of maximum \$2.2 million. Based on its judgement and estimates, the management believes future milestones will be paid in 2023 and 2024. The fair value of this contingent consideration as of December 31, 2022 is estimated at \$1.2 million over the period 2022-2023 (2021: \$1.6 million) and was accounted for as other financial liabilities (current and non-current) as detailed in Note 16.

As part of the acquisition of the GPS business from Exact Sciences in August 2022, an aggregate earn-out amount of up to \$70 million is to be paid by MDxHealth to Exact Sciences upon achievement of certain revenue milestones related to fiscal years 2023 through 2025, with the maximum earn-out payable in relation to 2023 and 2024 not to exceed \$30 million and \$40 million, respectively. The contingent consideration has been assessed at \$50.5 million which has been accounted for under other non-current liabilities as further detailed in Note 3. The liability recognized reflects a probability-weighted estimate at the current net present value which is expected to become payable. Future fair value adjustments to this contingent consideration will be recognized in the statement of profit or loss. The value of the contingent liability for GPS is \$52.9 million as of December 31, 2022 and was accounted for as other non-current financial liabilities as detailed in Note 16.

### 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) and University of California at Los Angeles (US) 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. With 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 Confirm mdx and Select mdx tests. MDxHealth's marketing partners include, Ferrer Internacional (Spain), Teva Pharmaceuticals (Israel), and SouthGenetics (South and Central America), LifeLabs (Canada) and, in the US, LabCorp, Miraca Life Sciences, Bostwick Laboratories.

In regard to intellectual property that MDxHealth has developed or improved, MDxHealth has sublicensed certain of its non-core technologies to commercial partners, several of whom have launched products that generate royalties and other fees. These sublicenses include an exclusive sublicense to Laboratory Corporation of America (LabCorp) for the MGMT test, which LabCorp began to commercialize in North America in 2008, and an exclusive sublicense to Vesica Health, Inc. for the Company's patented AssureMDx test for the purpose of bladder cancer detection on a worldwide basis.

### LITIGATION

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

NOTE 27: Subsequent events

On February 3, 2023, the Company announced the pricing of a registered public offering of 10,000,000 American Depositary Shares (“ADSs”) (each representing 10 ordinary shares of the Company without nominal value) (the “Offering”) at a price to the public of \$4.00 per ADS (equivalent to a price of €0.364 per share, assuming an exchange rate of €1 = \$1.0988 as published by the European Central bank on February 2, 2023 and a 10-for-1 ADS to share ratio) for total gross proceeds of \$40.0 million before deducting commissions and estimated offering expenses.

On March 6, 2023, the Company announced that, in the context of the above-mentioned offering, the underwriters exercised the option to purchase additional ADSs, on the same terms and conditions as stated above, in the amount of 750,000 ADSs for gross proceeds of USD 3.0 million, bringing the aggregate gross proceeds from this transaction to \$43.0 million.

On April 19, 2023, the Company announced that it has received notice that its Select mdx for Prostate Cancer test has successfully completed the technical assessment process with the Molecular Diagnostics Services (MoIDX) Program developed by Palmetto GBA. Select mdx will be reimbursed throughout the U.S. for Medicare patients who meet coverage conditions under the foundational Local Coverage Determination (LCD) for Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer.

NOTE 28: 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	236 at December 31, 2022, 176 at December 31, 2021 and 163 at December 31, 2020.

MDXHEALTH B.V.

Address	Transistorweg 5, 6534 AT Nijmegen, The Netherlands
Incorporation Date	October 18, 2006
Incorporated into MDxHealth on	September 18, 2015
Number of employees	12 at December 31, 2022, 11 at December 31, 2021 and 9 at December 31, 2020.

NOTE 29: Principal audit fees and services

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 detail is presented in the table below:

For the years ended December 31	In thousands of \$		In thousands of €	
	2022	2021	2022	2021
Audit fee for statutory and consolidated financials	239	182	226	155
Other audit fees	191	183	180	156
Audit related and other services	42	17	39	14
Total	472	382	445	325



# Auditor's opinion

Statutory auditor's report to the general meeting of the  
Company for the year ended 31 December 2022

## STATUTORY AUDITOR'S REPORT TO THE GENERAL MEETING OF MDXHEALTH SA FOR THE YEAR ENDED DECEMBER 31, 2022 (CONSOLIDATED FINANCIAL STATEMENTS)

In the context of the statutory audit of the consolidated financial statements of MDxHealth SA ('the Company') and its subsidiaries (together referred to as 'the Group'), we hereby present our statutory auditor's report. It includes our report of the consolidated financial statements and the other legal and regulatory requirements. This report is an integrated whole and is indivisible.

We have been appointed as statutory auditor by the general meeting of May 28, 2020, following the proposal formulated by the board of directors issued upon recommendation of the Audit Committee. Our statutory auditor's mandate expires on the date of the General Meeting deliberating on the financial statements closed on December 31, 2022. We have performed the statutory audit of the consolidated financial statements of MDxHealth SA for seventeen consecutive years.

## REPORT ON THE CONSOLIDATED FINANCIAL STATEMENTS

### *Unqualified opinion*

We have performed the statutory audit of the Group's consolidated financial statements, which comprise the consolidated statement of financial position as at December 31, 2022, and the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies and other explanatory information, and which is characterized by a consolidated statement of financial position total of \$ 119,135 (000) and for which the consolidated income statement and other comprehensive income shows a loss for the year of \$ 44,044 (000).

In our opinion, the consolidated financial statements give a true and fair view of the Group's net equity and financial position as at December 31, 2022, as well as of its consolidated financial performance and its consolidated cash flows for the year then ended, in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium.

### *Basis for unqualified opinion*

We conducted our audit in accordance with International Standards on Auditing (ISA) as applicable in Belgium. Our responsibilities under those standards are further described in the 'Statutory auditor's responsibilities for the audit of the consolidated financial statements' section in this report. We have complied with all the ethical requirements that are relevant to the audit of consolidated financial statements in Belgium, including those concerning independence.

We have obtained from the administrative body 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.

### *Key audit matters*

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current year. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

### Revenue recognition

#### *Discussion of the matter*

As described in notes 2.7 and 4 of the financial statements, the majority of the Group's revenue is derived from laboratory services with revenue recognized at a point in time when control of the services has transferred to the customer. This is generally when the test results are delivered to the customer. Other Group's revenue is derived from license fees, royalties and other revenues.

The group’s revenue recognition model includes critical accounting estimates based on management judgment. These estimates and underlying judgments are continuously revisited based on updated historical experience and the expected evolution of collections from third party payers.

Revenue recognition was significant to our audit procedures, because of its financial impact on the consolidated annual accounts, and the significant level of management judgment required in making the accounting estimates.

*Procedures performed*

Our audit procedures included, amongst others:

- We tested the Group's internal control procedures on revenues and evaluated the Group's assumptions and estimates used in assessing revenue recognition, in particular with respect to completeness, existence and accuracy.
- We tested the existence of persuasive evidence of underlying agreements and contracts and we substantively tested and challenged the underlying calculations, key assumptions and estimates used in the revenue model.
- We evaluated the reasonableness of the calculations of the ratio of claims collected in relation to claims billed, and of the trend of such ratio.
- We considered the historical accuracy of accrued amounts of revenue and used the information obtained as evidence for evaluating the appropriateness of the assumptions made in the current year including how these compare to the experience in previous years.
- We reviewed the adequacy of the Group’s disclosures in notes 2.7 and 4 in respect of the use of estimates and judgments in the revenue recognition model.

Accounting for Business Combinations

*Discussion of the matter*

As described in note 3 of the financial statements, the Group entered into an agreement with Genomic Health, Inc., a subsidiary of Exact Sciences Corporation, to acquire the Oncotype DX® GPS business;

We identified the accounting treatment of this acquisition as a key audit matter because of the significant management assumptions and judgments used to estimate the fair value of the acquired intellectual property and brand, the customer relations as well as the contingent consideration including discount rates, as well as certain other business-related assumptions that form the basis of forecasted financial results, including probability of success factors and revenue forecasts. Given the complexity of these assumptions, this matter required a high degree of auditor judgment, and increased extent of effort including involvement of valuation specialists..

*Procedures performed*

Our audit procedures related to the group’s accounting for the intellectual property and brand, the customer relations and the contingent consideration recognized in connection with the GPS test acquisition, included the following, among others:

- We tested whether the accounting treatments of the business combinations are consistent with the requirements of IFRS 3.
- We assessed the reasonableness of management's key estimates and assumptions used in the valuation models. We met with key individuals from the finance team and the Group’s external financial advisors involved to discuss and evaluate management’s evidence to support the relevant assumptions.
- With the assistance of our valuation specialists, we evaluated the reasonableness of the valuation methodologies used to determine the value of the acquired intellectual property and brand, the customer relations and the contingent consideration, including testing the mathematical accuracy of the calculations, the discount rate, and company specific risks.
- Additionally, we reviewed the appropriateness and adequacy of disclosures of these business combinations to the consolidated financial statements.

Impairment of goodwill and intangible assets

*Discussion of the matter*

The Company’s evaluation of goodwill and intangible assets for impairment, involves the comparison of the recoverable amount of the cash generating unit to its carrying value. The Company uses the expected discounted cash flow model to estimate the recoverable amount of the cash generating unit, which requires management to make significant estimates and assumptions related to forecasts of future revenue, gross margins, discount rate and perpetual growth rates. Changes in these assumptions could have a significant impact on the recoverable amount and potentially the amount of any goodwill impairment. Given the significant judgments made by management to estimate the recoverable amount contributed to the cash generating unit, performing audit procedures to evaluate the reasonableness of management’s estimates and assumptions required a high degree of auditor judgment and an increased extent of effort, including the need to involve our valuation specialists. Further disclosure regarding the Company’s impairment analysis and allocation of newly acquired goodwill to the cash generating unit can be found in Note 10.

*Procedures performed*

Our audit procedures related to the determination of forecasts of future revenues and gross margins used by management to estimate the recoverable amount of the cash generating unit, include the following:

- We evaluated the reasonableness of the valuation methodology and tested the mathematical accuracy of the calculations.
- We evaluated management’s determination of cash generating units used for impairment testing.
- We evaluated management’s ability to accurately forecast future revenue and gross margin by comparing actual results to management’s historical forecasts.
- We also evaluated the reasonableness of management's revenue and operating margin forecasts by comparing the forecasts to the historical operating results of the Group and appropriate internal and external evidence of growth.
- We reviewed the sensitivity analysis prepared by management to understand the effect of a change in assumptions.

***Responsibilities of the administrative body for the drafting of the consolidated financial statements***

The administrative body is responsible for the preparation of consolidated financial statements that give a true and fair view in accordance with the International Financial Reporting Standards (IFRS) as adopted by the European Union and with the legal and regulatory provisions applicable in Belgium, and for such internal control as the administrative body determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatements, whether due to fraud or error.

In preparing the consolidated financial statements, the administrative body is responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the administrative body either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

***Statutory auditor's responsibilities for the audit of the consolidated financial statements***

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue a statutory auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but it is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

When executing our audit, we respect the legal, regulatory and normative framework applicable for the audit of the consolidated financial statements in Belgium. However, a statutory audit does not guarantee the future viability of the Group, neither the efficiency and effectiveness of the management of the Group by the administrative body. Our responsibilities regarding the continuity assumption applied by the administrative body are described below.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;
- Obtain an understanding of internal control relevant to the audit 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 Group's internal control;
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the administrative body;
- Conclude on the appropriateness of the administrative body's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists,

we are required to draw attention in our statutory auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our statutory auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern;

- Evaluate the overall presentation, structure and content of the consolidated financial statements and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation;
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the management, the supervision and the performance of the Group audit. We assume full responsibility for the auditor's opinion.

We communicate with the Audit Committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control identified during the audit.

We also provide the Audit Committee with a statement that we respected the relevant ethical requirements relating to independence, and we communicate with them about all relationships and other issues which may influence our independence, and, if applicable, about the related measures to guarantee our independence. From the matters communicated with the Audit Committee, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current year, and are therefore the key audit matters. We describe these matters in our statutory auditor's report, unless law or regulation precludes public disclosure about the matter.

**OTHER LEGAL AND REGULATORY REQUIREMENTS**

***Responsibilities of the administrative body***

The administrative body is responsible for the preparation and the contents of the director's report on the consolidated financial statements and for the other information included in the annual report on the consolidated financial statements.

***Responsibilities of the statutory auditor***

In the context of our mission and in accordance with the Belgian standard (version revised 2020) which is complementary to the International Standards on Auditing (ISA) as applicable in Belgium, it is our responsibility to verify, in all material aspects, the director's report on the consolidated financial statements and the other information included in the director's report on the consolidated financial statements, as well as to report on these elements.

***Aspects relating to the director's report on the consolidated financial statements and to the other information included in the annual report on the consolidated financial statements***

In our opinion, after having performed specific procedures in relation to the director's report, this report is consistent with the consolidated financial statements for the same financial year, and it is prepared in accordance with article 3:32 of the Code of companies and associations.

In the context of our audit of the consolidated financial statements, we are also responsible for considering, in particular based on the knowledge we have obtained during the audit, whether the director’s report on the consolidated financial statements and the other information included in the annual report on the consolidated financial statements, namely:

- Part I: Business Review;
- Part II: Corporate Governance;
- Part III: Principle Risks & Uncertainties

contain a material misstatement, i.e. information which is inadequately disclosed or otherwise misleading.  
Based on the procedures we have performed, there are no material misstatements we have to report to you.

**Statement concerning independence**

- Our audit firm and our network did not provide services which are incompatible with the statutory audit of the consolidated financial statements and our audit firm remained independent of the Group during the terms of our mandate.
- The fees related to additional services which are compatible with the statutory audit as referred to in article 3:65 of the Code of companies and associations were duly itemised and valued in the notes to the consolidated financial statements.

**European Single Electronic Format (ESEF)**

In accordance with the draft standard of the Institute of Réviseurs d’Entreprises concerning the standard on auditing the conformity of financial statements with the European Single Electronic Format (hereinafter “ESEF”), we are required to verify whether the ESEF format complies with the regulatory technical standards established by Commission Delegated Regulation (EU) 2019/815 of 17 December 2018 (hereinafter: “Delegated Regulation”).

The administrative body is responsible for preparing, in accordance with ESEF requirements, the consolidated financial statements in the form of an electronic file in ESEF format (hereinafter “digital consolidated financial statements”) included in the annual report on the consolidated financial statements.

It is our responsibility to obtain sufficient and appropriate supporting information to conclude that the format and mark-up language of the digital consolidated financial statements comply in all material aspects with the ESEF requirements under the Delegated Regulation.

If, when auditing the digital consolidated financial statements, we conclude that there is a material misstatement, we will be required to report the matter to the administrative body and ask it to make the necessary changes. Failing that, we will be required to amend this report to the effect that the format and the mark-up of information in the official French version of the digital consolidated financial statements included in the annual report on the consolidated financial statements of MDxHealth SA comply in all material aspects with the ESEF requirements under the Delegated Regulation.

**Other statements**

- This report is in compliance with the contents of our additional report to the Audit Committee as referred to in article 11 of regulation (EU) No 537/2014.

Zaventem, April 25, 2023

BDO Réviseurs d’Entreprises SRL  
Statutory auditor  
Represented by Bert Kegels\*  
Auditor  
*\*Acting for a company*

## 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 3:10 and 3:12 of the Belgian Companies and Associations Code. 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](http://www.mdxhealth.com)).

## Statutory Income statement

Thousands of €/ For the years ended December 31	2022	2022 in \$ Equivalent <sup>1</sup>	2021
<b>I. Operating income</b>	<b>2,983</b>	<b>3,141</b>	<b>3,784</b>
A. Turnover	2,940	3,096	3,732
D. Other operating income	43	45	52
<b>II. Operating charges</b>	<b>12,241</b>	<b>12,896</b>	<b>9,303</b>
A. Purchase of goods and materials	-	-	3
B. Services and other goods	11,041	11,632	8,936
C. Remuneration, social security costs, pensions	378	398	339
D. Depreciation & amounts written off fixed assets	822	866	15
G. Other operating charges	-	-	10
<b>III. Operating profit/(loss)</b>	<b>(9,258)</b>	<b>(9,755)</b>	<b>(5,519)</b>
<b>IV. Financial income</b>	<b>6,183</b>	<b>6,514</b>	<b>1,467</b>
B. Income from current assets	3,357	3,537	1,103
C. Other	2,826	2,977	364
<b>V. Financial charges</b>	<b>44,747</b>	<b>47,137</b>	<b>3,310</b>
A. Recurring financial charges	2,682	2,824	1,262
C. Non-recurring financial charges	42,065	44,313	2,048
<b>VI. Current profit/(loss) before taxes</b>	<b>(47,823)</b>	<b>(50,372)</b>	<b>(7,362)</b>
<b>IX. Profit/(loss) before taxes</b>	<b>(47,823)</b>	<b>(50,372)</b>	<b>(7,362)</b>
<b>X. Income taxes</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>XI. Profit/(loss) for the year after taxes</b>	<b>(47,823)</b>	<b>(50,372)</b>	<b>(7,362)</b>

<sup>1</sup> Profit and loss items have been translated using the average rate 1.0535 USD/EUR and Balance Sheet items using the closing rate 1.0666 USD/EUR

## Appropriation account

Thousands of € For the years ended December 31	2022	2022 in \$ Equivalent	2021
A. Loss/gain to be appropriated			
A1. Loss/Gain for the period available for appropriation	(47,823)	(50,372)	(7,362)
A2. Loss brought forward	(127,303)	(136,025)	(119,941)
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	(175,126)	(186,788)	(127,303)

## Statutory statement of financial position

### Statutory statement of financial position after appropriations

Thousands of € For the years ended December 31	2022	2022 in \$ Equivalent	2021
<b>ASSETS</b>	<b>111,650</b>	<b>119,086</b>	<b>85,762</b>
<b>I. Formation expenses</b>	-	-	-
<b>II. Intangible assets</b>	<b>28,450</b>	<b>30,345</b>	-
<b>III. Tangible fixed assets</b>	<b>2</b>	<b>2</b>	<b>10</b>
B. Plant, machinery and equipment	2	2	10
C. Furniture and vehicles	-	-	-
<b>IV. Financial assets</b>	<b>83,198</b>	<b>88,739</b>	<b>85,752</b>
A. Affiliated enterprises	83,192	88,733	85,746
A1. Investments	3,422	3,650	3,422
A2. Amounts receivable	79,770	85,083	82,324
C. Other financial assets	-	-	-
C1. Investments	-	-	-
C2. Amounts received and cash guarantee	6	6	6
<b>CURRENT ASSETS</b>	<b>13,034</b>	<b>13,902</b>	<b>50,293</b>
<b>V. Amounts receivable after one year</b>	-	-	-
<b>VI. Stocks and contracts in progress</b>	-	-	-
<b>VII. Amounts receivable within one year</b>	<b>103</b>	<b>110</b>	<b>240</b>
A. Trade debtors	49	52	82
B. Other amounts receivable	54	58	158
<b>VIII. Investments</b>	<b>11,836</b>	<b>12,624</b>	<b>49,904</b>
B. Other investments and deposits	-	-	-
<b>IX. Cash at bank and in hand</b>	<b>11,836</b>	<b>12,624</b>	<b>49,904</b>
<b>X. Deferred charges and accrued income</b>	<b>1,095</b>	<b>1,168</b>	<b>149</b>
<b>TOTAL ASSETS</b>	<b>124,684</b>	<b>132,988</b>	<b>136,055</b>

### Statutory statement of financial position after appropriations

Thousands of € For the years ended December 31	2022	2022 in \$ Equivalent	2021
<b>CAPITAL AND RESERVES</b>	<b>74,894</b>	<b>79,884</b>	<b>117,840</b>
<b>I. Capital</b>	<b>123,539</b>	<b>131,367</b>	<b>118,662</b>
A. Issued capital	123,539	131,367	118,662
<b>II. Share premium account</b>	<b>126,481</b>	<b>134,905</b>	<b>126,481</b>
<b>III. Revaluation surpluses</b>	-	-	-
<b>IV. Reserves</b>	-	-	-
<b>V. Accumulated profit/(loss)</b>	<b>(175,126)</b>	<b>(186,788)</b>	<b>(127,303)</b>
<b>VI. Investment grants</b>	-	-	-
<b>VII. Provisions and postponed taxes</b>	-	-	-
A. Provisions for liabilities and charges	-	-	-
A4. Other liabilities & charges	-	-	-
<b>AMOUNTS PAYABLE</b>	<b>49,790</b>	<b>53,104</b>	<b>18,215</b>
<b>VIII. Debts payable after 1 year</b>	<b>33,220</b>	<b>35,431</b>	<b>5,712</b>
A. Financial debts	33,220	35,431	5,712
A4. Credit institutions	-	-	-
A5. Other debts	33,220	35,431	5,712
<b>IX. Debts payable within 1 year</b>	<b>2,798</b>	<b>2,984</b>	<b>5,567</b>
A. Current portion of debts after one year	-	-	-
B. Financial debts	-	-	3,273
B1. Credit institutions	-	-	3,273
C. Trade debts	2,706	2,886	2,224
C1. Suppliers	2,706	2,886	2,224
D. Advances received on contracts in progress	-	-	-
E. Taxes, remuneration & social security	92	98	70
E1. Taxes	-	-	-
E2. Remuneration & social security	92	98	70
<b>X. Accrued charges and deferred income</b>	<b>13,772</b>	<b>14,689</b>	<b>6,936</b>
<b>TOTAL LIABILITIES</b>	<b>124,684</b>	<b>132,988</b>	<b>136,055</b>

# 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.
DRE	Digital rectal examination procedure
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, collection device or test component that is packaged in a box which that can be shipped to end-user laboratories.
LCD	Local Coverage Determination – a local healthcare coverage and reimbursement policy issued by a Medicare Administrative Contractor appointed by CMS.
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.
MOLDX	The Molecular Diagnostic Services Program, administered by Palmetto GBA, which handles technical assessments and coverage and reimbursement policies for U.S. laboratories that perform molecular diagnostic testing for Medicare patients.
NCCN	National Comprehensive Cancer Network, a non- profit alliance of the 31 leading cancer centers in the United States.
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.
PCPTRC	The Prostate Cancer Prevention Trial Risk Calculator
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.
QALY	The quality-adjusted life year is a widely recognized academic standard for measuring how well medical treatments lengthen and/or improve patients' lives. The QALY metric has served as a fundamental component of cost-effectiveness analyses around the world for more than 30 years.
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.