Update Report

MDxHealth

Ongoing Strong Performance

MDxHealth

Chief Research Analyst

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Name:	**MDxHealth SA**
Country:	**Belgium**
Price:	**EUR 3.46**
ISIN Code:	**BE0003844611**
Reuters Code:	**MDXH.BR**
Market Cap (EUR m):	**156.7**
EV (EUR m):	**136.6**
Cash & cash eq. (EUR m):	**20.1**
Shares outstanding (m):	**45.3**
Volume:	**129,924**
Free float:	**73%**
52-week Range:	**3.21-5.88**

	2014A	2015A	2016E
Total Revenues	11.671	17.600	28.200
Net (Loss)/Profit	(15.256)	(14.500)	(11.800)
Net loss per share (cents)	(0.44)	(0.32)	(0.26)
R&D costs	2.376	3.300	2.500
Cash increase/(decrease)	(5.786)	12.000	(18.897)
Cash and marketable sec.	18.897	30.897	12.000

Executive Summary

- MDxHealth is a molecular diagnostics company that develops and commercializes advanced, accurate and scalable molecular diagnostic products to improve the diagnosis of urological cancers. The Company is a market leader in the fast growing field of molecular testing focused on the identification of DNA or RNA imprints, which can turn a healthy cell into a cancer cell. MDxHealth has a proven track record of developing and delivering molecular diagnostic assays in the field of urologic oncology and a proprietary portfolio of molecular biomarkers and know-how, validated by leading partners.

- The main commercial focus of the Company is on urologic cancers, including prostate and bladder cancer, and it currently commercializes its proprietary ConfirmMDx® for Prostate Cancer test on the U.S. market, and its liquid biopsy test SelectMDx™ for Prostate Cancer on the European and US markets. To date, over 45,000 ConfirmMDx® tests have been ordered by approximately 3,000 US urologists since its launch in mid-2012. MDxHealth markets the ConfirmMDx® test in the US via its direct sales force and via co-marketing agreements with national urology-focused laboratories including Bostwick and Miraca.

- Following the launch of its liquid biopsy test SelectMDx™ in the US, the company successfully signed a number of reimbursement contracts with large commercial and Medicare Advantage payer organizations. We have therefore increased our sales outlook for SelectMDx in the next few years. Besides, ConfirmMDx® was included in the US 2016 National Comprehensive Cancer Network (NCCN) guidelines which triggered a positive medical policy decision for ConfirmMDx® from Cigna. Cigna is one of the largest health insurers in the US.

- For other cancer types, the Company has established licensing agreements to commercialize its molecular diagnostic technologies, e.g. with the launches of Cologuard® for colon cancer by licensee Exact Sciences and PredictMDx® for Glioblastoma by licensee Laboratory Corporation of America (Labcorp). We especially consider the prospect for successful commercialization of Cologuard® to be very high. In 2015 Exact Sciences sold more than 104,000 test and is expected to sell more than 240,000 tests in 2016, generation revenue of USD 90-100 million, an increase of more than 130%. As it represents a rather low risk cash flow stream for MDxHealth, the market may underestimate the true value of the Cologuard® royalty stream for MDxHealth.

- Last year, the company acquired the privately held Dutch molecular diagnostics company NovioGendix for a price of USD 8.8 million. The acquisition strengthened MDxHealth's position in uro-oncology and provided vital access to the fast growing market for liquid biopsies, with a CE-marked non-invasive urine test for prostate cancer. In November 2015, the test was launched as SelectMDx™ for Prostate Cancer in the Benelux region, and subsequently it was launched as an IVD kit on the European market in 2016H1. MDxHealth also launched SelectMDx as a laboratory developed test (LDT) on the US market in 2016H1.

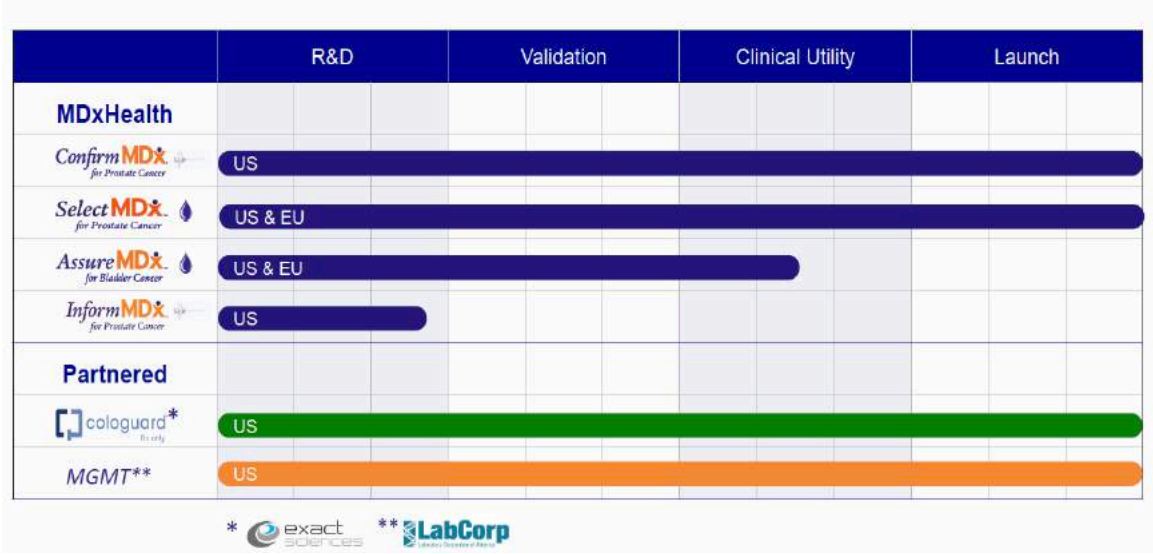
- The Company's cash position as of 30 June 2016 was EUR 20.1 million. Revenues for the first six months of 2016 grew more than 63% to USD 13 million, due to an ongoing increase in ConfirmMDx® test sales and first sales of it liquid biopsy test in Prostate Cancer SelectMDx™. Based on the company's guidance for 2016 projected revenues of USD 23-27 million, we estimate full year revenues of USD 28.2 million, including increasing royalty amounts from Exact Sciences on its Cologuard® test. Our forecasts reflect an outlook for a strong increase in sales volume and an ongoing high

reimbursement rate for Cologuard for 2016 (USD 484). We expect ongoing strong sales now that Cologuard® has been included in the finalized screening guidelines.

- Based on NPV based valuation, we believe that MDxHealth is seriously undervalued at the current share price of EUR 3.46. We have increased our valuation from EUR 395 million (or EUR 8.72 per share) to EUR 495 million (or EUR 11.00 per share) due to a better outlook for Cologuard and expected stronger revenues from both ConfirmMDx and SelectMDx™. This represents a substantial upside from the current share price.

Company Profile

MDxHealth is a multinational healthcare company that provides actionable epigenetic and molecular information to personalize the diagnosis and treatment of cancer. The company's tests are based on proprietary gene methylation (epigenetic) technology and assist physicians with the diagnosis of cancer, prognosis of recurrence risk, and prediction of response to a specific therapy. The term epigenetics refers to heritable changes in gene expression (active versus inactive genes) that does not involve changes to the underlying DNA sequence; a change in phenotype without a change in genotype. Epigenetic change is a regular and natural occurrence but can also be influenced by several factors including age, the environment/lifestyle, and disease state. Epigenetic modifications can manifest as commonly as the manner in which cells terminally differentiate to end up as skin cells, liver cells, brain cells, etc. Or, epigenetic change can have more damaging effects that can result in diseases like cancer. At least three systems including DNA methylation, histone modification and non-coding RNA (ncRNA)-associated gene silencing are currently considered to initiate and sustain epigenetic change.



In Prostate Cancer, the company currently has two marketed diagnostics tests, ConfirmMDx and its novel liquid biopsy test SelectMDx. MDxHealth's ConfirmMDx® for Prostate Cancer was launched mid-2012 and has enjoyed increasing commercial uptake. In the ConfirmMDx® has been shown to help distinguish patients who have a true negative biopsy from those who may have undetected cancer, thereby helping to reduce unnecessary repeat biopsies. To date, over 45,000 ConfirmMDx® tests have been ordered by approximately 3,000 urologists since launch. The final Medicare LCD for coverage of ConfirmMDx® became effective in November 2014 with a reimbursement price of USD 2,030.

SelectMDx™ for Prostate Cancer was launched in the US earlier this year and already signed coverage agreements with large US payers The SelectMDx test was designed to address an unmet need in the identification of men at risk for prostate cancer and importantly, the stratification of patients at risk for potentially lethal high-grade prostate cancer compared to those with low-grade cancer. SelectMDx will be sold as a laboratory developed test (LDT) and tested at MDxHealth's CAP and CLIA accredited laboratory facilities in Irvine, California. SelectMDx will be marketed in the US through MDxHealth's direct national sales force of over 37 representatives and managers to the Company's established and growing customer base of urologists and managed care providers. In November 2015, the test was launched as SelectMDx™ for Prostate Cancer in the Benelux region, and subsequently it was launched as an IVD kit on the European market in 2016H1.

Business Strategy: Focus on Urologic Cancers, successfully out-licensing others

Over the past several years, MDxHealth has built a proprietary portfolio of hundreds of epigenetic biomarkers and related expertise. Its focus is on urologic cancers, namely prostate, bladder, and kidney. The Company's lead product is the ConfirmMDx® for Prostate Cancer test which has been validated to help prevent unnecessary invasive repeat prostate biopsies on

prostate cancer-free men, while also helping to identify men at increased risk for an aggressive form of the disease who may benefit from early detection and treatment. The Company's second marketed product, SelectMDx™ for Prostate Cancer, is a non-invasive liquid biopsy test that the company obtained via its acquisition of NovioGendix in 2015. On page 21 we elaborate further on the SelectMDx test. In bladder cancer, MDxHealth has developed an epigenetic assay named AssureMDx™ for Bladder Cancer that helps identify patients at risk for bladder cancer. MDxHealth will offer the AssureMDx™ test, a urine-based liquid based biopsy test, as a Laboratory Developed Test (LDT) on the US market, and as a CE-marked IVD kit in Europe. The Company plans to launch the AssureMDx™ LDT service test in the US in the second half of 2016.

MDxHealth currently has 37 direct sales representatives. Through its co-marketing partnerships with Bostwick, Miraca and other lab partners across the US, there are an additional 40 partner sales reps, though these should not be considered as being devoted full-time to ConfirmMDx®. Rather, their key role is to introduce the MDxHealth sales rep to the client who will then take over the account management. The current sales team covers over 3,000 urologists who have placed an order, representing around 30% of the 10,000 urologists in the US.

For cancer outside of its urologic focus, the Company's strategy is to partner or out-license the commercialization of biomarkers and technologies. So far, MDxHealth has addressed colon cancer and brain cancer (MGMT biomarker).

- **Colon:** In 2010, MDxHealth entered into an exclusive licensing agreement with Exact Sciences Corporation for stool-based screening of colorectal cancer. Under the terms of the agreement, Exact Sciences obtained exclusive, worldwide rights to use MDxHealth's NDRG biomarker in stool-based detection of colorectal cancer, as well as non-exclusive access to MDxHealth's MSP platform technology for use with those biomarkers. It is the first non-invasive screening test for colorectal cancer that analyzes both stool DNA and

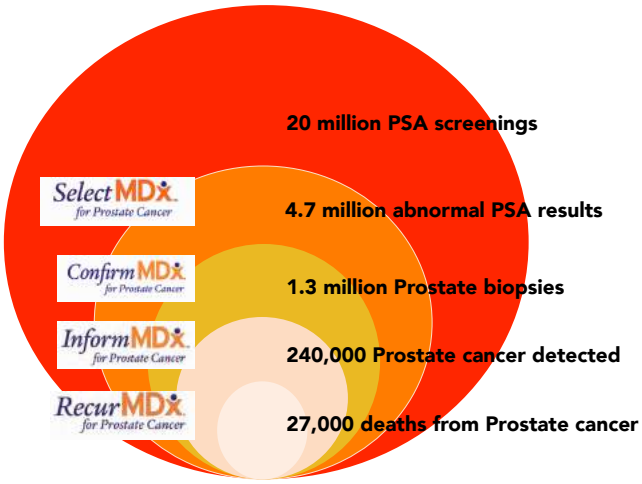
blood biomarkers. The test incorporates one of MDxHealth's epigenetic biomarkers and was FDA-approved August 2014. With the 2016H1 figures, Exact Sciences published that is it has sold around 94,000 Cologuard tests. Exact Sciences estimates that the addressable market opportunity for Cologuard is USD 4 billion; however, payers have been slow to approve reimbursement for the test. As a result, Cologuard's share of that market is still undeniably small. In 2015 the company conducted 104,000 tests that generated USD 39.4 million in sales. This year, management thinks it will complete 240,000 tests, and that sales will eclipse USD 90 million as more insurers sign on. The likelihood of capturing a more-meaningful share of that market opportunity may have improved following an update to the U.S. Preventative Services Task Force (USPSTF) colorectal cancer-screening guidelines. Last year, preliminary guidelines on colorectal cancer screening from the USPSTF labelled Cologuard an alternative screening option to other screening choices, such as FBOT and FIT. That preliminary guidance could have crimped Cologuard's market potential if it had been finalized. We therefore believe that for the next few years an ongoing strong increase of the number of Cologuard tests is expected. The total addressable market is estimated to be 80 million tests. MDxHealth receives a low to mid single digit royalty on sales of Cologuard. (2-4%). We expect MDxHealth to receive an increasing net cash flow from Exact Sciences to up to USD 20 million in 2020, growing further to USD 100 million in 2028. The license agreement with Exact Sciences is in place till 2028.

ConfirmMDx® in Urologic Cancers

Prostate cancer is globally recognised among the greatest unmet clinical needs for men over 40. A number of compelling clinical factors make it imperative to improve the diagnostic toolset. Prostate cancer is now viewed as not one disease, but a spectrum of diseases. It presents in many different forms, its onset controlled by small genetic changes, which may vary from male to male. The disease spectrum ranges from non-life threatening (indolent) forms to life threatening illnesses, with variations occurring because genetic differences between individuals make for differences in their cancers. Since 1990 treatment has relied on the Prostate-Specific Antigen (PSA) test, biopsies and Gleason scores to diagnose and stage prostate cancers. However, the PSA screening test has been roundly criticized by medical opinion leaders as flawed, inconclusive and even dangerous. Approximately 70-75% of men diagnosed with prostate cancer through PSA screening have an indolent form of prostate cancer, which may not require treatment, and 25-30% have life-threatening illnesses, which require treatment.

Annually, there are approximately 20 million men screened by the PSA test, resulting in approximately 4.7 million abnormal PSA test results (>4.0), leading to over 1.3 million biopsy procedures. Of these, 240,000 are diagnosed with prostate cancer, with 27,000 annual deaths.[1] Approximately USD 4.4 billion is spent annually on screening, diagnosing and staging, and an additional USD 9.9 billion is spent annually on treatment of these patients, totaling nearly USD 15 billion being spent annually on prostate cancer in the US alone. Annually, over USD 4 billion is spent on pharmaceuticals for prostate cancer, which is expected to increase to USD 8.7 billion by 2019.[1]

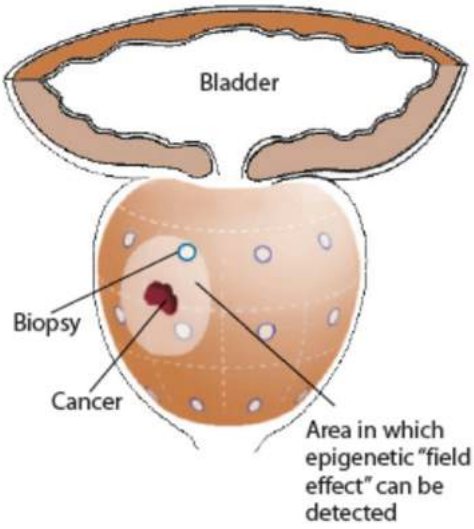
[1]Aubry et al; Budget Impact Model-Epigenetic Assay Can Help Avoid Unnecessary Repeated Prostate Biopsies and Reduce Healthcare Spending, American Health and Drug Benefits 2013



Source: Van Leeuwenhoek, MDxHealth

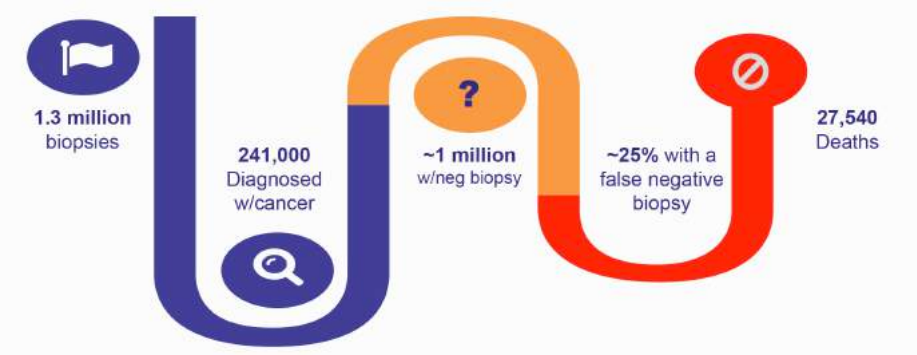
Earlier this year, the company announced positive data form two abstracts that demonstrated the prognostic value of ConfirmMDx® for Prostate Cancer. The data were made public at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) in San Francisco. The abstracts showed ConfirmMDx's ability to both detect an epigenetic field effect associated with the presence of anterior-predominant tumors that was missed in a previous negative biopsy, and identify patients likely to harbor clinically significant prostate cancer from negative biopsy tissue.

This is important since there is increasing awareness that anteriorly-focused prostate cancers (PCa) are poorly sampled by 12-core transrectal ultrasound-guided (TRUS) prostate needle biopsies.



Source: Oncology Journal, May 15 2013

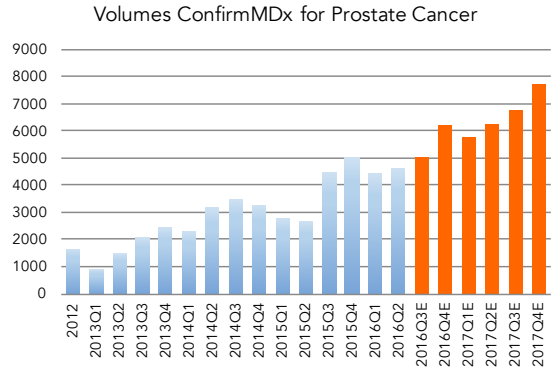
Over 975,000 American men are diagnosed with a negative prostate biopsy each year; however approximately 25% of those men receive false-negative results. Under the current standard of care, prostate biopsy procedures consisting of 10-12 needle biopsy cores only sample approximately 1% of a man's prostate. This approach leaves men at risk of undetected cancer, leading to a high rate of repeat biopsies, even on cancer-free men. There is an unmet medical need for a clinically effective diagnostic test to address this dilemma. ConfirmMDx® for Prostate Cancer is able to detect an epigenetic field effect or "halo" associated with the cancerization process at the DNA level. This "halo" around a cancer lesion can be present despite cells having a normal appearance under the microscope. Thus, ConfirmMDx aids urologists in identifying truly negative men who may forego an unnecessary repeat biopsy procedure



Currently there are several prostate cancer tests available on the market that are used in the decision making process of a urologist:

- When to perform a biopsy: SelectMDx™, Phi, Progensa PCA3, 4Kscore
- When to re-biopsy: ConfirmMDx, Progensa PCA3, 4Kscore, Phi
- To treat or not to treat: Oncotype DX, Prolaris, Decipher

The ConfirmMDx® test qualified for Medicare reimbursement as of November 3, 2014 and is also available to more than 152 million insured lives via private health insurance plans. To date over 45,000 ConfirmMDx® tests have been ordered by approximately 3,000 urologists since launch in 2012. In our view, ConfirmMDx® has clearly proven itself, by distinguishing patients who have a real negative biopsy from men that showed to have undetected. For the coming quarters we expect a further increase in volumes rising to more than 30,000 sold tests per year after 2017.



Source: MDxHealth, Van Leeuwenhoeck Institute

In March 2016 it was announced that ConfirmMDx has been included in the US 2016 National Comprehensive Cancer Network (NCCN) guidelines. The NCCN is an alliance of 27 of the world's leading cancer ceners top cancer centers in the US. The guidelines provide recommendations to ensure that patients receive the right diagnostic tests that are proven to get better clinical outcomes. ConfirmMDx for Prostate Cancer is the first epigenetic, and only tissue-based test in the 2016 NCCN Guidelines for early detection of prostate cancer which addresses false negative biopsy concerns.

This endorsement by the top cancer centers in the US is significant for MDxHealth for a number of reasons:

- It firmly establishes ConfirmMDx as a standard of care for patient management of men at risk for prostate cancer
- It strengthens the position of MDxHealth by both current users and late adopters because the endorsement provides them strong confidence to use the test for patient management
- It provides the sales force an important medical and legal justification for the utilization of the test.

And last but not least this type of endorsements is very important for a successful reimbursement strategy. It removes the final hurdle for every payor that has the question if ConfirmMDx is in the guidelines. MDxHealth can now strongly confirm that. This was also underpinned by the subsequent announcement that MDxHealth has contracted with Priority Health for coverage of ConfirmMDx for its 720,000 members. In August it was also announced that Cigna, one of the largest health insurers in the US, has made a positive medical policy decision for ConfirmMDx® test for Prostate Cancer. The positive medical policy decision follows the recently updated NCCN Guidelines for Prostate Cancer Early Detection Version 2.2016 and adds to the expanding list of payers that have adopted positive medical policy on ConfirmMDx for Prostate Cancer. Cigna currently is in merger discussions with Anthem. The new combination would create the biggest U.S. health insurer by membership, topping UnitedHealth. Together, the firms would have a large position in the market for coverage sold to big companies and other employers.

ConfirmMDx for Prostate Cancer is instrumental to distinguish men with a true negative biopsy from those men that may have undetected cancer missed in a previous biopsy. It provides urologists with actionable information firstly by ruling out prostate-cancer-free men from undergoing unnecessary repeat biopsies and screening procedures and secondly ruling in high risk men with a previous negative biopsy result who may be harboring undetected cancer. These men would benefit from a repeat biopsy and treatment. ConfirmMDx is an assay that consists of three biomarkers that detects the level of methylation in three separate genes (GSTP1, APC and RASSF1) that are associated with the presence of prostate cancer cells. GSTP1 is the most studied epigenetic biomarker associated with prostate cancer diagnosis due to its high sensitivity and specificity. Methylation of APC and RASSF1 genes are often found in prostate cancer and have demonstrated a field effect, aiding in the identification of biopsies with false negative histopathological results.

Liquid Biopsy Tests in Urologic Cancers

Liquid biopsy tests are gaining traction within the industry as a viable alternative to traditional screening methods for cancer. Although liquid biopsy applications are still in their early days, the potential uses for the technology is expected to grow quickly in the next few years. According to the analysis of BCC, the global market of liquid biopsy was about USD 1.6 billion in 2015. The market is continuously rising at a five-year compound annual growth rate (CAGR) of 22.3%. If this rate continued, it will reach USD 4.5 billion by 2020.

No doubt, liquid biopsy has won everyone's faith from medical communities to the investors. It has made the complex cancer screening as simple as a regular blood or urine test. This medical breakthrough has been envisaged to be enhancing the lives of cancer patients in forthcoming years. The SelectMDx™ for Prostate Cancer test was designed to address an unmet need in the identification of men at risk for prostate cancer and importantly, the stratification of patients at risk for potentially lethal high-grade prostate cancer compared to those with low-grade cancer. In clinical studies, SelectMDx has been shown to outperform the existing PCA3 assay, improving the information available to urologists seeking to further reduce unnecessary invasive biopsy procedures.

Liquid biopsy technology has a lot of potential applications and study results have shown promise for these new testing options. A urine-based test could provide a less-expensive and less-invasive way to monitor patients throughout treatment, help individuals avoid additional surgeries and help clinicians make better decisions about which procedures or drugs are the best fit for patients. The total market for liquid biopsies is estimated to be more than USD 32 billion, with oncology applications taking more than USD 28 billion. Within oncology, early cancer detection would be the largest opportunity with a expected market size of USD 15 billion based on USD 300 per test and 50 million people eligible for testing yearly.

SelectMDx for Prostate Cancer

Liquid biopsies are already commercially available for therapy selection and treatment monitoring with an increasing number of laboratories launching cancer recurrence monitoring tests in the near future. To date, MDxHealth has entered into an agreement with Dutch based DDL Diagnostic Laboratory for the manufacturing of the SelectMDx™ IVD kits. DDL was the largest service provider of the existing prostate cancer PCA3 test in the Netherlands, and recently announced its decision to discontinue processing of the PCA3 assay. As a result, through its state-of-the-art laboratory in Nijmegen, The Netherlands, MDxHealth anticipates that it will be the principal provider of urine-based prostate cancer testing for patients with elevated PSA levels. The novel biomarkers that make up SelectMDx™ were discovered by Prof. Dr. Jack Schalken, original developer of the PCA3 assay.

Overview Liquid Biopsy Prostate Cancer tests

Assay Characteristics	**Phi**	**4Kscore**	**Progensa PCA3**	**SelectMDx**
Company	Beckman Coulter	Opko	Hologic	MDxHealth
Specimen	Blood	Blood	Urine	Urine
Methodology	Immuno assay 3 Protein biomarkers tPSA and fPSA, proPSA	Immuno assay 4 kalikriens biomarkers PSA, fPSA, Intact PSA, HK-2	qPCR mRNA test, 1 biomarker PCA3	qPCR 2 mRNA biomarkers DLX1, HOXC6
Regulatory	FDA/CE	LDT/CLIA/CE	FDA/CE	LDT/CLIA/CE
List Price (USD)	499	1,900	500	500
Assay Performance (AUC)	AUC 0.73	AUC 0.82	AUC 0.68	AUC 0.89
Comments	Requires Phlebotomist	Requires Phlemotomist & Centrifuge	Urine Sample – In Office Procedure	Urine Sample – In Office Prodedure

Source: MDxHealth

In clinical studies, SelectMDx™ has been shown to outperform PCA3 in the identification of men at increased risk for aggressive prostate cancer, thereby improving the information available to urologists deciding on the need for a prostate biopsy while also aiding to identify men a sufficiently low risk for prostate cancer who may avoid unnecessary invasive biopsy procedures. See also the table above.

In March 2016, positive results of a multicenter validation study of its liquid biopsy test SelectMDx for Prostate Cancer were presented at the Annual European Association of Urology (EAU) Congress in Munich, Germany. Urine samples from two prospective, multicenter studies with 492 men (cohort A) and 371 men (cohort B) respectively were collected after digital rectal examination (DRE) to measure the mRNA expression levels of the two genes included in the SelectMDx test. These results were combined with traditional clinical risk factors, i.e. DRE, PSA, PSA density, age and family history to further improve patient stratification. An algorithm was developed in cohort A, and successfully validated in the independent cohort B. The optimal model was generated to assess the likelihood of detecting high-grade disease upon biopsy for an individual patient. The SelectMDx urinary molecular biomarker-based risk score resulted in an improved detection of men harboring high-grade PCa, with a negative predictive value (NPV) for significant cancer of 98%.

The SelectMDx test was designed to address an unmet need in the identification of men at risk for prostate cancer and importantly, the stratification of patients at risk for potentially lethal high-grade prostate cancer compared to those with low-grade cancer. In clinical studies, SelectMDx has been shown to outperform PCA3 in the identification of men at increased risk for aggressive prostate cancer, thereby improving the information available to urologists deciding on the need for a prostate biopsy while also aiding to identify men a sufficiently low risk for prostate cancer who may avoid unnecessary invasive biopsy procedures. See also the table on the next page.

The very high NPV of the test could reduce unnecessary biopsies by approximately 50%, as well as other expensive diagnostic procedures such as MRI scans, and thus could result in significant cost savings for healthcare providers. Prof. Dr. Jack Schalken, original developer of the PCA3 assay, discovered the novel biomarkers that make up SelectMDx.

AssureMDx: Liquid Biospy Test for Bladder Cancer

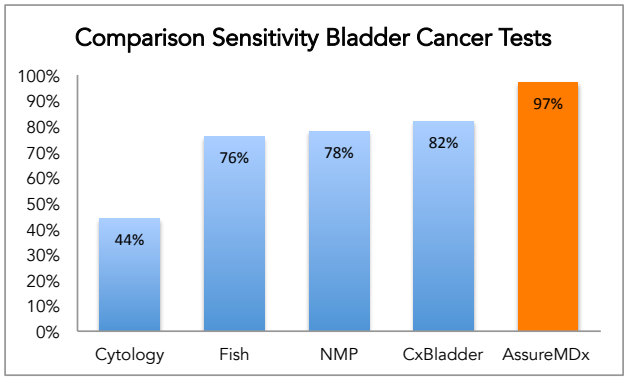
Concurrent to its liquid biopsy test, SelectMDx™ for Prostate Cancer, MDxHealth is developing the urine based liquid biopsy test AssureMDx™ for Bladder Cancer. It has entered into a license and collaboration agreement with Erasmus University Medical Center Rotterdam (Erasmus MC) in The Netherlands. AssureMDx is being validated in a, multi-center, two-arm, prospective randomized clinical trial financed by three organisations, including Erasmus MC. A total 435 patients will be enrolled into this trial (2,000 urine samples). The study is designed to assess the test's ability to safely reduce the number of invasive cystoscopies performed during follow-up of patients with NMIBC with a low/intermediate risk of recurrence or progression. The study will also examine whether the addition of urine tests to follow-up of patients with higher risk of recurrence and progression leads to earlier detection of potentially dangerous recurrences. All urine samples will be tested using AssureMDx™ assay.

Strong Data on AssureMDx published in The Journal or Urology

Earlier this year, the authoritative Journal of Urology published data demonstrating the clinical potential of its urine-based epigenetic bladder cancer test AssureMDx to aid urologists in the management of patients presenting with haematuria (blood in the urine). The AssureMDx for Bladder Cancer test, which analyses DNA methylation of three genes (*TWIST1*, *ONECUT2* and *OTX1)* in combination with mutation analyses of three others, was used

to create an epigenetic profile of 154 urine samples from haematuria patients without (n=80) and with (n=74) bladder cancer. The study demonstrated the test's high negative predictive value (99.2%) for the detection of bladder cancer in this cohort of haematuria patients.[2]

Van Leeuwenhoeck's analysis shows AssureMDx comparing favourably against Abbott's Urovysion in separate large-scale clinical trials, each with over 400 patients as well as to Pacific Edge's CxBladder. Urovysion was launched 2001 as an aid in monitoring bladder cancer and in 2005 to aid diagnosis. The test uses Abbott's FISH fluorescence technology to detect chromosomal abnormalities. In a trial conducted by Abbott, Urovysion showed an overall sensitivity of 68.6% and specificity of 77.7% in the detection of bladder cancer in 479 patients presenting with hematuria. CxBladder showed an overall sensitivity of 82% and specificity of 85% This compared with a sensitivity of 97% and specificity of 91% for AssureMDx™. We note some caution must be used with the comparisons, given tests were not compared head to head.



Source: Company Reports, MDxHealth

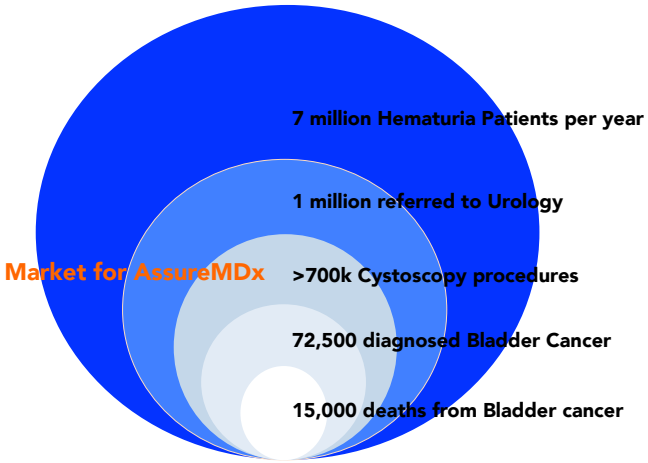
[2] Van Kessel et al; Evaluation of an Epigenetic Profile for the Detection of Bladder Cancer in Patients with Hematuria. The Journal of Urology

There are a number of commercially available IVD tests to detect bladder cancer in hematuria patients, although the specificity and sensitivity of such tests is variable. NMP22 has been widely adopted as an adjunct to cytology. However, no other test is being used as standard, as none has been shown to be more accurate than the existing benchmark.

Comparable with the liquid biopsy test SelectMDx™ for Prostate Cancer, the AssureMDx test for Bladder Cancer is being developed for the US market as a laboratory-developed test (LDT). LDTs are a class of in vitro diagnostic test manufactured, developed and validated for use in a single laboratory.

Bladder cancer is the sixth most common cancer worldwide and has the highest per patient medical costs of any cancer. There will be an estimated 75,000 new cases diagnosed in the US and over 300,000 world wide at an incidence rate of approximately 3%. Over 90% of bladder cancers are transitional cell carcinomas. Hematuria can be continuous or intermittent and either visible (gross) or microscopic. Screening studies have shown that in up to 20% of cases of gross hematuria, patients go on to be diagnosed with Urothelial Cancers, while only 5% of cases of microscopic hematuria turn out to be UCs such that the 2001 American Urological Association (AUA) Best Practice Policy on Asymptomatic Microscopic Hematuria recommends that all patients presenting with gross hematuria, particularly those without evidence of infections, should undergo full urologic work-up. This procedure includes provision of a urine sample for testing with cytology (manual examination under a microscope) in conjunction with cystoscopy (insertion of a flexible scope into the urinary tract). Some patients are also examined by means of upper tract imaging, typically with a CT scan or ultrasound imaging. Cytology tends to have low sensitivity (true positives), particularly at the earlier stages of cancer, and is subject to user variability. Importantly, bladder cancer is one of the most expensive cancers to treat, given more than half of all early stage bladder cancer patients will recur in the three years following

treatment.



The market for hematuria testing and monitoring represents a noteworthy commercial opportunity. In the US, an estimated USD 1 billion is spent investigating hematuria each year, with approximately one million people referred to an urologist annually. For patients treated for early stage bladder cancer, a high recurrence rate means continual monitoring at an estimated extra cost of USD 1-2 billion for those requiring regular follow-on testing.

Test/distributor	Methodology	Advantages	Limitations
UroVysion/Abbott	FISH fluorescence in situ hybridisation assay; detects chromosomal abnormalities	Higher sensitivity than cytology across all stages and grades	Requires a large specimen sample. Poor positive predictive value
NMP22 ELISA	Measures levels of protein NMP22, which is elevated in bladder cancer patients	Higher sensitivity than cytology for grade I/II	Low specificity; interference from benign urinary tract conditions
NMP22 BladderChek	Point of care test with 30 minute turnaround.	Improves detection vs cytology in cases of recurrent cancer.	Relatively high rate of false positives
BTA Stat/Polymedco	POC, detects human complement factor H related protein	Immediate result	High rate of false positive results in cases of co-existing genitourinary conditions
BTA Trak/Polymedco	Lab based immunoassay	Higher sensitivity than cytology for low grade tumors	High rate of false positive results in cases of genitourinary conditions
ImmunoCyt	Lab based immunofluorescence assay	Relatively high sensitivity in some patient groups	High rate of false positive results in cases of genitourinary conditions
UBC/IDL Biotech	Measures soluble fragments of cytokeratins 8 and 18. Cytokeratins are characteristic of epithelial cells	More accurate at detecting CIS than cytology	Overall performance not superior to cytology. Ongoing testing

Source: Company Reports, Van Leeuwenhoeck Institute

SWOT

Strengths	Weaknesses
Strong management with extensive relevant technical, commercial and financial expertise	Operating losses accumulating year-on-year
Focus on urological cancers with increasing revenues from marketed tests	Operating losses accumulating year-on-year
Well positioned in "next generation" market of non-invasive liquid biopsy tests	Current and future revenues still largely dependent on sales of one test: ConfirmMDx for Prostate Cancer
Covered by many health plans, as well as Medicare	MDxHealth relies on limited number of parties for manufacture and supply of its laboratory instruments
Opportunities	**Threats**
With the ageing population, cancer incidence will rise substantially	Increased competition from competitors developing novel or improved methods for detecting prostate cancer
Personalized medicine important driver for diagnostics	Failure to convince majority of urologists to use ConfirmMDx® and SelectMDx™
Increasing low risk income from successful sales of Cologuard (Exact Sciences)	

Financials

For the six months ended 30 June 2016, revenue from continuing operations was up 65% to USD 12.9 million (2015H1: USD 7.9 million) with strong sales from ConfirmMDx®, that comprised 83% of the first half revenue. According to our estimates, Volumes of ConfirmMDx® in 2015H1 rose 65% to over 9,100 tests compared to 5,500 tests in 2015H1. In total, more than 45,000 ConfirmMDx® tests have been ordered since its launch in 2012. Net loss for the first six months of 2016 increased by USD 2.1 million to USD 7.6 million. The higher loss is attributed to inclusion of NovioGendix costs, build-up of international sales organization for non-US, non-recurring corporate develop project costs, and cotinued investment in sales and managed care.

MDxHealth also was successful in securing new reimbursement coverage for both ConfirmMDx and SelectMDx for Prostate Cancer with large healthcare providers like Priority Health and Cigna. Following the launch of SelectMDx for Prostate Cancer in the US, the company received reimbursement coverage from large healthcare providers like ACPN and Fortified Provider Network. We expect the first revenues from sales of SelectMDx to be generated in 2016H2.

The company's cash position was USD 20 million as of June 2016. The average cash burn in the first six months of 2016 was USD 1.9 million per month. Combined with the increasing sales from ConfirmMDx® for Prostate Cancer, increasing royalty income from Cologuard and the near-term revenue potential from its novel non invasive tests SelectMDx™ for Prostate Cancer and AssureMDx™ for Bladder Cancer, we believe that the company has enough cash to further increase its sales and marketing efforts, and finance the further development costs of its product portfolio.

For 2016FY we expect revenues to amount to USD 28.2 million, which is somewhat above the guidance (increase in revenues up to 50%) that MDxHealth has provided. In the last few years, COGS that includes laboratory labor, material and overhead has decreased substantially from 77% in 2013 to 39% in 2015. COGS sold is expected to reduce further to 31-35% in the next few years. For the longer term, we expect the gross margin to improve further to 75%. Most important costs are associated with selling and marketing, which we expect to decrease in 2016 to 100% of total revenues and to be below 80% after 2017. We expect the company to reach near break even in 2018. For the longer term we estimate the company will reach an EBIT margin of 50-55%.

Financial Summary (USD million)

Profit&Loss Statement	2014A	2015A	2016H1A	2016E	2017E	2018E
Revenues	11.671	17.600	12.945	28.200	44.600	65.200
COGS	(6.453)	(6.900)	(4.700)	(9.300)	(12.400)	(15.900)
Gross Profit	5.218	10.700	7.900	18.800	32.200	50.900
R&D Costs	(2.376)	(3.300)	(1.600)	(2.500)	(2.000)	(1.500)
SG&A	(18.321)	(22.400)	(11.400)	(28.200)	(40.100)	(52.100)
Operating Profit/(Loss)	(15.342)	(14.500)	(5.100)	(11.800)	(9.900)	(2.700)
Financial Income/(Loss)	0.086	-	-	-	-	-
Income Taxes	0	0	0	-	-	0
Net Profit/(Loss)	(15.256)	(14.500)	(5.100)	(11.800)	(9.900)	(2.700)

Consolidated Statement of Cash Flows

	2014A	2015A	2016H1	2016E	2017E
Cash flow from operating activities	(18.513)	(14.394)	(10.000)	(17.500)	(9.000)
Cash flow from investing activities	(1.256)	7.576	(1.000)	(3.000)	(2.000)
Cash flow from financing activities	14.666	35.042	0.000	0.000	15.000
Cash and cash equivalents at beginning of the period	24.683	18.897	31.680	31.680	12.000
Net change in cash and cash equivalents	(5.786)	13.072	(11.000	(19.680)	4.000
Cash and cash equivalents at end of the period	18.897	31.680	20.680	12.000	16.000

Valuation

We have increased our valuation from EUR 395 million (or EUR 8.72 per share) to EUR 495 million (or EUR 11.00 per share) due to a better outlook for Cologuard and expected stronger revenues from both ConfirmMDx and SelectMDx. This represents a substantial upside from the current share price. We model sales and cash flow up until 2025. Our forecast includes sales of ConfirmMDx® for Prostate Cancer, SelectMDx™ and AssureMDx™ reaching revenues by 2025 of USD 200 million, USD 180 million and USD 40 million respectively, and reaching market shares in the subsequent markets of 8-12%.

Sales forecast and valuation ConfirmMDx® (USD)

Year	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Price	1200	1230	1261	1292	1325	1358	1392	1426	1462	1499
Number of tests	20450	26700	33482	40781	55191	70023	85289	100996	117155	133777
Market share	1.6%	2.0%	2.5%	3.0%	4.0%	5.0%	6.0%	7%	8%	9%
Tests US (million)	1.30	1.32	1.34	1.36	1.38	1.40	1.42	1.44	1.46	1.49
Revenues (million)	24.54	32.84	42.21	52.70	73.10	95.07	118.69	144.06	171.29	200.48
Net Margin 40%	9.82	13.14	16.89	21.08	29.24	38.03	47.48	57.63	68.52	80.19
WACC 11%	1.00	0.90	0.81	0.73	0.66	0.59	0.53	0.48	0.43	0.39
NPV (million)	9.82	11.83	13.70	15.41	19.26	22.57	25.38	27.76	29.73	31.35
Total NPV (million)										**207**
Value per share (EUR)										**4.58**

Sales forecast and valuation SelectMDx™ (USD)

Year	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Price	500	513	525	538	552	566	580	594	609	624
Number of tests	1800	11500	28000	44800	75200	105200	131200	188000	244000	300000
Market share	0.04%	0.2%	0.6%	1.0%	1.6%	2.2%	2.8%	4.0%	5.2%	6.4%
Tests US (million)	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7
Revenues (million)	0.90	5.89	14.71	24.12	41.50	59.51	76.08	111.74	148.65	187.33
Net Margin 35%	0.32	2.06	5.15	8.44	14.53	20.83	26.63	39.11	52.03	65.57
WACC 11%	1.00	0.90	0.81	0.73	0.66	0.59	0.53	0.48	0.43	0.39
NPV (million)	0.32	1.86	4.18	6.17	9.57	12.36	14.24	18.84	22.58	25.63
Total NPV (million)										**116**
Value per share (EUR)										**2.33**

Sales forecast and valuation AssureMDx™ (USD)

Year	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Price	500	500	500	500	500	500	500	500	500	500
Number of tests	-	8500	14566	20800	26520	34006	43357	53069	65613	75291
Market share	0.0%	1.2%	2.0%	2.8%	3.5%	4.4%	5.5%	6.6%	8.0%	9.0%
Tests US (million)	0.7	0.714	0.728	0.743	0.758	0.773	0.788	0.804	0.820	0.837
Revenues (million)	4.25	7.28	10.40	13.26	17.00	21.68	26.53	32.81	37.65	4.25
Net Margin 35%		4.25	7.28	10.40	13.26	17.00	21.68	26.53	32.81	37.65
WACC 11%		2.13	3.64	5.20	6.63	8.50	10.84	13.27	16.40	18.82
NPV (million)		4.25	7.28	10.40	13.26	17.00	21.68	26.53	32.81	37.65
Total NPV (million)										**52**
Value per share										**1.05**

We also factor in royalty income estimates for Cologuard (Exact Sciences) of up to USD 65-75 million, based on potential total revenues for Cologuard in 2025 of USD 2.5 billion and an estimated royalty percentage of 3.0% on net sales.

Sales forecast and valuation: Cologuard Royalty Stream

Year	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Price per test	390	390	390	390	390	390	390	390	390	390
Number of tests sold	250000	500000	850000	1360000	2040000	2856000	3712800	46410000	5569200	6404580
Market share	0.31%	0.63%	1.06%	1.70%	2.55%	3.57%	4.64%	5.80%	6.96%	9.0%
Addressable Market in tests	80.00	80.00	80.00	80.00	80.00	80.00	80.00	80.00	80.00	80.00
Revenues (million)	97.50	195.00	331.50	530.40	795.60	1113.84	1448.00	1810.00	2172.00	2497.80
Net Margin 35%	34.13	68.25	116.03	185.64	278.46	389.84	506.80	633.50	760.20	874.23
Royalties 3.0% of net sales	2.93	5.85	9.95	15.91	23.87	33.42	43.44	54.30	65.16	74.93
WACC 11%	1.00	0.90	0.81	0.73	0.66	0.59	0.53	0.48	0.43	0.39
NPV (million)	2.93	5.27	8.07	11.63	15.72	19.83	23.22	26.15	28.27	29.29
Total Value								170.0		
Per share (EUR) (EUR/USD: 1.10)								**3.43**		

In our valuation model for MDxHealth, we do not include additional pipeline products as well as potential revenues outside of the US. Additional revenues from new test and other geographical areas offer additional upside potential. **Applying a WACC of 11%, we value MDxHealth at EUR 11.00 per share (based on a EUR/USD exchange rate of 1.10).**

Competitive Landscape

During examination of comparable companies we looked at companies that are developing diagnostic tests in cancer, preferably urological cancers. Next to that we specifically looked for companies that are developing or already commercializing liquid biopsy tests. With evidence building that monitoring a tumor's mutational landscape can be done by evaluating circulating tumor DNA or circulating tumor cells, companies are increasingly looking to move into the liquid biopsy market Companies like Biocept, Chronix Biomedical, Genomic Health, Trovagene and Myriad Genetics.

Peer Group Company Profiles

Biocept (NASDAQ:BIOC)

Biocept develops and commercializes circulating tumor cell (CTC) and circulating tumor DNA (ctDNA), tests utilizing a standard blood sample. The Company's marketed tests are OncoCEE-BR for breast cancer CTC enumeration and analysis, OncoCEE-GA for gastric cancer CTC enumeration and analysis and OncoCEE-LU for non-small cell lung cancer, or NSCLC, CTC enumeration and analysis. Its marketed test and the tests under development for the enumeration and analysis of CTCs utilize its Cell Enrichment and Extraction, or CEE, technology, and the tests under development for the detection and analysis of ctDNA utilize the Company's CEE-Selector technology, each performed on a standard blood sample. The CEE technology is an internally developed, microfluidics-based CTC capture and analysis platform, with enabling features that change how CTC testing can be used by clinicians by providing real-time biomarker monitoring with a standard blood sample. The CEE-Selector technology enables mutation detection with enhanced sensitivity and specificity and is applicable to nucleic acid from CTCs or other sample types, such as blood plasma for ctDNA. The Company is also conducting research and development for additional OncoCEE CTC tests for other cancer types with a focus on large population solid tumor types, or cancers for which there are approved therapies that rely on

biomarker tests developed previously. The tests under development are OncoCEE-CR for Colorectal Cancer, OncoCEE-PR for Prostate Cancer, OncoCEE-ME for Melanoma, OncoCEE-DTC for Breast and Prostate Cancer and CEE-Selector, which is sequencing application for multiple cancer types.

Genomic Health (NASDAQ: GHDX).

Genomic Health offers its Oncotype DX tests as a clinical laboratory service, where it analyzes the expression levels of genes in tumor tissue samples and provides physicians with a quantitative gene expression profile expressed as a single quantitative score, which it calls a Recurrence Score for invasive breast cancer and colon cancer, a DCIS Score for ductal carcinoma in situ (DCIS) and a Genomic Prostate Score (GPS) for prostate cancer. The Company's Oncotype DX platform utilizes quantitative genomic analysis known as reverse transcription polymerase chain reaction (RT-PCR), in standard tumor pathology specimens to provide tumor-specific information, or the oncotype of a tumor. The Company's Oncotype DX prostate cancer test measures the level of expression of 17 genes across four biological pathways to predict prostate cancer aggressiveness in men with low risk disease. Its offerings also include Oncotype DX Breast Cancer Test, Oncotype DX Colon Cancer Test and Oncotype DX Prostate Cancer Test. The Company's Oncotype DX platform utilizes quantitative genomic analysis known as reverse transcription polymerase chain reaction, or RT-PCR, in standard tumor pathology specimens to provide tumor-specific information, or the oncotype of a tumor. Its diagnostic approach correlates gene expression to clinical outcomes and provides an individualized analysis of each patient's tumor. The Company has built a diagnostic infrastructure that allows it to move from research into development through to processing actual patient samples in its clinical reference laboratory. The Company's technologies allow it to analyze tumor tissue samples in its clinical reference laboratory and provide physicians with genomic information specific to the patient's tumor. The Company analyzes tissues that are handled, processed and stored under routine clinical

pathology laboratory practices. The Company offers its Oncotype DX tests as a clinical laboratory service, where it analyzes the expression levels of genes in tumor tissue samples and provides physicians with a quantitative gene expression profile expressed as a single quantitative score. Its Oncotype DX prostate cancer test measures the level of expression of 17 genes across 4 biological pathways to predict prostate cancer aggressiveness in men with low risk disease. All of The Company's testing services are made available through its clinical reference laboratory located in Redwood City, California, which is accredited under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and by the College of American Pathologists. As of December 31, 2014, approximately 19,000 physicians in approximately 70 countries had ordered approximately 500,000 Oncotype DX tests. The Company has a direct commercial presence with employees and consultants in the United States and certain other countries, and its Oncotype DX breast and colon cancer tests are also available outside of the United States through a network of distributors.

Chronix Biomedical (Private, Germany)

Chronix Biomedical is a molecular diagnostics company developing blood tests primarily for cancer, including companion diagnostics and tests for detecting minimal residual disease. Chronix is scaling up to offer its pioneering tests through its own laboratories under CLIA certification in North America and the CE mark in Europe. The Company's initial product is a test to be used by cancer treatment centers and oncologists in the treatment of breast cancer patients. The Company has two issued patents on the detection of cell-free DNA and RNA, and four patents pending using next-generation sequencing technology for the detection of breast cancer, prostate cancer and colorectal cancer. Chronix is privately held with headquarters in San Jose, California, and laboratories in Göttingen, Germany and Brookings, South Dakota.

Exosome Diagnostics

Exosome Diagnostics is a privately held company focused on developing and commercializing biofluid-based diagnostics. Exosome Diagnostics' non-invasive urine-based ExoIntelliScore™ Prostate test in development analyzes exosomal RNA for three biomarkers known to be expressed in men with high-grade prostate cancer. Using a proprietary algorithm that integrates this three-gene signature, ExoIntelliscore Prostate assigns an individualized risk score for patients that predicts the presence of high-grade (Gleason Score ≥ 7) prostate cancer. Exosome Diagnostics plans to proceed with a commercial launch of a laboratory developed test in the United States in 2016. The company also plans future submissions in Europe for a CE Mark, as well as for approval of an in vitro diagnostic version of the test with the U.S. Food and Drug Administration.

Myriad Genetics

Myriad Genetics is engaged in the discovery, development and marketing of transformative molecular diagnostic tests. The Company operates through two segments: diagnostics and other. The diagnostics segment provides testing and collaborative development of testing that is designed to assess an individual's risk for developing disease later in life, identify a patient's likelihood of responding to drug therapy and guide a patient's dosing to enable optimal treatment, or assess a patient's risk of disease progression and disease recurrence. The other segment provides testing products and services to the pharmaceutical, biotechnology and medical research industries, research and development, and clinical services for patients, and also includes corporate services, such as finance, human resources, legal and information technology. Myriad offers diagnostic tests for a range of diseases, such as Myriad myRisk Hereditary Cancer test for hereditary breast cancer, hereditary ovarian cancer, hereditary pancreatic cancer, hereditary uterine (endometrial) cancer and hereditary colon cancer; Myriad myPlan Lung Cancer test for lung cancer; Myriad myPath Melanoma test for melanoma; Prolaris

test for prostate cancer, and Vectra DA for rheumatoid arthritis (RA). Prolaris® is a genomic test developed to aid healthcare professionals in predicting prostate cancer aggressiveness, in conjunction with clinical parameters such as Gleason score and PSA.

Oncocyte (part of BioTime: NYSE: BTX)

OncoCyte Corporation, is developing PanC-Dx™, a novel non-invasive blood-based cancer screening test designed to detect the presence of various human cancers, including cancers of the breast, lung, bladder, uterus, stomach, and colon, during routine check -ups. OncoCyte has determined that the initial diagnostic tests that it plans to develop and commercialize will be laboratory developed tests ("LDTs") that will be performed at a diagnostic laboratory that OncoCyte plans to operate. OncoCyte will need to receive certification for its planned diagnostic laboratory under the Clinical Laboratory Improvements Amendment ("CLIA"). The company intends to initially seek regulatory approval to market PanC-Dx™ in Europe before seeking regulatory approvals required to market the product in the U.S. and other countries. OncoCyte is a subsidiary of BioTime, a company in regenerative medicine and a clinical-stage biotechnology company.

Pacific Edge (NSX: PEB)

Pacific Edge Limited) is a New Zealand based cancer diagnostic company that develops and sells molecular diagnostic tests based on biomarkers for the early detection and management of cancer. The company is developing and commercialising its range of Cxbladder bladder cancer tests. Its first commercial product, Cxbladder Detect, is now being actively marketed to physicians and clinicians in New Zealand, Australia, and the USA through the company's wholly owned subsidiaries and selected commercial partners.

Trovagene (NASDAQ: TROV)

Trovagene is is a development-stage molecular diagnostic company that focuses on the development and commercialization of urine-based cell-free molecular diagnostic technology for use in disease detection and monitoring across a variety of medical disciplines. The Company's primary internal focus is to leverage its urine-based molecular diagnostic platform to facilitate improvements in the field of oncology, while the Company's external focus includes entering into collaborations to develop the Company's technology in areas, such as infectious disease, transplant medicine and prenatal genetics. The Company's fundamental cell-free molecular diagnostic platform is also known as 'Precision Cancer Monitoring' (PCM) platform. The Company's cell-free BRAF test is a laboratory developed test (LDT), designed to detect and monitor this mutation in metastatic cancer patients with biopsy-proven V600E BRAF mutation in their tumor. It is a commercial assay within the Company's cancer monitoring portfolio, which is performed using a droplet digital polymerase chain reaction (ddPCR) platform. BRAF is a human gene encoding a cellular growth signaling protein, which has been shown to be mutated in certain cancers. This test confirms the presence of a BRAF V600E mutation in urine DNA at levels of greater than or equal to 0.03% in comparison to the wild-type BRAF genes. The Company's KRAS mutation assay detects and monitors the seven commonly encountered mutations of the KRAS oncogene, and is a multiplexed oncogene mutation assay utilizing sequencing as a mutation detection platform. This mutation commonly occurs in patients diagnosed with either colorectal cancer, pancreatic cancer, or lung cancer. The Company has a range of programs to evaluate the detection and monitoring of EGFR mutational status in lung cancer patients. A focus of these studies is the emergence of the resistant mutation EGFR T790M in lung cancer patients. The Company's collaborators for this program include Memorial Sloan Kettering Cancer Center, City of Hope Comprehensive Cancer Center, UC San Diego Moores Cancer Center, and Genomac Research Institute

Glossary

Alkylating agents	*A class of oncology therapeutic drugs. Alkylating agents stop tumor growth by making DNA strands unable to uncoil and separate, a necessary step in DNA replication and tumor growth.*
Assay	*A term for a single experiment or a diagnostic test incorporating the required markers to analyze a clinical specimen.*
Bioinformatics	*The use of techniques from applied mathematics, informatics, statistics, and computer science to solve biological problems and identify significant correlations.*
Biopsy	*A procedure where a tumor tissue sample is removed from the body for laboratory examination to determine whether or not cancer or some other disease is present. A biopsy can be performed using a needle to extract a small amount of cells or as a surgical procedure to remove a larger piece of tissue.*
Biotechnology	*Biotechnology is a technology based on or influencing biological processes, especially when used in agriculture, food science, and medicine.*
Cancer	*Cancer is a type of disease caused by genetic instability and characterized by uncontrolled division of cells and the ability of these cells to invade other organs.*
Cell	*The basic unit of a living organism. Each cell is surrounded by a membrane and has a nucleus containing a set of genes that provide it with the information necessary to operate and divide.*
cGMP certification	*Current Good Manufacturing Practices- quality systems requirements for manufacture, testing and development of medical products to ensure manufacturing practices , designs and controls provide safe, accurate, reliable and repeatable*

	results. cGMP's are enforced by the FDA Food and Drug Administration. GMP compliance is recognized worldwide as an international standard of manufacture.
Chemotherapy	*Drug treatment that destroys cancer cells. Chemotherapy may be used in addition to surgery and is sometimes used in combination with other therapies such as radiation.*
CLIA	*The U.S. Clinical Laboratory Improvement Amendments (CLIA) establishes quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results.*
Clinical sample	*A sample taken from the body (ex. blood, urine, tissue) and analyzed in order to gain information about a person's medical state.*
Clinical trial	*A research study, usually in diseased patients, to test drugs, procedures, or testing technologies to determine how well they work compared to other practices or the natural course of the disease.*
Clinical verification	*A product development stage that consists of testing a product prototype on a set of clinical samples.*
Commercial Implementation Trial	*A phase within the product development process that supports the acceptance of the newly developed assay in the market.*
Commercial Pivotal Trial	*A phase within the product development process to evaluate the clinical validation of the assay in collaboration with a clinical facility*
CPT codes	*Current Procedural Terminology Codes- numbers assigned to every medical task used by physicians and or laboratories to determine amount of reimbursement that practitioner will receive from insurer. CPT codes are assigned by AMA American Medical Association to provide uniform definition for services and reimbursement.*

Cytosine	*Cytosine is one of the 5 main nucleotides of DNA and RNA used in storing and transporting genetic information.*
Development Validation	*A phase within the product development process to evaluate the performance of the newly developed assay using a defined sample set.*
Development Verification	*A phase within the product development process to define the performance characteristics of the assay*
Diagnosis	*Identification of a condition or disease (ex. breast cancer), by its signs, symptoms, and the results of laboratory or histopathological tests.*
DNA (Deoxyribonucleic Acid)	*DNA is a nucleic acid polymer, usually in the form of a double helix, of which the genes are made and code for life processes.*
Freedom to operate (FTO)	*FTO, within an intellectual property setting, refers to the ability of a company to commercially produce, market and use a new product, process or service without infringing the intellectual property rights of others.*
Gene	*A unit of genetic information. Genes are encoded in a cell's DNA and the proteins they express control the physical development and behavior of the cell or the whole organism.*
Gene expression	*Gene expression is a multi-step process by which a gene's DNA sequence is converted into proteins.*
In-Vitro Diagnostics (IVD)	*IVDs are tests performed outside the human body on clinical samples such as blood, urine, or biopsy tissue.*
Kit (diagnostic kit)	*In-vitro diagnostic test that is packaged in a box which that can be shipped to end-user laboratories.*

LDT	*Laboratory Developed Test-refer to assays developed in a laboratory for use within that laboratory. While these tests are not currently regulated by FDA Food and Drug Administration, the lab must validate all aspects of the test to ensure patient safety, reliability, repeatability, accuracy as well as validating all instruments, reagents and or supplies used in the test.*
Marker	*A substance native to the organism, whose presence is indicative of a particular medical condition. Marker ID A product development stage that consists of identifying and prioritizing promising markers.*
Marker & Assay Development	*A product development stage that consists of testing promising markers on clinical samples (to establish initial sensitivity and specificity for a defined clinical indication), and consequently developing a robust and reproducible assay for the marker in question.*
Methylation	*Control mechanism that regulates gene expression in DNA without causing a permanent genetic alteration.*
Methylation-Specific PCR (MSP)	*A technology for detecting gene methylation.*
MGMT	*The O6-methylguanine DNA-methyltransferase (MGMT) gene has been widely studied and shown to be able to predict glioblastoma cancer patient response to alkylating agents*
PCR	*The polymerase chain reaction is a technique for the in vitro amplification of specific DNA sequences by the simultaneous primer extension of complementary strands of DNA.*
Pharmacogenomics	*The study and application of DNA and RNA based biomarkers to predict how an individual's genes affect the body's response to a therapeutic drug.*
PSA	*Prostate-Specific-Antigen, a widely used but widely criticized blood-based screening test for prostate cancer.*

Recurrence	*A return of cancer after treatment.*
Research Discovery	*Research phase of the product development process that consists primarily of discovering new biomarkers in clinical samples from patients with and without cancer or between samples from patients responding or not responding to a certain drug.*
Research Feasibility	*A phase within the product development process to optimize the biomarker performance for the development of the diagnostic assay.*
Screening	*The testing of a population for disease.*
Sensitivity	*A measure of a diagnostic test's accuracy. Sensitivity measures the percentage of people with a certain medical condition that produces a positive test result. Tests with good sensitivity produce few false negative results.*
Service laboratory	*Laboratory that provides medical testing services.*
Service lab and kit development	*The final stages of product development that are specific to the underlying product's intended distribution channel (service laboratories or diagnostic kit companies).*
Specificity	*A measure of a diagnostic test's accuracy. Specificity measures what percentage of people without a medical condition the test result is negative. Tests with good specificity produce few false positive results.*
Temozolomide	*An approved alkylating chemotherapeutic drug marketed by Schering-Plough corporation.*
Tumor	*Tissue growth where the cells that make up the tissue have multiplied uncontrollably. A tumor can be benign (non-cancerous) or malignant (cancerous).*

Analyst: Marcel Wijma MSc

Marcel Wijma, Chief Research Officer and managing partner, has a longstanding history in financial biotech research. After selling Van Leeuwenhoeck Research (VLR) to SNS Securities in 2006, he established an award winning analyst team in biotech/life sciences at SNS Securities. In 2009, Marcel was awarded by Financial Times/Starmine as being one of the Top-3 biotech analysts in Europe. Later that year, Marcel purchased VLR from SNS Securities after which the company was reconstituted. At VLR, he leads the professional VLR research organisation, which is augmented by selected external financial researchers with a specialisation in Life Sciences. Mr. Wijma has a Masters degree in Financial Economics from Erasmus University in Rotterdam.