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Initial Report

MDxHealth SA

Rating: Speculative Buy

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MXDHF $4.03 (OTC - Other)

May 5, 2016

	2014A	2015A	*2016E*	*2017E*
Total revenues (in millions)	$11.7	$15.2	***$25.3***	***$35.4***
Earnings (loss) per share	($0.40)	($0.32)	***($0.39)***	***($0.32)***

52 - Week range	$5.95 – $ 3.90	Fiscal year ends:	December
Shares outstanding as of Dec. 31, 2015	45.2 million	Revenue/share (ttm)	$0.43
Approximate float	31.7 million	Price/Sales (ttm)	9.4X
Market Capitalization	$188 million	Price/Sales (2017)E	5.5X
Tangible Book value as of Dec. 31, 2015	$2.21	Price/Earnings (ttm)	NA
Price/Book	1.8X	Price/Earnings (2017)E	NA

MDxHealth SA, headquartered in Herstal, Belgium, is a molecular diagnostics company that has developed and launched genetic tests for cancer assessment and the personalized treatment of patients. MDX operates laboratories in Irvine, CA and Nijmegen, the Netherlands. Its tests, based on proprietary gene methylation technology, assist physicians with the diagnosis of cancer, prognosis of recurrence risk, and prediction of response to a specific therapy. The company's lead products, ConfirmMDx and SelectMDx, focus on prostate cancer that enable patients with suspected prostate cancer to avoid unnecessary biopsies and more accurately characterize the extent and nature of their disease.

Key Investment Considerations:

Initiating as Speculative Buy with a 12-month price target of $7.00 per share based on a year-ahead value of projected 2017 revenue.

In the US alone, there are 1.3 million prostate tissue biopsies performed annually. Many are inconclusive due to doubts about accuracy. Up to 750,000 patients who test negative on their first biopsy, as well as a million men being considered for an initial tissue biopsy, are potential candidates for MXDHF's non-invasive diagnostics. We believe the size and characteristics of the Western European market are roughly equal to the US.

The diagnostic and detection capabilities of ConfirmMDx are well established; the service has experienced sharp increases in sales since its 2012 US launch. SelectMDx, launched in the US in late 2015, assesses suspected prostate cancer cases for the likelihood of high- vs. low-grade disease. SelectMDx should start making a substantive revenue contribution in 2017.

Revenue growth should accelerate in 2016 and 2017 as ConfirmMDx gains acceptance and is more widely reimbursed by Medicare and private payors. Significant losses will continue as the company sustains heavy spending on its sales infrastructure. But revenue should increase 43% to $25.3 million in 2016, and rise another 40% to $35.4 million in 2017. With better leverage of costs and expenses, MDX's operating losses should begin to narrow in 2017.

For 1Q16 (results released May 3, 2016), MDX incurred a net loss of $3.4 million on revenue of $6.7 million. In the year-earlier period, the company lost $2.5 million on revenue of $4 million.

By our estimates, MDX's cash should fund operations into 2017 but the company will need an estimated $12 million in additional financing by next year to support increases in working capital stemming from 40%+ increases in revenue.

See disclosures on pages 15 - 17

Investment Recommendation

Initiating as Speculative Buy with a 12-month price target of $7.00 based on projected 2017 revenue per share.

MDXH is trading at 9.4X trailing revenue, a significant premium vs. a comparison group of 10 US medical laboratory stocks (market values of $450 million and up), which is trading at 4.3X trailing revenue. In our view, MDX's premium reflects revenue growth potential based on sustained market penetration of ConfirmMDX and the ramp of newly launched SelectMDX.

Within the next 12 months, MDXH shares should be trading at around 9.5X estimated 2017 revenue of $0.74 per share, a target of $7.00 per share.

In our view, MDXHF shares are suitable mainly for highly risk tolerant accounts seeking exposure to a molecular diagnostic stock with high growth potential.

First Quarter 2016 Results

On May 23, 2016, the company reported a first quarter loss of $3.4 million in revenue of $6.7 million. In the year-earlier quarter, MDX lost $2.5 million on revenue of $4 million. Revenue for 1Q16 increased 67% but the loss for the period widened due to increased spending aimed at driving sales of ConfirmMDx and supporting the launch of SelectMDx, largely through reinforcement of the sales force.

Overview

MDxHealth, headquartered in Herstal, Belgium, was established in 2003. The company maintains a US headquarters in Irvine, CA, and operates a CLIA (Clinical Laboratory Improvement Act) diagnostic laboratory in Irvine, California, and a laboratory in Nijmegen, the Netherlands. MDx brings its molecular biology technology to bear on cancer diagnostics, currently focusing on urological cancers.

The company has developed noninvasive diagnostics based on epigenetics, which uses selected biomarkers to detect the presence of cancer and gauge the extent of its progress by analyzing a patients' tissue, blood or urine samples. Biomarkers are measurable structures or processes in the body that indicate the presence of a disease and, potentially, the effects of treatments for that disease.

The potential for penetration of the US and European prostate cancer diagnostics market is substantial. By 2050, the number of US men in their most prostate cancer-prone years will increase to 102 million, up from 72 million in 2015. While declining prostate cancer incidence and mortality rates sound encouraging, prostate cancer screening, diagnosis (including 20 million PSA tests and 1.3 million biopsies), treatment and follow-up remain a massive effort that, according to the National Cancer Institute, will cost the US approximately $12 billion annually by 2020.

MDx's lead product, ConfirmMDx, was launched in 2012. ConfirmMDx, analyzes a biopsy tissue sample from suspected prostate cancer cases who have tested negative. As initial biopsies (as well as follow-up ones) can be inconclusive, repeat biopsies are frequently performed to verify or rule out a diagnosis of prostate cancer. ConfirmMDx can confirm a true negative biopsy, sparing the patient the ordeal and risks of unnecessary repeat biopsies. It can also identify cases of undetected cancer.

In September 2015, the company acquired NovoGendix, the developer of SelectMDx, a non-invasive laboratory-based prostate cancer test. SelectMDx was launched in Europe in 2015 and in the US in March 2016. SelectMDx, an initial diagnostic tool, analyzes a patient's urine and identifies patients at low risk for prostate cancer, as well as patients at high risk for undetected aggressive prostate cancer that should be treated with greater urgency.

MDx is also developing AssureMDx, a bladder cancer test, and is exploring diagnostics for kidney cancer. The company has developed markers for non-urologic – colon, brain and cervical – cancers that have been licensed to other diagnostic companies, adding royalties and milestone payments to its potential revenue stream.

At current incidence rates, the number of US men diagnosed with prostate cancer could rise to 255,000 by 2050, up from an estimated 181,000 in 2016. Almost three million men in the US who have been diagnosed with prostate cancer at some point in their lives are alive today. Roughly 26,000 US patients will succumb to the disease in 2016. year. We believe that the statistics for Western Europe are comparable to the US.

Most confirmed cases of prostate cancer initially diagnosed with the widely used PSA (prostate specific antigen) test are slow-growing tumors that are not likely to prove harmful during the life of the patient. But the old adage that most prostate cancer patients die with the disease rather than from it, is not as reassuring as it sounds, as an estimated 10% to 15% of initially diagnosed cases are aggressive cancers that can metastasize rapidly and prove fatal.

As non-invasive and inexpensive diagnostics, ConfirmMDx and SelectMDx could significantly reduce the cost of prostate cancer diagnosis by enabling patients to avoid biopsies − they cost the US healthcare system around $4 billion annually − and improve outcomes by identifying cases of potentially lethal fast growing disease more quickly.

Strategy

MDxHealth aims to leverage its molecular diagnostics technology and achieve a leadership position in the market for urological oncology diagnostics. Driven initially by growing acceptance of ConfirmMDx in the US, the company's market position should be buttressed by SelectMDx and AssureMDx.

US revenue gains will hinge in large measure on approval of unrestricted Medicare reimbursement for the company's diagnostic tests. In September 2014 the Medicare contractor with jurisdiction over most molecular diagnostic cancer tests (MolDX) issued a local coverage determination (LCD) for the ConfirmMDx test. Under the LCD, Medicare reimbursement for ConfirmMDx is limited to patients treated by physicians who are enrolled in a company training and certification program, and MDx must, as a condition for eventual unrestricted reimbursement, collect clinical trial-based data demonstrating the clinical utility of ConfirmMDx. Despite these limitations, Confirm MDx revenue increased sharply last year, refecting an acceptance that should broaden considerably as Medicare reimbursement restrictions are loosened.

In March 2016 the company announced that ConfirmMDx was included in the US 2016 NCCN (National Comprehensive Cancer Network) guidelines for the treatment of prostate cancer, a decision that informs the oncology community that ConfirmMDx is now recognized as part of the standard of care. ConfirmMDx's inclusion in the NCCN guidelines should ease reimbursement approvals, drive wider acceptance of this test, and strengthen the sale force's case for increased adoption of the test.

MDx's sales force consists of 87 sales representatives, the company's direct sales force of 41, another 37 deployed by distribution partners, three managed care and six client services representatives. The company's sales representatives cover the US, Italy, Germany and the Netherlands. Distribution partners sell to Mexico, most of South America (excluding Brazil) and Western Europe. The potentially huge patient populations of Asia and South Asia offer significant overseas expansion opportunities.

Revenue Growth Accelerated in 2015

In 2015, MDX incurred a loss of $14.5 million, or ($0.35) per share, on revenue of $17.6 million. The 59% revenue gain was driven by a 45% increase in product and service revenue, largely ConfirmMDX test services, to $15.8 million and a threefold increase in royalty and milestone revenue from Exact Sciences to $1.7 million.
In 2015, ConfirmMDx tests delivered were up 25% to 15,000. Those 15,000 tests had an estimated sales value of roughly $36 million but due to reimbursement uncertainty stemming from restricted reimbursement for ConfirmMDx within the Medicare system, the company recognized only $15.8 million as revenue. The uncollected balance of $20.8 million represents unrecognized revenue that could lend upside revenue potential to future operating periods.

Gross profit doubled to $10.7 million, reflecting the increase in revenue and a rise in gross margin to 61% from 45% that was driven mainly by laboratory process improvements that reduced test costss. Excluding royalties, the gross margin for 2015 increased to 56% from 42%.

Operating expenses increased 22% to $25.1 million, lead, in dollar terms, by a 22% increase in SG&A expenses to $22.4 million. The increase in SG&A was due to the establishment of the CLIA laboratory in Irvine, CA and the development of related support functions, and the recruitment of a direct sales force in connection with the commercialization of ConfirmMDx. R&D increased 37% to $3.3 million, reflecting an increase in development collaborations and trials, and a difficult comparison with 2014, during which capitalization of certain costs reduced R&D expense.

The rise in gross profit offset the increase in operating expenses, narrowing the operating loss for 2015 by 6% to $14.4 million, and reducing the net loss by 5% to $14.5 million. The 2015 loss per share narrowed to ($0.35) from ($0.44) due to a reduced net loss and an increase in average shares outstanding to 41.3 million from 34.9 million.

Finances In 2015, MDX burned cash of $13.1 million and increased working capital by $1.3 million due to increases in receivables and inventory that were offset in part by an increase in payables. Proceeds of $34.8 million from the issuance of common stock and $1 million (net) in borrowings covered cash of $14.4 million used in operations, the $5.4 acquisition cost of NovoGendix, and capital expenditures of $1.6 million, increasing cash by $12.8 million to $31.7 million at the end of 2015.

Sustainable Gains in 2016 and 2017

Accelerating US acceptance of ConfirmMDx, the 2017 ramp of SelectMDx in the US, and the recognition of product and service revenue relating to tests delivered in prior years should underlie robust sales gains in 2016 and 2017. Those gains, however, will be constrained by relatively limited reimbursement by Medicare, whose coverage decisions tend to generalize to private payors covering non-Medicare beneficiaries.

Under the conditions of a 2014 Medicare Limited Coverage Determination (LCD), Medicare will require additional ConfirmMDx clinical utility data to qualify for unrestricted Medicare reimbursement. Medicare reimbursement for ConfirmMDx is currently limited to patients treated by providers who are enrolled (currently 2,800) in the company's certification and training program. With sufficient positive data from ongoing clinical trials, restrictions on ConfirmMDx reimbursement will be lifted.

Gross margin gains stemming from increased overhead coverage and laboratory process improvements will offset increases in operating expenses to some degree. However, reinforcement of the sales force will continue to exert upward pressure on SG&A through 2017. But between the higher gross margin and narrowing expense margins, operating losses should begin to diminish by 2017.

For 2016, we project a net loss of $16.4 million, or ($0.39) per share, on revenue of $25.3 million, up 43% from 2015 revenue. The increase in 2016 revenue stems from a 55% increase in product and service revenue to $24.4

million, most of that from sales of ConfirmMDx. Royalties will drop to nil in 2016 as a licensee discontinues sales of a product based on MDX technology. But the loss should be offset by an estimated $750,000 in milestone payments based on the revenue performance of that licensed product prior to its discontinuance.

Gross profit will increase by 47% to $15.2 million due to revenue gains, offset in part by slight compression in the gross margin due to a drop in royalty/milestone revenue. But on product and service sales alone, gross margins should increase to 60% from 56%.

Operating expenses will increase by 25% to $31.5 million, a largely undiminished rate as heavy spending on sales and marketing continues. Although gross profit expands and operating expense margins narrow, the operating loss will widen to $16.3 million from $14.4 million, a consequence of higher SG&A spending.

For 2017, we project a loss of $15.5 million, or ($0.32) per share, on revenue of $35.4 million. Revenue growth will slow to 40% in 2017 (vs. a 43% gain in 2016) due to a drop in royalty/milestone revenue. Product and service sales, however, will increase an estimated 44% to $35.2 million, driven by increasing ConfirmMDx penetration in the US, the US commercialization of SelectMDx, and the recognition of a portion of 2016's uncollected revenue.

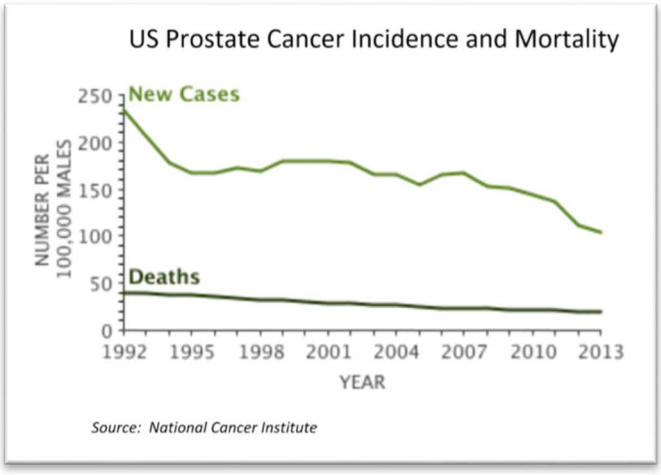
Gross profit will increase by 42% to $21.6 million, driven by the increase in revenue and an improvement in the gross margin to 61% from 60%. Operating expenses will rise at a more moderate rate, increasing 18% to $37 million. Improved leverage, reflected in lower expense margins, should reduce the 2017 operating loss to $15.4 million from $16.4 million.

Finances In 2016, the company will burn cash of $15.4 million and increase working capital by $5.1 million due to increases in receivables and inventory, offset in part by an increase in payables. Despite the increase in cash used in operations to $20.5 million from $14.4 million, MDX company should have sufficient cash to cover its 2016 needs, ending the year with $10.7 million in cash.

That cash, however, will run short in 2017. Cash burn of $14.4 million and a $5.8 million increase in working capital stemming from an increase in receivables and inventory, partly offset by a rise in payables, will use up cash of $20.2 million. To cover a $9.5 million shortfall, MDXHF will have to raise additional capital, ending 2017 with cash of $2 million.

Target Patient Population

The potential for penetration of the US and European prostate cancer diagnostics market is substantial. Despite demographic trends, the incidence of prostate cancer has fallen steadily since it peaked in 1992. Some of that decline has been attributed in part to a 2012 US. Preventive Services Task Force recommendation against the use of PSA screening. That recommendation was based on evidence that a significant proportion of asymptomatic men have prostate cancer will not progress or will progress so slowly that it will never pose a significant danger. As incidence rates have fallen, so has the US death rate from prostate cancer, which dropped from 39 (per 100,000) in 1993 to 19 in 2013.



Demographic trends are likely to offset, at least in part the decline in incidence rates, sustaining a high number of patients requiring diagnoses for prostate cancer. By 2050, the number of US men in their most prostate cancer-prone years will increase to 102 million, up from 72 million in 2015. By our estimates, the immediate US market opportunity for Confirm DX consists of at least

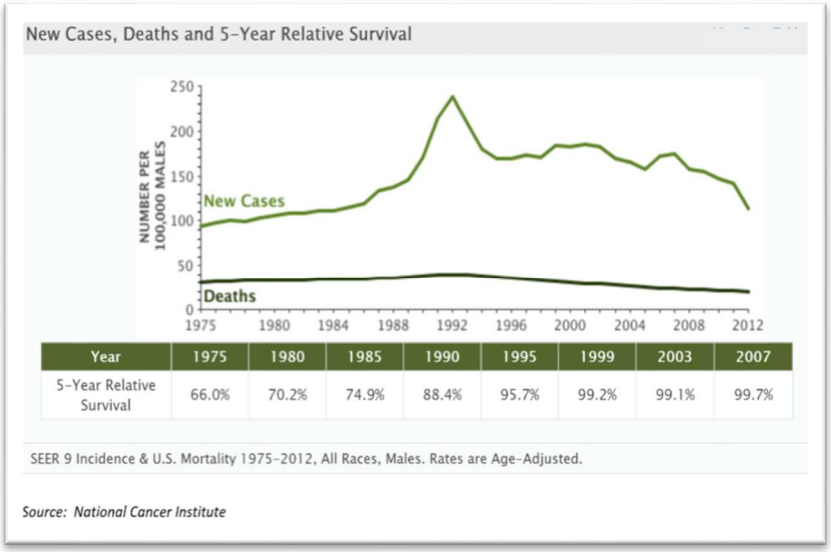
750,000 men who test negative on their first biopsy; for Select MDX it would be the one million men considered for an initial prostate biopsy. The total market (US + Europe) opportunities for each product would be roughly double theUS target patient population estimates.

In the US almost 20 million men are screened annually for prostate cancer with a prostate specific antigen (PSA) test. A higher than normal PSA reading (≥4.0 ng/mL) in combination an abnormal digital rectal exam (DRE) result often leads to a prostate biopsy. Each year one million US men undergo an initial prostate biopsy; roughly one quarter of them (estimates range from 17% to 44%) test positive for prostate cancer. The remaining 750,000 could be subject to additional biopsies if subsequent PSA tests and DRE exams continue to support suspicions of prostate cancer, leading to an additional 250,000 to 300,000(repeat) biopsies. While the pattern of repeat biopsies seen in the Ploussard study (described on page 7) may not necessarily generalize to the US and Europe, we believe that it offers a reasonable view of how efforts to confirm or dispel suspicions of prostate cancer drive the demand for prostate biopsies.

At the Ploussard rebiopsy rates, approximately 260,000 repeat biopsies would be performed on the estimated 750,000 men who tested negative for prostate cancer on their first biopsy. Around 230,000 of those would need no further biopsies beyond the second one but 27,000 would undergo up to four more biopsies. Annual and repeat biopsies would total an estimate 1.3 million (though follow-ups between a patient's rebiopsies could stretch beyond a year).

Outlook

The World Health Organization reports that in 2012, 1.1 million worldwide were diagnosed with prostate cancer, accounting for 15% of all male cancers diagnosed. Almost 70% of prostate cancer cases were diagnosed in more developed regions. Prostate cancer rates are highest in Australia/New Zealand, Northern America, and Western and Northern Europe, areas where use of prostate specific antigen testing and subsequent biopsy are more widespread.



Year	1975	1980	1985	1990	1995	1999	2003	2007
5-Year Relative Survival	66.0%	70.2%	74.9%	88.4%	95.7%	99.2%	99.1%	99.7%

SEER 9 Incidence & U.S. Mortality 1975-2012, All Races, Males. Rates are Age-Adjusted.

Source: National Cancer Institute

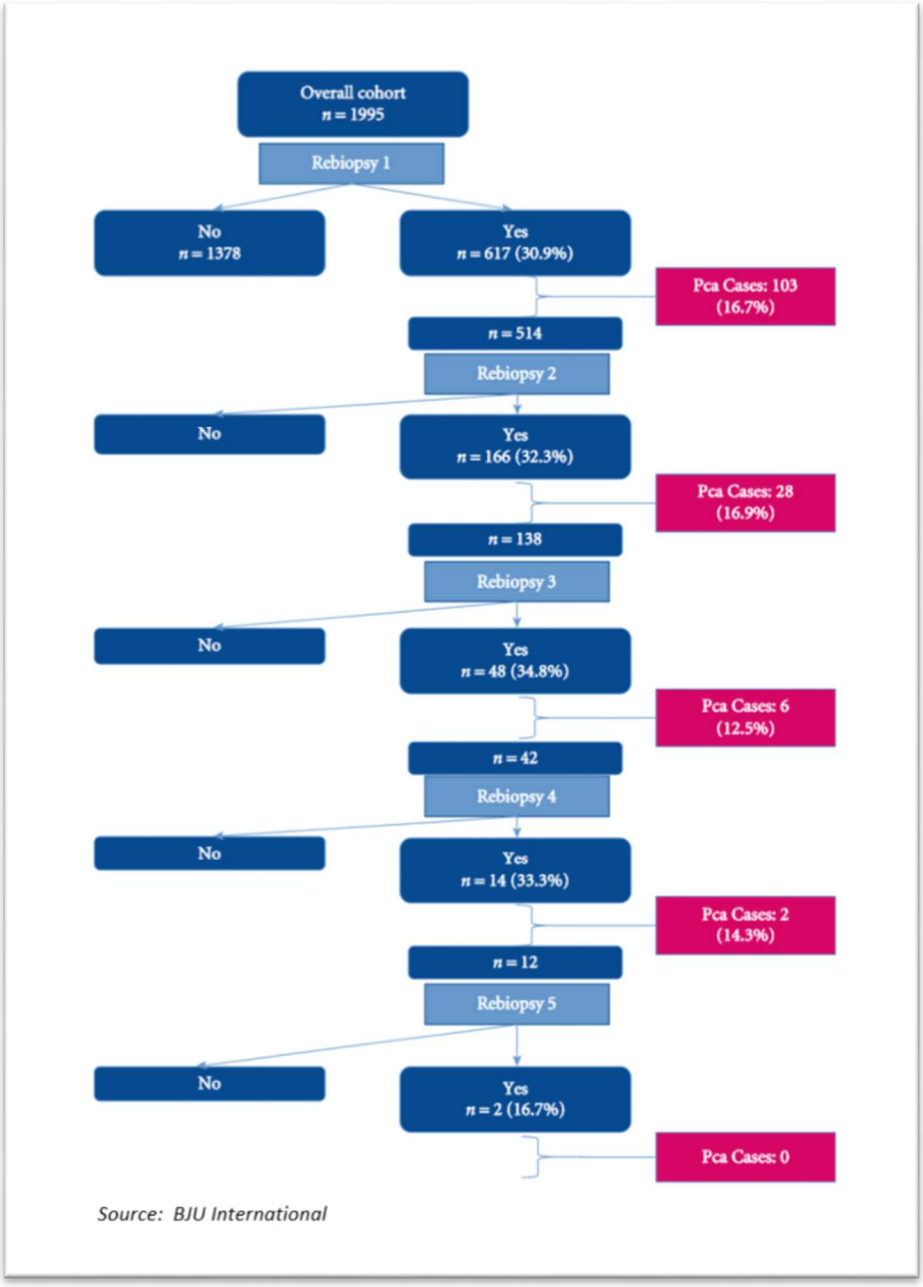
There are now three million US men living who have at some point been diagnosed with prostate cancer; many of these survivors will be subject to follow up. More than 180,000 men in the US will be diagnosed with prostate cancer in 2016. The incidence rate implied by that 2016 figure suggests that by 2050, when the number of age 40+ US men has increased to 102 million (from 72 million in 2015), the number of men diagnosed with prostate cancer will increase to around 254,000.

Prostate cancer is diagnosed at an early stage in more than 90% of all cases, and only 10% to 15% of cases suffer from the more dangerous, fast growing type of the disease. So survival rates are relatively high - 99% at five years, 98% after 10 years, and 95% at 15 years. However, for patients diagnosed with metastatic prostate cancer, the five-year survival rate drops to 28%. Annual US prostate cancer fatalities, at 26,000, rank second among cancer deaths, trailing only deaths from lung cancer.

A high overall survival rate masks the uncertainty attending prostate cancer diagnoses, which begin with a prostate-specific antigen (PSA) test that measures the level of PSA protein in the blood. A PSA test is widely administered

to age 50+ men undergoing routine physical exams. The PSA test was approved by the FDA more than 20 years ago for use in conjunction with a digital rectal exam (DRE) to test for prostate cancer even in cases where no symptoms are evident. A PSA level of 4.0ng/mL or less is widely considered normal so any score exceeding that often leads doctors to recommend a biopsy to test for prostate cancer.

PSA tests, by themselves, are inconclusive but persistently high or rising PSA readings are worrisome enough to drive doctors to order a biopsy, a trans rectal ultrasound-guided (TRUS) extraction of tissue samples from several sites in the prostate gland. If microscopic examination of the samples reveals cancer cells, the patient is diagnosed with prostate cancer. Biopsy results, while more definitive, often lead to mistaken diagnoses. Biopsies extract tiny tissue samples at 12 sites in the prostate, accounting, in aggregate, for less than one half of one percent of the gland's total volume. Biopsies frequently miss small tumors elsewhere in the gland (example on page 8), a sampling error that leads to a false negative result.



Of the 1.3 million prostate biopsies (both initial and repeat procedures) performed annually in the US, roughly 25% lead to a diagnosis of prostate cancer. Based on rates of positive diagnoses and current US incidence figures, we estimate that results of an estimated 700,000+ initial biopsies are negative. But approximately 25% of those negative results are false, representing a failure of the biopsy to identify a significant number of cancer cases. Due to oncologists' doubts stemming from sustained or rising PSA readings, roughly 500,000 to 600,000 patients undergo at least one or more subsequent rebiopsies, a significant percentage of which detect cancer.

Consider the results of a ~2,000-patient study (*Risk of repeat biopsy and prostate cancer detection after an initial extended negative biopsy: longitudinal follow-up from a prospective trial)* by Ploussard et al published in 2013 *(see flow chart at right)*. For 11 years through 2012, the study followed 1,995 men whose initial biopsies were negative. Suspicion of prostate cancer persisted due to high PSA readings, an increase in PSA during follow-up (within six months after the initial negative biopsy, and annually thereafter), and the persistence of nodules detected during

digital rectal exams. An estimate of a 25% positive rate on initial biopsies would imply that almost 8,000 men underwent biopsies, prior to the selection of 1,995 men for the Ploussard study.

The rates of rebiopsy seen here may not be typical of all patients monitored for prostate cancer but, in our view, they convey a sense of how negative biopsies, despite several repetitions over time, do not necessarily dispel suspicions of cancer. Of the 1,995 men with initial negative biopsies selected for the Ploussard study, 1,400 did not undergo anymore biopsies. But 617 men (31% of the study group) went on for more; 514 for a second, 166 for a third one, 48 for a fourth, and 14 for a fifth. These subsequent biopsies detected a total of 139 cases (7% of the study group) of prostate cancer. The rate of detection in the rebiopsies ranged from 13% to 17%, an arguably significant rate that argues for repeated biopsies when symptoms warrant.

But the sheer number of biopsies performed in the drive for ultimately accurate diagnoses imposes a significant cost burden on the healthcare system and can take a heavy emotional toll on patients who endure prolonged uncertainty and repeated biopsies, sometimes over a period of months or years.

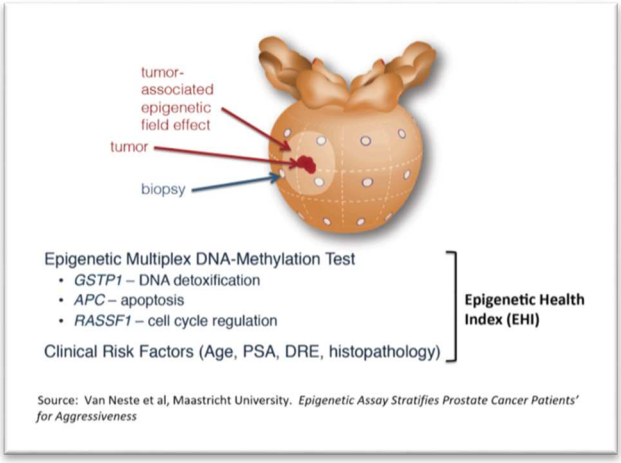
Lead Products, and What Makes Them Work

MDx's prostate cancer diagnostics aim to improve the accuracy and timeliness of diagnoses, obviating the need for invasive and costly biopsies without increasing the risk of undetected cancer. Confirm MDX and Select MDX can more effectively confirm or rule out prostate cancer, and distinguish between low-grade and aggressive forms of the disease. Aside from more accurate and nuanced diagnoses, these products significantly reduce the cost of the process and improve outcomes by better informing oncologists' treatment decisions.

At an estimated cost of $3,200 per procedure (Aubry et al, 2013), the annual cost for US prostate cancer biopsies totals around $4.2 billion; the annual cost of repeat biospsies is approximately $830 million. Aubry's cost estimate includes the cost of treating complications, the most common of which are infection (a 1% to 4% rate), some requiring hospitalization), bleeding, and urinary retention. The Aubry study concluded that a hypothetical health insurance plan that administered the Confirm MDx test to plan beneficiaries who had had an initial biopsy would annually reduce the number of repeat biopsies to 368 from 1,462, resulting in plan savings of around $600,000, or $588 per patient.

Confirm MDx Currently the company's lead product, ConfirmMDx, a laboratory-developed test (LDT) was launched in 2012 and has since been used in diagnoses of 40,000 patients. Priced at $3,300 (subject to discounts) per test, ConfirmMDx accounts for most of MDx's revenue through 2015.

Simply put, ConfirmMDX uses an epigenetic assay consisting of following: GST-Pi, an enzyme expressed profusely in tumor cells; the gene RASSF1, the loss of which is associated with the progression of several different cancers; and APC, a tumor suppression gene which mutation can result in uncontrolled tumor growth. APC and RASSF1 are key field effect markers (chart right) that increase the diagnostic sensitivity of the test. The term field effect describes molecular changes in tissues adjoining a tumor that denote the presence of cancer that cannot be detected by microscopic examination of the tissue. The assay assesses changes in DNA methylation, a distinct chemical process, relative to normal tissues in the same person, that can signal early stages in the development of prostate cancer and the degree of its aggressiveness.



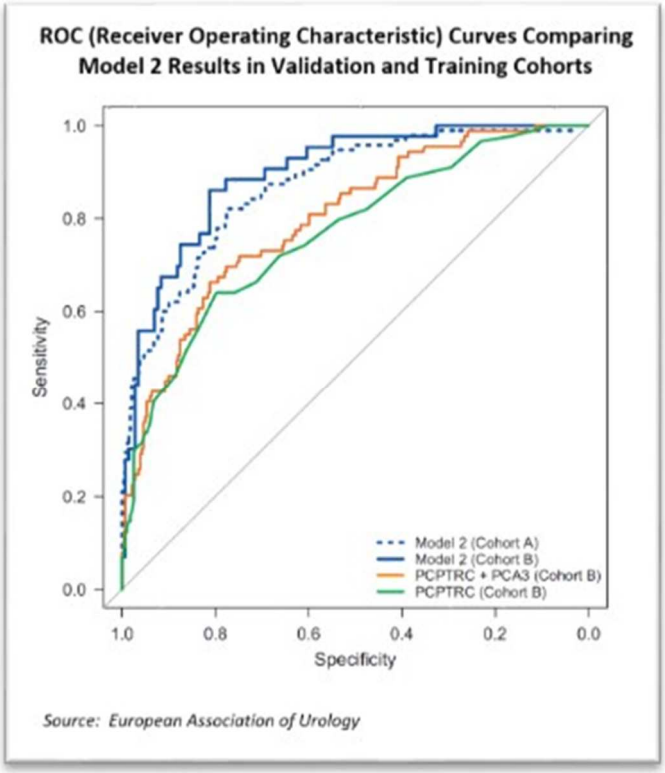
The 2013 MATLOC (Methylation Analysis to Locate Occult Cancer) [Stewart et al] evaluated almost 500 patients from the UK and Belgium, blindly testing prostate biopsy tissue samples, with follow-up within 30 months. The test performed on the first negative biopsies resulted in a negative predictive value of 90%, i.e., in samples with a negative result, the probability of the patient being disease-free was 90%. The 2014 DOCUMENT (Detection Of Cancer Using Methylated Events in Negative Tissue) study [Partin et al] evaluated the archived, cancer negative prostate biopsy tissue samples of 320 patients from five US urological centers. This study observed that DNA methylation is a significant independent predictor of prostate cancer, as is the presence of abnormal cells (atypia). Other factors measured for value as predictors –somewhat significantly abnormal cells (HGPIN) viewed as precancerous), PSA test results, age and race – proved to be of significantly less value. DOCUMENT resulted in a negative predictive value of 88%, affirming the findings of the earlier MATLOC study.

SelectMDx In September 2014 MDX acquired NovoGendix (the Netherlands), the developer of SelectMDx, which was launched in Belgium/the Netherlands in 2015 as an in-vitro diagnostic test, and in the US in March 2016 as a laboratory developed test performed in the company's Irvine, CA laboratory. SelectMDx assesses suspected prostate cancer cases for the likelihood of high- vs. low-grade disease, a determination that sends suspected high-grade cancer cases for biopsies while sparing low-grade cases the need for one.

In a multicenter study *(multicenter validation study of a urine-based molecular biomarker algorithm to predict high-grade prostate cancer)* by Hendriks et al the DLX1/ HOXC6 urine test showed a negative predictive value of 97% for Gleason ≥ 7 prostate cancer and reduced unnecessary rebiopsies by 53%. This study tested urine samples from almost 900 men who were scheduled for prostate biopsy. Hendriks et al established that the DLX1/ HOXC6 urine test was useful as a predictor of high-grade prostate cancer, correlated strongly with higher Gleason scores, and delivered consistent results in subjects with PSA scores (between 4 and 10) in the so-called grey zone.

PSA scores within the grey zone might indicate prostate cancer, or merely reflect other factors such as infection or an enlarged prostate. In grey zone cases, biopsy confirms cancer around 25% of the time, making the three-quarters of test subjects with grey zone PSA scores liable to rebiopsies. In the Hendriks et al study, SelectMDX consistently predicted the presence of high-grade cancer effectively across a range of "grey zone" cases.

A 2016 multicenter study of 900 patients by Van Neste et al *(Detection of High-grade Prostate Cancer Using a Urinary Molecular Biomarker)* developed two models of a test that would combine DLX1and HOXC6 biomarkers with traditional risk factors – PSA scores, PSA density, prior biopsy, family history, age, and DRE results - that could identify patients with high-grade prostate cancer (defined here as cases with Gleason scores ≥7. The second model (which excluded DRE results as a risk factor), validated in the validation group (cohort B) of patients, proved to be a very effective predictor of high-grade prostate cancer.



The model 2 test administered to Cohort B subjects showed an area under the ROC curve value, commonly called the AUC, of 0.90, denoting a highly effective test. The curve (graph at right) shows the tradeoff between sensitivity (ability of a test to correctly identify those with the disease) and specificity (ability of the test to correctly identify those without the disease); the more closely the curve follows both the left and right borders of the graph, the more accurate the depicted test is. The most effective of the tests/models in the comparison was the Model 2 test

administered to Cohort B, which showed an AUC value of 0.90. A score this high would be rated as excellent in terms of accuracy. By comparison, the model 1 test, which factored in DRE results, scored an AUC of 0.86, a "good" result as far as accuracy goes. AUCs for the PCPTRC and PCPTRC+PCA3 respectively, were 0.77 and 0.80, both considered "fair".

Competition

The company's products compete with other molecular diagnostic tests that aim to detect and/or assess the grade or aggressiveness of prostate cancer. Products and services are vulnerable to intervening technology and intense price and service completion. But within their orbits, MDX's products are very competitive, Confirm MDx directly competes with Hologic's PCA3 test. Sold at a lower price than Confirm MDx, PCA3 is based on one biomarker (vs. three for Confirm MDx). In trials sponsored by the developer the PCA3, it showed a 90% negative predictive value, much lower than the 96% NPV demonstrated by ConfirmMDx. While PCA3 is FDA-approved, a factor that might influence a urolologist's choice, sales of PCA3 have declined in recent quarters.

On measurements of AUC, Select MDx, with a score of 0.90 ((van Neste et al, 2016) significantly outperformed direct competitors PHI and 4K. The Prostate Heath Index (PHI), a test that combines PSA, free PSA and proPSA tests. PHI is more effective at detecting prostate cancer in general and high-grade prostate cancer than any of its individual component tests used alone. Evaluations by some groups showed that PHI had an AUC ranging from 0.70 (Scanttoni et al, 2013) to 0.77 (Fero et al, 2013), significantly lower than the AUC as measured by Van Neste et al (2016), but higher than the AUC for the PCA3 test.

The 4Kscore test marketed by Opko can identify patients in likely need of a prostate biopsy due to a high probability of aggressive prostate cancer. 4K, priced roughly three times higher than Select MDx, combines three PSA measures (total, free, and intact) with another prostate-specific measure, human kallikrein 2 (hK2), in an algorithm that factors in patient age, digital rectal exam result, and previous biopsy status. In an evaluation of 4K (Lin et al, 2014), this test's AUC measured 0.82.

Management

The following are the principal operating executives of the company.

Dr. Jan Groen, President & Chief Executive Officer Joined MDxHealth in 2010. Over 30 years of executive and board level experience in the clinical diagnostic and biotech industry, with a particular focus on emerging technologies, product development and commercialization. Previously president and COO of Agendia Inc, a venture backed CLIA laboratory developing and commercializing proprietary genomic products, and responsible for US and European diagnostic operations. Prior to Agendia, was vice-president of research & development at Focus Diagnostics, Inc., a private owned company focusing on infectious diseases and immunology, that was acquired by Quest Diagnostics in 2006. Numerous management and scientific positions at ViroClinics B.V., the Erasmus Medical Center, and Akzo-Nobel. Board member of MyCartis BvBa. Ph.D., medical microbiology, Erasmus University, Rotterdam The Netherlands.

Francis Ota - Executive Vice President of Finance MDxHealth in March 2012. Prior to joining MDxHealth, was CFO of Captek Holdings, and senior director of finance at Focus Diagnostics, Inc. a CLIA service laboratory acquired by Quest Diagnostics in 2006. Also held senior finance roles with Medtronic and Hewlett Packard. MBA, Haas School of Business, University of California, Berkeley. BS, Finance and International Business, Leeds School of Business, University of Colorado, Boulder.

Christopher Thibodeau - Chief Commercial Officer Joined MDxHealth in September 2010. Twenty years of commercial leadership experience, principally in the life sciences and diagnostics arena. Prior to joining MDxHealth, was senior director of marketing at Agendia Inc., vice president of sales and marketing for Numira

Biosciences, national director of sales at US LABS. Also had sales and marketing management roles at Ventana Medical. BA East Stroudsburg University, Pennsylvania. Studied French at the Faculté des Lettres in Nancy, France.

Risks

In our view, these are the principal risks underlying the stock:

Regulatory The company's laboratory-based diagnostic tests and other products could be subject to regulatory clearance in the US and other overseas markets. Delays in, or failure to secure regulatory approval could delay the launch of newly developed products and services.

Competition and Intervening Technology The markets for molecular diagnostic tests are contested by larger, stronger companies that have an established market presence. Based on direct comparisons for certain indications, the company believes that its tests deliver superior outcomes compared to existing competitive products but new diagnostic tests could potentially gain market share at MDx's expense.

Dilution Based on our estimates, MDx will need additional financing by 2017. The issuance of more common shares in connection with additional financing would dilute the ownership interest of current shareholders.

Execution The company has achieved some revenue growth momentum based on a presence in the US market for prostate cancer diagnostics but achieving critical mass will require better penetration, which will hinge on acceptance of SelectMDx, leverage of the sales infrastructure and broader reimbursement coverage.

Microcap Concerns Shares of MDXHF have risks common to the stocks of other microcap (which we define as market capitalizations of $250 million or less) companies. These risks often underlie stock price discounts from the valuations of larger-capitalization stocks. Liquidity risk, typically caused by small trading floats and low trading volume, can lead to large spreads and high volatility in stock price. The company has approximately 32 million shares in the float. Major institutional shareholders, and the respective percentage of outstanding shares owned, as reported to the company during 2H15, were as follows: Alychio NV (3.23%), Biovest Comm VA (13.63%), and Valiance Asset Management (12.99%). The stock is traded mainly on a European exchange. Average daily volume in the US is nominal.

Miscellaneous Risks The company's financial results and equity values are subject to other risks and uncertainties known and unknown, including but not limited to competition, operations, financial markets, regulatory risk, and/or other events. These risks may cause actual results to differ from expected results.

Balance Sheets
($ 000)
2013A –2017E

	2013A	2014A	2015A	2016E	2017E
ASSETS					
Goodwill			1,145	1,145	1,145
Intangible assets	981	2,011	10,030	10,000	10,000
Fixed assets (net)	781	724	1,888	1,813	1,687
Financial assets					
Grants receivable		105	33	100	100
Non-current assets	1,762	2,840	13,096	11,913	11,787
Grants receivable	23	139	180	200	200
Trade receivables	1,997	7,500	10,978	16,997	24,030
Prepayments & other	748	717	381	644	911
Inventory	171	860	1,427	2,147	3,035
Cash + equivalents	24,683	18,897	31,680	10,728	2,019
Current assets	27,622	28,113	44,646	30,716	30,195
TOTAL ASSETS	29,384	30,953	57,742	42,629	41,983
LIABILITIES AND EQUITY					
Total equity	24,537	23,776	44,262	26,667	22,027
Deferred tax liabilities			842	850	900
Grants payable		83	15	25	25
Long-term liabilities			1,390	1,500	1,500
Loans and borrowings			408	408	408
Non-current liabilities		83	2,655	1,933	1,933
Loans and borrowings			440	440	440
Trade payables	3,271	5,264	6,610	8,285	10,402
Grants payable		110	104	110	110
Other current liabilities	1,576	1,720	2,801	4,294	6,071
Short-term liabilities			870	900	1,000
Current liabilities	4,847	7,094	10,825	14,029	18,023
TOTAL EQUITY & LIABILITIES	29,384	30,953	57,742	42,629	41,983

Source: Company reports & Taglich Brothers estimates

Annual Income Statements
($ 000)
2013A –2017E

	2013A	2014A	2015A	2016E	2017E
Revenue					
Product & service income	7,554	10,896	15,752	24,375	35,208
Royalties		583	1,715	750	
Govt grants		192	173	175	200
Total	7,554	11,671	17,640	25,300	35,408
Cost of goods/svcs sold	5,793	6,453	6,905	10,120	13,809
Gross profit	1,761	5,218	10,735	15,180	21,599
Expenses					
R&D	4,567	2,376	3,257	3,542	3,895
SG&A	13,219	18,321	22,358	28,463	33,638
Other operating income	(147)	(139)	(498)	(500)	(500)
Other operating expenses	193	2			
Total	17,832	20,560	25,117	31,505	37,033
Operating loss	(16,071)	(15,342)	(14,382)	(16,325)	(15,434)
Financial income	114	109	13	11	4
Financial expenses	(218)	(23)	(104)	(100)	(100)
Loss	(16,175)	(15,256)	(14,473)	(16,414)	(15,530)
Average shares outstanding	29,924	34,857	41,351	42,500	48,000
Earnings (loss) per share	(0.54)	(0.44)	(0.35)	(0.39)	(0.32)
Margin Analysis					
Gross margin	23%	45%	61%	60%	61%
R&D	60%	20%	18%	14%	11%
SG&A	175%	157%	127%	113%	95%
Operating loss	(213%)	(131%)	(82%)	(65%)	(44%)

Source: Company reports and Taglich Brothers estimates

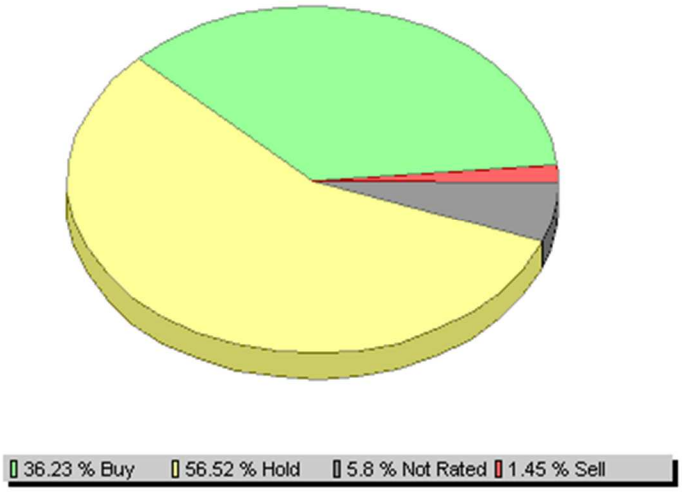
Annual Cash Flow Statements
($ 000)
2013A –2017E

	2013A	2014A	2015A	2016E	2017E
Operating activities					
Operating profit (loss)	(16,071)	(15,342)	(14,382)	(16,414)	(15,530)
Depreciation/ amortization	418	333	881	575	625
Share-based compensation	312	437	437	450	500
(Gain)/loss on disposal of fixed assets	60	(1)			
Interest paid			(5)		
Cash burn/throwoff	(15,281)	(14,573)	(13,069)	(15,388)	(14,404)
Inventories	(171)	(688)	(567)	(720)	(888)
Accts rec	467	(5,693)	(3,111)	(6,019)	(7,033)
Accts pay	880	2,441	2,353	1,675	2,117
Changes in working capital	1,176	(3,940)	(1,325)	(5,064)	(5,804)
Net cash from operations	(14,105)	(18,513)	(14,394)	(20,452)	(20,209)
Investing activities					
Acquisition of subsidiary (net of cash acquired)			(5,389)		
Proceeds from sale of fixed assets	70				
Interest received	8	14	13		
Other financial profit (loss)	(112)	72	(99)		
Capital expenditures	(257)	(264)	(1,577)	(500)	(500)
Purchase of intangibles	(960)	(1,078)	(524)		
Cash from (used in) investing actitvities	(1,251)	(1,256)	(7,576)	(500)	(500)
Financing activities					
Payment on long-term obligations			(617)		
Proceeds from long-term obligations			1,036		
Payments on loans and borrowings			(188)		
Proceeds from inssuance of shares	24,280	14,666	34,811		12,000
Cash from (used in) financing actitvities	24,280	14,666	35,042		12,000
Exchange rate effects	304	(683)	(289)		
Net change in cash	9,228	(5,786)	12,783	(20,952)	(8,709)
Cash - beginning	15,455	24,683	18,897	31,680	10,728
Cash - ending	24,683	18,897	31,680	10,728	2,019

Source: Company reports and Taglich Brothers estimates

Price Chart

Taglich Brothers Current Ratings Distribution



Investment Banking Services for Companies Covered in the Past 12 Months

Rating	#	%
Buy	2	8
Hold		
Sell		
Not Rated		

Important Disclosures

At this writing, none of Taglich Brothers' affiliates, officers, directors or stockholders, or any member of their families have a position in the stock of MDxHealth SA. Taglich Brothers, Inc. does not have an investment banking relationship with MDxHealth SA and was not a manager or co-manager of any offering for the company within the last three years.

All research issued by Taglich Brothers, Inc. is based on public information. The company will pay to Taglich Brothers, Inc. the sum of US$1,500 per month for the production and dissemination of research reports for a period of at least six months after the initial research report on MDxHealth SA is published.

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Analyst Certification

I, Juan Noble, the research analyst of this report, hereby certify that the views expressed in this report accurately reflect my personal views about the subject securities and issuers; and that no part of my compensation was, is, or will be directly or indirectly related to the specific recommendations or views contained in this report.

Public companies mentioned in this report

Hologic (HOLX: NasdaqGS) Opko (OPK: NYSE)

Meaning of Ratings

Buy – The growth prospects, degree of investment risk, and valuation make the stock attractive relative to the general market or comparable stocks.

Speculative Buy – Long term prospects of the company are promising but investment risk is significantly higher than it is in our BUY-rated stocks. Risk-reward considerations justify purchase mainly by high risk-tolerant accounts. In the short run, the stock may be subject to high volatility and could continue to trade at a discount to its market.

Neutral – Based on our outlook the stock is adequately valued. If investment risks are within acceptable parameters, this equity could remain a holding if already owned.

Sell – Based on our outlook the stock is significantly overvalued. A weak company or sector outlook and a high degree of investment risk make it likely that the stock will underperform relative to the general market.

Dropping Coverage – Research coverage discontinued due to the acquisition of the company, termination of research services, non-payment for such services, diminished investor interest, or departure of the analyst.

Some notable Risks within the Microcap Market

Stocks in the Microcap segment of the market have many risks that are not as prevalent in Large-cap, Blue Chips or even Small-cap stocks. Often it is these risks that cause Microcap stocks to trade at discounts to their peers. The most common of these risks is liquidity risk, which is typically caused by small trading floats and very low trading volume which can lead to large spreads and high volatility in stock price. In addition, Microcaps tend to have significant company specific risks that contribute to lower valuations. Investors need to be aware of the higher probability of financial default and higher degree of financial distress inherent in the microcap segment of the market.

From time to time our analysts may choose to withhold or suspend a rating on a company. We continue to publish informational reports on such companies; however, they have no ratings or price targets. In general, we will not rate any company that has too much business or financial uncertainty for our analysts to form an investment conclusion, or that is currently in the process of being acquired.