

Diagnostic Testing and Healthcare Industry News Update

March 11, 2010

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Who We Are

The Emmes Group is a strategic consulting, information and knowledge provider whose core competency is conceiving and implementing proprietary research-based investigations that fulfill clients' explicit needs.

What We Do

We specialize in obtaining vital market facts, judgments, preferences and perceptions -- without delay, and converting this information into applicable knowledge. We deliver unique understandings whose depth and breadth provides our clients with enhanced insights and wisdom.

Who We Support

The Emmes Group counsels and supports managers who are seeking greater understanding and desire better results. Our practice is concentrated on the essential characteristics of healthcare, including diagnostics, medical information management/technology, biotechnology, medical devices, and lab instruments.

Our Credentials

The methods, skill sets, and analyses we offer are based upon decades of first-hand experience and success, not only in research, but also in significant operational roles for industry leaders. Thus, in any project we undertake for you, we can foreshorten the learning curve and help you to be better informed.

Contact Us

For more information please contact Edward Weiner at **(508) 358-2221** or e-mail us at: **EMMES@aol.com**



Diagnostic Testing and Healthcare Industry News Update

March 11, 2010

March 10, 2010

Emmes Launches 2010 MDx Database -- Essential Information Regarding 30+ Assays Performed In 1,000 Labs – Last Chance To Enjoy Early Subscriber Discount

Subscribers Can Easily Access Desired Information For Over 30 MDx Assays - By Assay, By Vendor, By Test Volume, By Test Type (FDA-Cleared, ASR or Homebrew) By Sales Region, By Customer Satisfaction and Much More -- Individually or in Combination With Virtually Any Set of Designated Criteria -- Directly or Online.

The Emmes Group, a leading provider of essential IVD market information and insights for over 25 years is now accepting subscriptions to its acclaimed 2010 Molecular Testing Database as well as access to its recently completed 2009 Molecular Testing Database.

Molecular diagnostics is one of the fastest growing components of the IVD market. For anyone interested in obtaining a better understanding of the specifics of this segment, the Emmes Molecular Testing Database is an invaluable management resource.

The database is easy to use, comprehensive, efficient and interconnected. It is extraordinarily useful for a wide range of business disciplines including, but not limited to, marketing, sales, product development, strategic planning, and competitive analysis.

The Emmes Molecular Testing Database provides a critical foundation whose friendly design encourages users to apply advanced analytics, resulting in better-informed and improved decision-making, and leading to superior business outcomes.

An authentic (low-resolution) profile of 1 of the 1,000 laboratories that comprise the 2009 Emmes Molecular Testing Database is shown on the next page.

For FREE profiles, an online demonstration, or for any additional information regarding access to the 2009 Database, or a subscription to the 2009 Database, please contact:

Edward Weiner
Emmes@aol.com
Tel: 508-328-6800

Emmes 2009 Molecular Testing Database

| | | |
|--|--|--|
| Lab: <input type="text" value="Tacoma General Hospital"/> Address: <input type="text" value="315 Martin Luther King Jr. Way"/> City: <input type="text" value="Tacoma"/> State: <input type="text" value="WA"/> Zip: <input type="text" value="98405"/> Telephone: <input type="text" value="253-403-1113"/> Name: <input type="text" value="Dwain Peterson"/> Title: <input type="text" value="Microbiology Supervisor"/> | Type of Institution: <input type="text" value="Teaching Hospital"/> Labs Performing MDx Testing: <input type="text" value="Microbiology"/> <input type="text" value="Immunology"/> Interview Number: <input type="text" value="467"/> Number of Beds: <input type="text" value="521"/> | Month of Interview: <input type="text" value="March"/> Year of Interview: <input type="text" value="2009"/> |
|--|--|--|

| Test | Perform | Annual Volume | Trend +/- % | Commercial, ASR, Homebrew | Manufacturer/Platform | Will Change | Reason Why Considering Change | Will Likely Add |
|----------------------|---------|---------------|-------------|---------------------------|-----------------------|-------------|-------------------------------|-----------------|
| Chlamydia Gonorrhea | YES | 12000 | Same | Commercial | BD - Probe Tec | no | N/A | N/A |
| HRSA | YES | 3128 | Same | Commercial | Cepheid - SmartCycler | no | N/A | N/A |
| HPV | YES | 11700 | Same | Commercial | Qiagen - HC2 | YES | Sample prep too cumbersome | N/A |
| HPV Genotyping | no | | | | | | | YES |
| HIV Viral Load | YES | 130 | Same | Commercial | Siemens - 348 90NA | no | N/A | N/A |
| HIV Genotyping | no | | | | | | | no |
| HCV Viral Load | YES | 960 | Same | Commercial | Siemens - 348 90NA | no | N/A | N/A |
| HCV Genotyping | YES | 144 | Same | ASR | Hologic - Invader | no | N/A | N/A |
| Herpes (HSV) | YES | 780 | Same | Commercial | Roche - LightCycler | no | N/A | N/A |
| Group A Strep | no | | | | | | | no |
| Group B Strep | YES | 1908 | Same | ASR | Gen-Probe | no | N/A | N/A |
| CMV | no | | | | | | | no |
| Bordetella | YES | 1808 | Same | Commercial | Roche - LightCycler | no | N/A | N/A |
| Influenza A/B | no | | | | | | | YES |
| Factor V Leiden | YES | 300 | Same | ASR | Hologic - Invader | no | N/A | N/A |
| Factor B Prothrombin | YES | 300 | Same | ASR | Hologic - Invader | no | N/A | N/A |

| | | |
|-------------------------------------|--|--------------------------------|
| Lab: Tacoma General Hospital | Emmes 2009 Molecular Testing Database | Type: Teaching Hospital |
| City/State: Tacoma, WA | Page: 2 | Interview Number: 467 |

| Test | Perform | Annual Volume | Trend +/- % | Commercial, ASR, Homebrew | Manufacturer/Platform | Will Change | Reason Why Considering Change | Will Likely Add |
|------------------------------------|---------|---------------|-------------|---------------------------|-----------------------|-------------|-------------------------------|-----------------|
| CF | YES | 130 | Same | ASR | Hologic - Invader | no | N/A | N/A |
| Tuberculosis | YES | 72 | Same | ASR | Gen-Probe - TMA | no | N/A | N/A |
| Enterovirus | no | | | | | | | YES |
| MTHFR | no | | | | | | | no |
| EBV | no | | | | | | | no |
| HBV Viral Load | YES | 180 | Same | ASR | Roche - HBV | no | N/A | N/A |
| BCR/ABL (Chronic Myeloid Leukemia) | no | | | | | | | no |
| Fragile X | no | | | | | | | no |
| Her2Neu | no | | | | | | | no |
| VRE | no | | | | | | | no |
| C. Diff | no | | | | | | | YES |
| Respiratory Virus | no | | | | | | | YES |
| BK Virus | no | | | | | | | no |
| K-RAS | no | | | | | | | no |
| VZV | no | | | | | | | no |

Which Molecular Tests, if Any, Does Your Lab Send Out Rather Than Perform In-House

| | | | |
|----------|-------|-----|--|
| BK Virus | MTHFR | VZV | |
|----------|-------|-----|--|

| | |
|---|--|
| Other Molecular Tests Your Lab Would Like To Add To Its Test Menu: <input style="width: 100%;" type="text" value="Marfan"/> | Any Molecular Tests You Perform For Which We Did Not Inquire: <input style="width: 100%;" type="text" value="Bladder Cancer"/> |
|---|--|

March 9, 2010

The Great Prostate Testing Mistake – Discoverer of PSA Questions Value of PSA Testing

Each year some 30 million American men undergo testing for prostate-specific antigen, an enzyme made by the prostate. Approved by the Food and Drug Administration in 1994, the P.S.A. test is the most commonly used tool for detecting prostate cancer.

The test's popularity has led to a hugely expensive public health disaster. It's an issue I am painfully familiar with — I discovered P.S.A. in 1970. As Congress searches for ways to cut costs in our health care system, a significant savings could come from changing the way the antigen is used to screen for prostate cancer.

Americans spend an enormous amount testing for prostate cancer. The annual bill for P.S.A. screening is at least \$3 billion, with much of it paid for by Medicare and the Veterans Administration.

Prostate cancer may get a lot of press, but consider the numbers: American men have a 16 percent lifetime chance of receiving a diagnosis of prostate cancer, but only a 3 percent chance of dying from it. That's because the majority of prostate cancers grow slowly. In other words, men lucky enough to reach old age are much more likely to die with prostate cancer than to die of it.

Even then, the test is hardly more effective than a coin toss. As I've been trying to make clear for many years now, P.S.A. testing can't detect prostate cancer and, more important, it can't distinguish between the two types of prostate cancer — the one that will kill you and the one that won't.

Instead, the test simply reveals how much of the prostate antigen a man has in his blood. Infections, over-the-counter drugs like ibuprofen, and benign swelling of the prostate can all elevate a man's P.S.A. levels, but none of these factors signals cancer. Men with low readings might still harbor dangerous cancers, while those with high readings might be completely healthy.

In approving the procedure, the Food and Drug Administration relied heavily on a study that showed testing could detect 3.8 percent of prostate cancers, which was a better rate than the standard method, a digital rectal exam.

Still, 3.8 percent is a small number. Nevertheless, especially in the early days of screening, men with a reading over four nanograms per milliliter were sent for painful prostate biopsies. If the biopsy showed any signs of cancer, the patient was almost always pushed into surgery, intensive radiation or other damaging treatments.

The medical community is slowly turning against P.S.A. screening. Last year, The New England Journal of Medicine published results from the two largest studies of the screening procedure, one in Europe and one in the United States. [The results from the American study](#) show that over a period of 7 to 10 years, screening did not reduce the death rate in men 55 and over.

[The European study](#) showed a small decline in death rates, but also found that 48 men would need to be treated to save one life. That's 47 men who, in all likelihood, can no longer function sexually or stay out of the bathroom for long.

Numerous early screening proponents, including Thomas Stamey, a well-known Stanford University urologist, have come out against routine testing; last month, the American Cancer Society urged more caution in using the test. The American College of Preventive Medicine also concluded that there was insufficient evidence to recommend routine screening.

So why is it still used? Because drug companies continue peddling the tests and advocacy groups push "prostate cancer awareness" by encouraging men to get screened. Shamefully, the American Urological Association still recommends screening, while the National Cancer Institute is vague on the issue, stating that the evidence is unclear.

The federal panel empowered to evaluate cancer screening tests, the Preventive Services Task Force, recently recommended against P.S.A. screening for men aged 75 or older. But the group has still not made a recommendation either way for younger men.

Prostate-specific antigen testing does have a place. After treatment for prostate cancer, for instance, a rapidly rising score indicates a return of the disease. And men with a family history of prostate cancer should probably get tested regularly. If their score starts skyrocketing, it could mean cancer. But these uses are limited. Testing should absolutely not be deployed to screen the entire population of men over the age of 50, the outcome pushed by those who stand to profit.

I never dreamed that my discovery four decades ago would lead to such a profit-driven public health disaster. The medical community must confront reality and stop the inappropriate use of P.S.A. screening. Doing so would save billions of dollars and rescue millions of men from unnecessary, debilitating treatments.

March 7, 2010

ExonHit, BioMerieux Kill Colon Cancer Program, Continue to Develop Prostate Cancer Diagnostics

ExonHit Therapeutics and BioMérieux this week said they will discontinue co-developing biomarkers related to colon cancer, but will continue to develop markers for prostate cancer.

The French firms said they made the decision to end the colon cancer partnership after reviewing data generated to date. Loïc Maurel, president of the management board of ExonHit, said in a statement that although ExonHit was "able to produce a robust and reproducible test," the "final results from the colon cancer program did not reach the level of performance we were aiming to achieve."

The firm had envisioned the test, referred to as EHT Dx12 internally, as having the "potential to become an alternative to colonoscopy."

Meantime, ExonHit still believes that its prostate cancer test, referred to as EHT Dx13, has the "potential to become the first blood-based diagnostic test with significantly increased accuracy," compared to prostate specific antigen tests.

Paris-based ExonHit and Marcy-l'Étoile-based BioMérieux launched a partnership in October 2005 to co-develop microarray-based test kits that screen for a variety of cancer markers in blood. The alliance, which was amended in January 2008, combines ExonHit's gene expression-analysis expertise and IP with BioMérieux's *in vitro* diagnostics know-how. The agreement grants ExonHit the right to market the test kits to pharmaceutical companies or to hospitals, which would use them to recruit patients for clinical studies.

ExonHit and BioMérieux began working on the colon cancer assay in 2005 and added prostate cancer in 2007. At that time, the companies said the purpose of the prostate cancer work was to "create DNA biochips that will allow screening for the presence of cancer markers from blood samples." They added that arrays are "perfectly adapted tools" to "enable the characterization of multigenic pathologies such as cancers."

Besides colon cancer and prostate cancer, ExonHit and BioMérieux have worked together to develop a breast cancer diagnostic. They last provided an update on their breast cancer program in April 2007. Last year, though, ExonHit licensed separate breast cancer assays from the Institut Gustave Roussy in Paris.

The first of these assays is a tissue-based test and is to be used following a mammography in association with fine-needle aspiration. The second is a blood-based test and could become an alternative to mammography. Matthew Pando, executive

vice president of therapeutics for the company, told *BioArray News* last month that ExonHit plans to launch the first assay for research purposes in the third quarter.

The future of ExonHit's breast cancer collaboration with BioMérieux is unclear. An e-mail seeking comment from ExonHit was not returned in time for this publication. The companies did not discuss the program in their most recent press release.

Stéphane Bancel, CEO of BioMérieux, said in a statement that biomarker discovery continues to be a "strategic focus of innovation research" for his firm, but said that it is a "challenging scientific, medical, and business endeavor."

ExonHit and BioMérieux have both separately inked deals with Affymetrix that allow them to develop tests on the Affy GeneChip platform. ExonHit is a certified Affy service provider and sells Affy-manufactured, whole-genome SpliceArrays for research, and has separate array-based diagnostic programs ongoing, including one for Alzheimer's disease. The company expects to the Alzheimer's test, called AclarusDx Alzheimer's, in Europe by year end.

March 8, 2010

Quest Diagnostics To Offer New Ovarian Cancer Test

Medical lab operator Quest Diagnostics Inc. said Monday it is selling the OVA1 blood test, which aims to better assess a woman's likelihood for ovarian cancer.

The OVA1 test, which was approved by the Food and Drug Administration in September, will be sold through Quest, based in Madison, N.J. The test was developed in collaboration with molecular diagnostics company Vermillion Inc.

OVA1 is used as a pre-surgical evaluation of a woman's ovarian mass for cancer. It allows physicians to assess, before a planned surgery, the likelihood that a woman's ovarian mass is malignant. The test allows physicians to direct the patient to a specialist more quickly, the company said.

"The availability of a new test that can help gynecologists and other physicians determine the likelihood a woman's mass is benign or malignant is a significant development in the battle against this devastating disease," said Dr. Karen Orloff Kaplan, CEO of the patient advocacy group the Ovarian Cancer National Alliance, in a statement. "It is a big step towards helping each woman get the most appropriate care for her unique situation."

Ovarian cancer is the leading cause of death from gynecologic cancers in the U.S. and the fifth-leading cause of cancer deaths in women, Quest said. Ovarian masses affect an estimated 1 million women and lead to as many 300,000 ovarian mass surgeries in the U.S. each year, Quest added, citing an analysis by third parties on behalf of the company.

The company said about 21,600 new cases of ovarian cancer will be diagnosed in the U.S. in 2009, and about 14,600 women will die of the disease.

March 4, 2010

bioTheranostics Announces Commercial Availability of Expanded Tumor-Type Database for CancerTYPE ID and the Launch of KRAS Testing

bioTheranostics, a bioMérieux company that discovers, develops and commercializes innovative molecular diagnostic tests in oncology, announces the launch of an expanded tumor-type database for its flagship product, CancerTYPE ID®, and the launch of KRAS mutational testing.

CancerTYPE ID predicts cancer origin in patients whose primary cancer was initially “unknown or uncertain” using conventional diagnostics. Knowing the site where the cancer originated impacts physicians’ therapeutic decisions, and the results of the CancerTYPE ID assay can help physicians select optimal therapies earlier in the diagnostic process.

The larger CancerTYPE ID database allows for an increase of reportable tumor types from 39 to 54, while maintaining overall accuracy. Specificity across all tumor types remains high at >99 percent. This new database enhances the ability of the CancerTYPE ID assay to discriminate between clinically relevant metastatic tumors occurring within the GI tract, head and neck, lung (squamous, non-squamous adenocarcinoma, and mesothelioma), and intestine, while incorporating coverage of certain tumor types that frequently present diagnostic challenges such as cholangiocarcinoma, ovarian-mucinous adenocarcinoma, and small intestinal carcinoma.

In tissue samples for which CancerTYPE ID returns a positive result for colorectal cancer, the availability of KRAS, a companion diagnostic test for anti-EGFR therapy, enables medical professionals to obtain additional valuable information and make individualized treatment decisions. KRAS will also be offered as a stand-alone test.

“Since the CancerTYPE ID molecular classifier became available two years ago, we’ve carefully tracked both our customer feedback and our own clinical laboratory experience to identify important, emerging diagnostic opportunities,” said Richard Ding, bioTheranostics’ chief executive officer. “The addition of these new tumor types and the KRAS assay are significant steps in addressing the evolving needs of our customers and making the CancerTYPE ID assay the leading molecular solution for clinicians and patients.”

March 3, 2010

Simple Test For A Marker of Bacterial Infection (PCT) Could Cut Excessive Antibiotic Use

If doctors used an existing simple lab test on patients with coughs or flu-like symptoms they would be better able to decide which of them might benefit from antibiotics, scientists said on Thursday.

They said prescriptions of expensive antibiotics for respiratory tract infections could be reduced by more than 40 percent if tests became more commonplace.

The German researchers found that testing for a marker of bacterial infection known as procalcitonin (PCT) helped identify patients whose respiratory tract infections would respond to antibiotics, and stopped others being offered unnecessary drugs.

Respiratory infections are very common and doctors are taught to prescribe antibiotics on the basis of features like sputum or fever, which suggest there may be bacterial infection.

But this judgment is not always easy, the researchers said, and lab tests can help sort bacterial from viral infections.

Excessive prescribing of antibiotics adds to healthcare costs and to the worldwide problem of multi-drug resistant bacteria, or "superbugs," like MRSA. Superbugs kill about 25,000 people a year in Europe and 19,000 in the United States.

Experts say varying patterns of antibiotic resistance around Europe are strongly linked to varied prescription habits among doctors, and more concrete guides are desperately needed. The European Center for Disease Prevention and Control said last year that overuse of antibiotics in the region was building widespread resistance to a level with could threaten modern medicine.

In a study in the European Respiratory Journal, Tobias Welte of Hannover Medical School said "a simple PCT-guided strategy of decisions on antibiotic treatment" could cut the antibiotic treatment rate by more than 40 percent with no risk to patients.

"There is huge potential for further reduction of antibiotic treatment," Welte wrote in the study, which used a test made by the German diagnostics maker Brahms AG.

In healthy people, PCT concentrations are low, but in those with bacterial infection it occurs at high concentrations in the blood as early as 3 hours after infection. In people with viral infections, PCT levels rise only marginally, if at all.

Welte's team ran a two part study involving more than 1,200 patients with respiratory tract infections and found that testing for PCT helped doctors decide which patients really needed antibiotics and which would safely recover without them.

"A PCT-guided strategy applied in primary care in unselected patients presenting with symptoms of acute respiratory infection reduces antibiotic use by 41.6 percent without compromising patient outcome," they wrote.

March 3, 2010

Abbott and GSK Collaborate on MDx Test to Select Candidate Patients for Skin Cancer Immunotherapy

Abbott (NYSE: ABT) announced today that it has entered into an agreement with GlaxoSmithKline (GSK) to develop a molecular diagnostic test intended for use as an aid in selecting patients who may benefit from a skin cancer treatment in development by GSK.

GSK's MAGE-A3 ASCI (Antigen-Specific Cancer Immunotherapeutic) candidate is currently being evaluated as an adjuvant treatment in melanoma biopsy specimens in the Phase III clinical study DERMA. To be eligible to receive GSK's MAGE-A3 ASCI, patients must have MAGE-A3 expressing melanoma tumors.

Under terms of the agreement, Abbott, in conjunction with GSK, will develop and commercialize a PCR (polymerase chain reaction) test for use on the Abbott *m2000*TM automated molecular instrument system. The test will be designed to detect MAGE-A3, a tumor-specific antigen that is expressed in skin cancer and a wide variety of other cancers, but not in normal cells. In July 2009, both companies announced a similar collaboration and Phase III investigation for the MAGE-A3 marker in non-small-cell lung cancer.

Currently, there are no nucleic acid-based tests approved by the U.S. Food and Drug Administration for use in identifying patients who may derive treatment benefits from targeted skin cancer therapies. Abbott, in collaboration with GSK, will seek regulatory approval for the test in several markets, including the United States and Europe.

"This is an exciting continuation of our important collaboration with GSK, a leading company in cancer immunotherapy research," said Stafford O'Kelly, head of Abbott's molecular diagnostics business. "The agreement is indicative of our commitment to personalized medicine and our focus on developing innovative companion diagnostic tests that can be used to identify patients most likely to benefit from specific cancer therapies."

According to the Skin Cancer Foundation melanoma is the most serious form of skin cancer. However, if it is recognized and treated early, it is nearly 100 percent curable. While it is not the most common of skin cancers, it causes the most deaths. The American Cancer Society estimates that in 2008, there were 8,420 fatalities in the U.S. alone, 5,400 in men and 3,020 in women. The number of new cases is estimated at more than 62,000; of these, approximately 35,000 will be in men and approximately 27,000 in women.

GSK's ASCIs represent a novel class of medicines designed to train the immune system to recognize and eliminate cancer cells in a highly specific manner. These candidate cancer immunotherapeutics combine tumor antigens, delivered as purified recombinant proteins, and GSK's proprietary immunostimulants, which are specific combinations of immunostimulating compounds selected to increase the anti-tumor immune response. ASCIs are being investigated in the clinic to support their use to reduce the risk of tumor recurrence following surgery, or to impact tumor growth in an early metastatic setting.

The highly specific mode of action of GSK's ASCIs is linked to the development of diagnostic tools to aid in selecting patients eligible for the treatment, depending on the expression of the tumor antigens. MAGE-A3 is a tumor-specific antigen that is expressed in a large variety of cancers, including melanoma, non-small cell lung cancer, liver and bladder cancer, with no expression in normal cells. MAGE-A3 ASCI is an investigational compound and it is not approved for use in any indication in any country at this time.

March 2, 2010

Merck KGaA To Acquire Millipore; Price May Leave Investors Waiting for Return

Merck KGaA's \$6 billion agreement to acquire Millipore Corp., the U.S. supplier of equipment to biotechnology companies, may leave investors waiting longer for the "pure value creation" the German company promised three years ago when it bought Serono SA, analysts said.

Still, the price is so high that Merck's return on the investment will be less than the cost of the financing to fund the deal, according to Sachin Jain, an analyst at Bank of America Merrill Lynch. Merck last week said earnings this year will increase less than analysts had estimated and proposed a 33 percent reduction in the dividend.

"The deal appears expensive and we have the impression that investors would have preferred an enhancement of the pharma segment and now might interpret the acquisition at that price as a defensive move," Peter Duellmann, an analyst for Sal. Oppenheim Jr. & Cie. in Cologne, wrote in a report yesterday. He has a "buy" rating on Merck.

Merck rose 1.70 euros, or 2.9 percent, to close at 59.50 euros yesterday in Frankfurt. The stock is unchanged in the past year, compared with a 31 percent increase in the Bloomberg Europe Pharmaceutical Index. Millipore, based in Billerica, Massachusetts, surged \$10.49, or 11 percent, to \$104.90 on the New York Stock Exchange.

Thermo Fisher doesn't plan to try to top Merck's bid, said a person with knowledge of the matter.

Investors haven't profited yet from the company's last big acquisition, the 2007 purchase of Swiss drugmaker Serono SA for \$13.3 billion. Merck, which outpaced the pharmaceutical index more than threefold in the three years leading up to the announcement of the Serono acquisition, has fallen more than the benchmark since then, according to Bloomberg data. "This is not a cost-cutting exercise, the goal is pure value creation," Elmar Schnee, the head of Merck's pharmaceutical operations, said at the time.

Six analysts cut their recommendations on Merck shares last week after the disappointing forecast and reduced dividend. Its debt rating may be next. The cost to protect Merck's debt from default jumped on concern that its credit rating would be cut after agreeing to the Millipore acquisition.

Merck's credit-default swaps surged 21 basis points to 86 late yesterday in London, the highest since July, according to CMA DataVision. Rising prices for the contracts,

used to bet on a company's ability to repay debt, indicates deterioration in the perception of credit quality.

Merck will use available cash and a loan provided by Bank of America Merrill Lynch, BNP Paribas SA and Commerzbank AG to pay for Millipore. Merck, which plans to refinance part of the loan with new bonds, said it's "committed to retaining a solid investment-grade rating."

"The acquisition makes sense, as it adds a high-growth business that is not vulnerable to patent expiry as Merck's pharma portfolio, which suffered some setbacks recently," said Rocco Schilling, a credit analyst at UniCredit SpA who recommends selling Merck bonds, in an interview.

"The size of the transaction is a surprise though, and Merck's rating will likely be lowered," he said. Merck's debt is rated A- by Standard & Poor's, the fourth-lowest investment grade, and an equivalent A3 by Moody's Investors Service.

Credit-default swaps pay the buyer face value in exchange for the underlying securities or the cash equivalent should a company or country fail to adhere to its debt agreements. A basis point on a contract protecting 10 million euros (\$13.5 million) of debt from default for five years is equivalent to 1,000 euros a year.

Adding Millipore will reduce Merck's reliance on pharmaceuticals, increasing the portion of revenue from the chemical unit to 35 percent from about 25 percent now, the company said. The acquisition will result in costs of about \$150 million though it will generate savings of about \$100 million a year, Merck said.

Last year, U.S. regulators rejected Merck's application to sell multiple sclerosis pill cladribine as incomplete and European regulators refused to approve Erbitux for use in lung cancer.

"This acquisition is a further, important step in the transformation of Merck," said Merck Chief Executive Officer Karl-Ludwig Kley on a conference call yesterday. The price Merck is paying is "fair" and the acquisition will contribute to core earnings per share "from day one," he said.

Core earnings exclude the amortization that Merck will incur for the deal, Jain, the Bank of America Merrill Lynch analyst, wrote in a report. The company will have a return of 5 percent or 6 percent annually through 2014 on the capital it's investing in the acquisition, and the company's cost of that capital is 10 percent, he said.

The acquisition will enable Merck to straddle the chemical and pharmaceutical industries by offering equipment and technologies to help its drugmaker customers develop antibodies, vaccines and proteins. Merck Millipore will compete with Life Technologies Corp., Thermo Fisher, Qiagen AG, Lonza Group AG and Sigma-Aldrich

Corp. Merck already makes chemicals used the in drug and biotechnology industries. Millipore had long-term debt of \$890 million as of Dec. 31. Merck valued the acquisition at about \$7.2 billion, including debt.

The purchase values Millipore at 13.4 times earnings before interest, taxes, depreciation and amortization, according to Bloomberg data. That matches the median multiple for 22 deals in the industry over the past five years, the data show.

February 23, 2010

IL Receives 510(K) Clearance From FDA and Canadian License for HemosIL D-Dimer HS 500 Assay

Instrumentation Laboratory (IL) today announced that it has received 510(k) clearance from the US Food and Drug Administration (FDA) for its HemosIL D-Dimer HS 500 assay. Additionally, the Company received a license from Health Canada for the product. The Company will now initiate commercialization of HemosIL D-Dimer HS 500 in North America, with their distribution partner, Beckman Coulter, Inc. In April 2009, the assay was previously released in Europe, after receiving the CE IVD Mark.

HemosIL D-Dimer HS 500 is a liquid, ready-to-use, automated latex-enhanced immunoassay for the quantitative determination of D-Dimer in human citrated plasma on the ACL TOP® Family of Hemostasis Testing Systems for use in conjunction with a clinical pretest probability (PTP) assessment model to exclude venous thromboembolism (VTE) in outpatients suspected of deep venous thrombosis (DVT) and pulmonary embolism (PE). The assay's liquid, ready-to-use format, with time to results in less than five minutes, provides customers with superior ease of use and efficiency versus traditional methods.

"HemosIL D-Dimer HS 500 is the latest generation assay to join our robust D-Dimer assay family, including HemosIL D-Dimer and D-Dimer HS assays, which are among a select few cleared by the FDA for the exclusion of VTE," said Giovanni Russi, Director of Worldwide Marketing, Hemostasis Reagents at IL. "This new assay offers even greater ease of use and enhanced clinical performance, and is another example of IL's commitment to innovation in Hemostasis diagnostics."

As part of the 510(k) filing, IL submitted data from single and multi-center management studies. The studies demonstrated that HemosIL D-Dimer HS 500 is highly accurate with 100% Negative Predictive Value for VTE on the ACL TOP and can thus be an invaluable patient management tool. It has a cut-off for the exclusion of DVT and PE of 500 ng/mL FEU.

DVT occurs when a blood clot forms in a large vein, usually in a leg. A potentially fatal PE happens if the blood clot breaks loose, migrates to the lungs and blocks a pulmonary artery or one of its branches. These conditions can occur after any surgery, as well as in patients with spinal fractures and spinal-cord injury, though it is most commonly seen in patients who have recently undergone orthopedic surgery. Two hundred thousand new cases of DVT and PE occur in the US annually and 20% suffer sudden death as a result of PE.

February 21, 2010

Affymetrix, Asuragen Sign Agreement to Supply RNA Control Kits for Molecular Diagnostic Applications

Asuragen Inc., a leading molecular biology diagnostic company and service provider, today announced an agreement to develop and manufacture RNA Control Kits for Affymetrix (Nasdaq:AFFX). The RNA Control Kit is intended for use with *in vitro* transcription (IVT) reagent kits for clinical molecular diagnostic applications that Asuragen has licensed and supplied to Affymetrix. The RNA Control Kits manufactured by Asuragen under cGMP will enable Affymetrix to deliver a complete solution to its molecular diagnostic partners. The products will be configured for use with the GeneChip® System 3000Dx v.2. This is the only available diagnostic microarray platform that has earned 510(k) clearance from the United States Food and Drug Administration and the CE mark from the European Union.

“Affymetrix offers a continuous path to discover, develop, and commercialize biomarker signature assays,” said Matt Winkler, Chief Executive Officer and Chief Scientific Officer of Asuragen. Affymetrix is partnering with the world’s leading diagnostic companies through the Powered by Affymetrix™ (PbA) Program to bring to market new diagnostic tests that employ the latest genomic discoveries. There are currently more than 20 different molecular assay tests based on the Affymetrix platform under development by Affymetrix and its 11 PbA Partners. The resulting microarray-based tests will enable clinicians to provide more efficient and complete methods to diagnose, classify, and manage patients suffering from complex diseases like cancer.

February 21, 2010

BG Medicine Forges Pact with Merck To Develop A Molecular Diagnostic for Lipid Disorders

BG Medicine and Merck & Co. are joining forces to develop an in vitro diagnostic for lipid disorders. Merck has granted BG Medicine a semi-exclusive license to certain intellectual property and technologies in exchange for testing services, data sharing, and other considerations. BG Medicine is eligible to receive milestone-based payments.

BG Medicine will work to develop an immunoassay and validate its clinical utility as a biomarker. If successful, the company plans to complete these studies and seek regulatory clearance for the test.

“This project holds the potential to improve the management of a common disorder that plays an important role in the risk for heart attack and stroke, two of the most deadly medical conditions of our time,” says Pieter Muntendam, M.D., president and CEO of BG Medicine.

BG Medicine focuses on the discovery, development, and commercialization of molecular diagnostics. It has four cardiovascular-related biomarkers in development as tests for heart failure (HF), HF post myocardial infarction, acute atherothrombosis, and lipid disorders. The HF test, BGM Galectin-3™, is available in for clinical use only in the EU and certain other European countries. The company says that it has submitted a 510(k) application to obtain FDA clearance to sell the test in the U.S.

BGM Galectin-3 measures blood plasma or serum levels of galectin-3, which has been linked to adverse remodeling of the heart. Cardiac remodeling is an important determinant of the clinical outcome of heart failure and is linked to disease progression and poor prognosis.

The company also has discovery-stage programs in multiple sclerosis, autoimmune disorders, and cardio-metabolic diseases. The firm’s strategy is to focus on novel content for existing automated laboratory instruments to facilitate broader and more rapid adoption of its diagnostic tests.

February 21, 2010

Molecular Diagnostics Forecast To Grow At A CAGR of 14% Over Next Two Years

The molecular diagnostic market has become an important segment of the overall IVD market and represents the most potential IVD segment for future growth. The introduction of new innovative techniques has boosted growth in the market. According to the research report "Global In Vitro Diagnostic Market Analysis", the market for molecular diagnostic techniques is expected to grow at a CAGR of around 14% during 2010-2012.

This research has predicted that the molecular diagnostic market will show the highest potential among all IVD segments. Expansion of molecular diagnostic market will be driven by products with improved specificity and sensitivity; technology that simplifies, automates, and speeds up testing; and an increase in high-quality molecular market.

The research has also found that changing consumer behavior and approach have given a new direction to the industry development. People are more cautious about their health and therefore giving more importance to diagnosis tests. This fact has also boosted the point of care tests markets which are expected to post a double digit growth.

February 3, 2010

Novartis Molecular Dx Group Looks to 'Rescue' Lumiracoxib with Companion Diagnostic Test

A Novartis official said today that the company has identified a genetic marker that it plans to market as a companion diagnostic for a COX-2 inhibitor that was previously withdrawn from several non-US markets due to liver toxicity issues.

Michael Little, global head of diagnostics development at Novartis Molecular Diagnostics, told attendees of the Molecular Medicine Tri-Conference here that the company has resubmitted the compound, in combination with the genetic marker, for marketing in the European Union for the treatment of osteoarthritis symptoms.

The compound, lumiracoxib, was approved in the EU in 2006, but was withdrawn from the market in several countries the following year in the wake of a handful of serious liver adverse events. The US Food and Drug Administration in 2007 issued a "not approvable" letter for the drug, which was originally marketed under the name Prexige.

Little said today that the company's molecular diagnostics unit, which it launched last year, has been conducting biomarker studies for the drug and has identified a marker that can identify patients who should not receive it due to the risk of liver-related adverse events.

Little said resubmission of lumiracoxib could be the "first example" of a molecular diagnostic-based "drug rescue" in the industry. A Novartis spokesperson said that the company submitted the compound and the genetic marker to the EU in December.

"The genetic biomarker can identify patients at risk of certain liver-related side effects from lumiracoxib and make them ineligible for therapy," the spokesperson explained via e-mail. "A risk mitigation system would be implemented to screen out [osteoarthritis] patients with the genetic biomarker and exclude them from lumiracoxib treatment."

At a separate conference on pharmacogenomics in Bethesda, Md., today, Kevin Carl, Novartis' director of global drug regulatory affairs, said that Novartis submitted data on the biomarker last year under the FDA's Voluntary Exploratory Data Submissions program. FDA's VXDS program allows sponsors to submit and discuss genomic data associated with its products without regulatory repercussions. Although he indicated that Novartis was planning to submit the drug with the aid of a genetic biomarker, for marketing approval with regulatory authorities around the world, he did not specifically discuss a resubmission strategy with the FDA.

Carl noted that the predictive PGx marker associated with hepatic safety in lumiracoxib-treated patients, DQA1*0102, was identified by researchers via retrospective analysis of the Therapeutic Arthritis Research and Gastrointestinal Event Trial, or TARGET, which involved more than 18,000 patients.

DQA1*0102 was shown in studies to have 83 percent sensitivity, 68.2 percent specificity, and 99.7 percent negative predictive value. Novartis used an FDA-cleared *in vitro* diagnostic to genotype patient samples, Carl said.

Little cited the lumiracoxib marker as an early success story for Novartis' year-old molecular diagnostic group, which operates as a "standalone" business within the company. He noted that the Novartis approach to developing companion diagnostics differs from that of most pharmaceutical firms, which either own large clinical diagnostic businesses, like Roche and Abbott; or partner with smaller, third-party diagnostic companies, as Amgen has done with DxS.

By maintaining an internal molecular diagnostic unit, Novartis is able to get involved "early" in the drug discovery process to ensure that it is also identifying relevant biomarkers that may prove useful in guiding therapy, Little said.

So far, he said, Novartis has identified more than 150 programs in clinical development that have the "potential" for companion diagnostics.

February 6, 2010

Tecan and Enigma Diagnostics Sign Agreement For Point-of-Care Molecular Diagnostics Instruments

The Tecan Group a leading global provider of laboratory instruments and solutions, and Enigma Diagnostics Limited, the decentralised and point-of-care molecular diagnostics company, announced today the signing of a manufacturing and supply agreement for Enigma's ML instruments.

Under the agreement, Tecan will industrialize and deliver commercially manufactured ML instruments for Enigma's global market supplies for an initial five-year contract and will also manage the ML instrument's supply chain. The first ML demonstration instruments have been delivered for Enigma's GlaxoSmithKline delivery commitments for point-of-care molecular diagnostic influenza tests.

The launch of Enigma ML and supply of commercial series systems for its initial use to identify specific influenza virus strains is anticipated in Q4 2010, subject to successful clinical trials and regulatory approval. Enigma will also add additional tests for other areas such as infectious disease management to the ML system test menu in the future. Financial details of the agreement were not disclosed.

John McKinley, Chairman and CEO of Enigma, said: "This is a milestone agreement for Enigma. We chose Tecan for its leading reputation as a developer and manufacturer of commercial medical instruments and its global range of technical and support services network. This represents the first of a number of potential additional agreements relating to Tecan's support of the Enigma ML system."

Thomas Bachmann, CEO of Tecan, said: "We are excited to be partnering with such an innovative company as Enigma. We are highly committed to contributing to the success of the wide range of potential applications and tests the ML instrument platform offers with our experience in manufacturing and servicing high quality and regulatory compliant diagnostic products. The dedicated and modular ML instrument marks a breakthrough in point-of-care molecular diagnostics."

The Enigma ML instrument delivers fully-automated results from swab samples in less than 60 minutes at the point of care and to the same accuracy standards as reference laboratories. This will mean that patients can be tested for a broad range of diseases including specific influenza subtypes in the community and receive appropriate treatment rapidly. Currently the existing network of government diagnostic laboratories, staffed by specialist operators, can often take several days before the results of tests are known. Operators of the Enigma ML system will not require specialist training.

Tecan (www.tecan.com) is a leading global provider of laboratory instruments and solutions in biopharmaceuticals, forensics, and clinical diagnostics. The company specializes in the development, production and distribution of automation solutions for laboratories in the life sciences sector. With its subsidiary REMP (www.remp.com), Tecan is the market leader in automated laboratory storage and logistics systems. Its clients include pharmaceutical and biotechnology companies, university research departments, forensic and diagnostic laboratories.

As an original equipment manufacturer, Tecan is also a leader in developing and manufacturing OEM instruments and components that are then distributed by partner companies. Founded in Switzerland in 1980, the company has manufacturing, research and development sites in both Europe and North America and maintains a sales and service network in 52 countries.

In 2008, Tecan generated sales of CHF 396 million (USD 366.7 million; EUR 250.7 million). Registered shares of Tecan Group are traded on the SIX Swiss Exchange (TK: TECN/Reuters: TECZn.S/ ISIN CH0012100191).

Enigma Diagnostics Limited specialises in developing next generation rapid molecular diagnostic instrument platforms for decentralized and point-of-care settings.

Enigma's innovative and proprietary technology combines the speed and sensitivity of real-time PCR (polymerase chain reaction) with the simplicity needed for decentralized and point-of-care testing providing results from a raw sample in less than 60 minutes.

The Company is targeting a number of multi-billion pound markets, core among which are the Clinical and high-value Applied Markets. Enigma's commercialisation strategy is to maximize revenues from a continuous flow of market leading rapid diagnostic point-of-care instrument and assay platforms, based on unique technologies and underpinned by its broad Intellectual Property portfolio.

Enigma will partner with market leaders where global penetration of markets is required and where appropriate, will engage regional partners and build in-house sales and marketing capability to direct distribution of its products.

February 6, 2010

Pfizer and DxS (QIAGEN) To Develop Companion Diagnostic Test Kit For Brain Tumour Patients

Pfizer Inc. and DxS (a wholly owned subsidiary of Qiagen N.V.) announced that they have entered into an agreement to develop a companion diagnostic test kit for PF-04948568 (CDX-110), an immunotherapy vaccine in development for the treatment of glioblastoma multiforme (GBM). Financial terms of the diagnostic agreement have not been disclosed.

On April 16, 2008, Pfizer and Celldex Therapeutics, Inc. entered into an agreement to grant Pfizer an exclusive worldwide license to PF-04948568 (CDX-110) which is currently in phase 2 clinical development for the treatment of newly diagnosed GBM.

Glioblastoma multiforme is the most common malignant primary brain tumour in adults and occurs in around 25,000 patients worldwide each year. Pfizer's investigational drug PF-04948568 (CDX-110) is a peptide vaccine which targets the tumour-specific Epidermal Growth Factor Receptor variant III (EGFRvIII), a mutated form of the epidermal growth factor receptor that is only present in cancer cells and occurs in 25-40 per cent of GBM tumours. The Qiagen assay is designed to identify those patients whose tumours express the EGFRvIII mutation, allowing for the possibility of more targeted and personalized treatment.

The EGFRvIII companion diagnostic will be developed and manufactured at Qiagen's Center of Excellence for Companion Diagnostics in Manchester, UK. The diagnostic will be a real-time PCR assay used to detect EGFRvIII RNA in tumour tissue. The assay is designed to offer a simple workflow, which supports its clinical utility in routine mutation testing.

Commenting on this announcement, Dr Stephen Little, vice president personalized healthcare, for Qiagen, said, "We are very pleased to have signed this agreement with Pfizer, as it is another important step toward the realization of personalized medicine. Qiagen is aligned to deliver companion diagnostics to our pharmaceutical partners and this deal is further evidence of our commitment to develop our scientific and operational capabilities to help select the right patient for the right medicine."

"We look forward to collaborating with Qiagen's DxS unit in the development of this important diagnostic tool that could potentially help physicians better define the most appropriate treatment for patients who suffer from glioblastoma multiforme," said Garry Nicholson, president and general manager of Pfizer's Oncology Business Unit.

Qiagen N.V., a Netherlands holding company and the leading global provider of sample and assay technologies. The company's products are sold to molecular diagnostics

laboratories, academic researchers, pharmaceutical and biotechnology companies, and applied testing customers and include one of the broadest panels of molecular diagnostic tests for prevention, profiling and personalized healthcare available worldwide.

February 1, 2010

QIAGEN to Host Panel Discussion Of Molecular Diagnostics and Personalized Medicine

QIAGEN, a company that specializes in molecular diagnostics technologies, reportedly announced that it will host a panel discussion with experts in the field of personalized medicine.

Every year, more money and time is spent treating patients using methods which may prove to be unsuitable for them. Molecular diagnostics has made it possible to find out which treatment will suit a particular patient best by a simple test. Physicians can then select a treatment method based on defined characteristics.

QIAGEN proposes to host a panel discussion with experts in the field including Edward Abrahams, Ph.D., executive director of the Personalized Medicine Coalition; Nancy Roach, co-founder and Board Chair of Colorectal Cancer Coalition; and Peer Schatz, CEO of QIAGEN. The event will be held at the Four Seasons Hotel in New York on Feb. 11.

The company's tests and tools are used by physicians, researchers and some pharmaceutical companies to determine patients' potential responses to drug treatments based on specific genetic markers.

"We are honored to have such a distinguished panel to address many of the facets of personalized medicine, including public policy, science, and patient care," Schatz said. "With the nation focused on healthcare reform, the timing of this event couldn't be better,"

"For instance, some of the most popular treatments for cardiovascular and neurological diseases, and most prominently cancer, are effective in only about 60 percent of patients," he said. "That leaves a significant portion of the population searching for a treatment that works for them, often at considerable expense. Personalized medicine can dramatically improve the success rate, while significantly reducing unnecessary and ineffective treatments."

Personalized diagnostics solutions help physicians to give the most appropriate treatment to the patient instead of going for a trial and error method. For example, two of QIAGEN's research tests can detect the presence of biomarkers K-RAS and B-RAF in certain cancer patients.

Identifying any mutations of the K-RAS gene, may indicate presence of other cancers. This will help doctors to assess whether patients suffering from metastatic colorectal cancer may benefit from treatment with the most common and expensive anti-EGFR drugs. Such details help doctors choose different courses of treatment for the patient without wasting precious time in such serious cases, QIAGEN sources said.

QIAGEN provides assay technologies. The process uses sample technologies to isolate and process DNA, RNA and proteins from biological samples such as blood or tissue. Assay technologies are used to make such isolated biomolecules visible to help tailor the treatment method.

February 1, 2010

Thermo Fisher To Acquire Finnzymes, Provider Of Tools For Molecular Biology Analysis

Thermo Fisher Scientific announced today that it has signed a definitive agreement to acquire Finnzymes, a well-recognized provider of integrated tools for molecular biology analysis, including reagents, instruments, consumables and kits. Headquartered in Espoo, Finland, Finnzymes has 90 employees and generated revenue of \$20 million in 2009.

Finnzymes provides comprehensive solutions for high-performance polymerase chain reaction (PCR), reverse transcription-PCR (RT-PCR) and real-time quantitative PCR (qPCR). The company's expertise in DNA polymerases has led to significant increases in the performance of these enzymes, making the PCR process faster and more accurate. The ability to quickly and reproducibly amplify and quantify particular DNA sequences benefits a variety of applications, including basic genomic research, genetic testing, forensics and food testing.

The acquisition of Finnzymes expands Thermo Fisher's portfolio of reagents and other consumables for the molecular biology research and diagnostics markets through the addition of its proprietary DNA polymerases, Phire™ and Phusion™, and high-speed miniaturized thermal cyclers and innovative plastic tubes and plates. These products complement the recently launched Thermo Scientific Solaris qPCR gene expression assays and, together, deliver a more complete solution for customers. Combining the

gene-specific MGB[®]-based probes from Thermo Scientific with the advanced enzyme performance from Finnzymes will further enhance qPCR assay technology.

“The addition of Finnzymes’ innovative enzyme portfolio and unique PCR instrument platform strengthens our broad range of life science reagents and consumables, as well as our specialty diagnostics product offering,” said Marc N. Casper, president and chief executive officer of Thermo Fisher Scientific. “This combination brings together key complementary technologies for molecular biology and diagnostics, allowing us to create significant value for our customers.”

Finnzymes will be integrated primarily into Thermo Fisher Scientific’s Analytical Technologies Segment, with some equipment and consumables product lines being added to the Laboratory Products and Services Segment. The transaction is expected to close during the first quarter of 2010. The company does not expect this transaction to have a material impact on its 2010 financial results.

February 1, 2010

Asuragen Allies with Clinical Centers to Validate miRNA Pancreatic Cancer Test

Asuragen is teaming up with a number of academic research centers to develop an miRNA-based test that will help diagnose pancreatic cancer from fine-needle aspirate (FNA) biopsies. The institutes involved in this arrangement are The University of Pittsburgh Medical Center, Brigham and Women’s Hospital, H. Lee Moffitt Cancer Center, Dartmouth’s Hitchcock Medical Center, and the University of Sherbrooke. The collaborating sites will provide clinical expertise and samples so that Asuragen can evaluate the clinical utility of its miRNA test to distinguish pancreatic adenocarcinoma from chronic pancreatitis and other noncancerous disorders.

Asuragen’s miRNA test currently uses formalin-fixed biopsy or resection specimens to help resolve cases for which standard cytopathology has been inconclusive. The company claims if the test can be validated for FNA biopsies, patient samples could be obtained less invasively, and it may negate the need for surgery.

Asuragen offers a range of capabilities for molecular diagnostics and services, from identifying and validating novel mRNA and miRNA biomarkers to developing and manufacturing new assays under specific regulatory requirements. The company emerged from what was left of RNA company Ambion in 2005/2006. Ambion sold off its research products division to Applied Biosystems Group and formed Asuragen with about 100 employees from its diagnostics and molecular biology services divisions.

Asuragen established its CLIA lab in Austin in 2007/2008 and launched the first miRNA-based diagnostic test for distinguishing pancreatic cancer from chronic pancreatitis. In December 2007, the decision was made to move the miRNA therapeutics activities into a new entity call Mirna Therapeutics. Mirna was seeded with \$3M from Asuragen and is actively developing oncology candidates.

In November 2009, Asuragen signed an exclusive agreement with Life Technologies for worldwide distribution of an in vitro diagnostic test to aid in the monitoring and treatment of patients with chronic myeloid leukemia. As part of the agreement, Asuragen will pursue CE marked-IVD registration in Europe and regulatory clearance in the U.S. The diagnostic test will then be distributed by Life Technologies and will run exclusively on the Applied Biosystems 7500 Fast Dx real-time PCR instrument.

In October 2009, Asuragen won over \$3.8 million in new grant funding from the SBIR, STTR, and American Recovery and Reinvestment Act initiatives of the NIH. The grants will be used to fund research and product development in the fields of oncology and genetic disease.

February 1, 2010

Will Philips Healthcare Pursue IVD Acquisition?

With no major economic cycle upturn in sight and a cash hoard on its books, Philips must take decisive action in its healthcare business in the next six months—bullish analysts' estimates for organic growth notwithstanding.

Management is right to rule out stock buybacks or a dividend increase this year. But if the Dutch conglomerate is to hit, and maintain, its 10-11% medium-term group target for adjusted Ebita margin, it must consider bolt-on acquisitions in the BRIC regions to expand and diversify its healthcare portfolio.

In the meantime it should sound out the feasibility of entering in-vitro diagnostics (IVD), a business offering high double-digit operating margins. Philips's U.S. healthcare woes will likely be a drag on its performance. The U.S. diagnostics market has been weak on the back of the federal Deficit Reduction Act, which cuts reimbursement rates for diagnostic imaging procedures. And the sword of Damocles is hovering above management's head, with the imminent threat of further taxation on devices and diagnostics under the Obama administration's U.S. health-care reform.

As it awaits the outcome of the reforms, Philips could bolster its healthcare portfolio by tapping growth in the BRIC regions, where health-care expenditure rose to \$500 billion last year, according to the Millennium Research Group.

Local players in the BRIC countries are small and the market is fragmented; in India, an option could be teaming up with privately held Transasia Bio-Medicals, one of the largest clinical diagnostic companies in the country.

To add to its portfolio, the Dutch group could look at mature markets, where IVD specialists like France's Biomerieux and U.S.-based Beckman Coulter enjoy high double-digit margins. One M&A option is U.S.-based Inverness Medical Innovations, an IVD player that has been very active in recent times acquiring point-of-care diagnostics specialists. One caveat is that the U.S. company's M&A strategy has pushed its total debt/Ebitda multiple to 4.5x. Yet its current Ebitda margin is around 25%.

There's little doubt that in the U.S. or Western Europe, Philips would face fierce competition in IVD from rivals Siemens and General Electric Corp., which have already started consolidation in the area. In 2006, the German company acquired Bayer Diagnostics for EUR4.2 billion and one year later it snapped up Dade Behring for \$7 billion, while GE has consolidated partnerships in the field and attempted, but failed, to acquire Abbott Laboratories' IVD unit for \$8 billion in 2007. Whatever its M&A strategy proves to be—and Philips has so far decided against big IVD acquisitions—there's little doubt the Dutch group needs a breath of fresh air.

Philips' consensus beating fourth quarter figures were driven by growth in emerging and mature markets ex-U.S., but given its exposure to healthcare in North America, which accounts for roughly 40% of the division, the healthcare unit's soft performance is worrisome, in particular for Imaging Systems.

Despite an eye-catching 7% year on year seasonal surge in total group equipment orders, Philips's U.S. equipment intake book came in at Philips Healthcare -6% in 4Q 2009. That not only makes for poor reading, but is in striking contrast to the performance of GE, which increased U.S. equipment orders by 9% over the same period.

Diverting capital away from three of its U.S. healthcare units—Imaging Systems, Clinical Care Systems and Healthcare Informatics—to seek alternative partnerships in the BRIC regions is an option well worth considering for Philips.

It would be no surprise if this were followed by a reshuffle of parts of the company's lighting division exposed to the sluggish auto and commercial real-estate sectors. The Dutch group's fourth-quarter results have fuelled analysts' enthusiasm about future prospects, but closer reading clearly paints a less rosy picture. As it stands, Philips is still a pure restructuring play and faces an uphill struggle to grow organically.