Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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Roche, Gen-Probe, Becton Dickinson Propose New Premarket Regulatory Path Aimed At Microarrays

As the FDA contemplates new rules for bringing analyte-specific reagents (ASRs), including DNA microarrays, to market, three big IVD vendors have submitted a draft proposal of their own to the agency. While the document, "In Vitro Analytical Tests (IVATs); Draft Guidance for Industry and FDA," does not address microarray-based technologies specifically, the timing and language of the proposal suggest that it's aimed at speeding guidance from the FDA for this budding market segment.

The draft suggests that the FDA create a new IVD category—in vitro analytical tests, or IVATs—with a new path for companies seeking regulatory approval to market these products. In a nutshell, it proposes a marketing clearance path "based on review of the same analytical data that FDA now examines in premarket notification submissions" minus clinical trial data. FDA clearance for an IVAT would allow the manufacturer to make analytical claims, but not clinical claims about their test, according to the draft.

Regarding the fact that numerous IVD companies are already selling microarrays on a research-use-only (RUO) or ASR basis, one executive tells *DTTR*, "Everybody's out there on a limb. This industry could be in big trouble depending on what the FDA does."

➡ *p. 3*

DiagnoCure Launches Genetic Test For Prostate Cancer

DiagnoCure Inc. (Toronto, Canada), a small publicly traded IVD company, says Bostwick Laboratories (Richmond, VA) has begun selling its uPM3 test to detect prostate cancer effective October 15. Pierre Desy, chief executive of DiagnoCure, tells *DTTR* that the test is the first gene-based test for prostate cancer and offers significantly improved accuracy over the traditional total PSA test. Desy says the test reagents will initially be sold by DiagnoCure in ASR form, and Bostwick, a privately held lab that specializes in urological diseases, will perform a homebrew version at an expected price of around $300 to $400. Of course the big question is will Medicare and managed care pay up for this test, which is roughly 10 times the cost of the total PSA.

➡ *p. 2*

▲ **DiagnoCure To Launch Genetic Test,** *from page 1*

David Bostwick, M.D.

"The sensitivity and specificity of uPM3 surpasses PSA and all other existing prostate cancer detection tests other than biopsy," says David Bostwick, M.D., president of Bostwick Laboratories. Dr. Bostwick is widely considered to be one of the world's preeminent urological pathologists.

He was formerly a professor of pathology and urology at the Mayo Clinic (1991-1999), and left in June 1999 to found Bostwick Laboratories, which has become the largest independent lab in the United States focused on the diagnosis of cancer of urological organs (*i.e.*, prostate, urinary, bladder, kidney, and testis).

Bostwick Labs currently has 90 employees, including 27 salespeople, and generates an estimated $10 million per year in revenue. In addition to its main lab in Richmond, Virginia, the company recently opened a second facility in Orlando, Florida. Donna Batterham, president of Bostwick Labs, says Bostwick has exclusive rights to the uPM3 test until the end of this year and is working to extend the agreement.

Prostate cancer is the most frequent cancer in men, with 189,000 new cases diagnosed last year in the United States, according to the American Cancer Society. It also accounted for 30,200 deaths, making it the second leading cause of cancer deaths in men, surpassed only by lung cancer.

The uPM3 test is based on PCA3, a specific gene that is profusely expressed in prostate cancer tissue (on average, 34 times greater than in benign prostate tissue). No other human tissues have ever been shown to produce PCA3. DiagnoCure has licensed the worldwide patents rights to the PCA3 gene for diagnostic and therapeutic applications from Universite Hospital Nijmegen in Holland, according to Desy.

Patients who receive the uPM3 test undergo a digital rectal prostate exam by a urologist. This exam causes cells from the patient's prostate to be shed into the urine, and the urine sample, containing the released cells, is sent to Bostwick Laboratories to be tested for genetic expression of the PCA3 gene.

An abstract (#469-Multicenter Study of the uPM3 Test, a New Molecular Urine Assay to Detect Prostate Cancer. Saad, Aprikian, et al.) presented at the American Urology Association's annual conference in Chicago earlier this year showed that the uPM3 test has an overall sensitivity of 67% and an overall specificity of 89%.

The abstract, which was based on 443 evaluable urine samples from patients undergoing biopsy in five centers from September 2001 to April 2002, also showed that uPM3 has a predictive value of 75% compared with 38% predictive value for total PSA. Overall accuracy for uPM3 was 81% compared to 47% for total PSA.

Desy anticipates that the test will initially be used as a tool to help resolve indeterminate prostate cancer cases where a man has a positive PSA level (>4.0 ng/ml) that has been followed up with a negative biopsy. The use of uPM3 could eliminate the need of second and third prostate biopsies, which can cost in the range of $1,000 to $2,000 each depending on the number of "cores" or specimens extracted and analyzed with each biopsy procedure.

Desy estimates that there are some 25 million PSA tests performed each year in the

United States, of which roughly 25% turn up positive. Of the 6 million positive PSA tests, roughly two out of three have a negative biopsy. Thus the initial potential market for uPM3 is roughly 4 million tests per year, according to Desy.

Of course the big challenge will be getting Medicare and other payers to reimburse for uPM3, especially when you consider that the total PSA is currently reimbursed at a national limit of just $25.70 per test under the Part B fee schedule. Although no formal studies have been published regarding the cost effectiveness of uPM3, Desy believes the test will more than pay for itself by eliminating unnecessary biopsies.

uPM3 Sensitivity & Specificity

tPSA	Number	Sensitivity	Specificity
<4	94	78%	91%
4-10	243	58%	91%
>10	106	80%	80%
Overall uPM3	443	67%	89%

Source: Multicenter Study of the uPM3 Test, A New Molecular Urine Assay to Detect Prostate Cancer. Saad, Aprikian, et al.

Separately, Blair Shamel, senior vice president of corporate development at DiagnoCure, tells *DTTR* that the company is in the process of negotiating a deal with a major IVD firm to help commercialize the uPM3 test. Once a deal is reached, which could be within weeks, further clinical trials and research will be pursued with a long-term goal of submitting an application for the test to the FDA, according to Shamel.

DiagnoCure, which trades on the Toronto Stock Exchange, reported a net loss of $2.4 million Canadian dollars (US $1.83 million) in the nine months ended July 31, 2003 versus a net loss of $2.9 million (US $2.2 million) in the same period a year earlier; revenue was up 60% to $491,412 (US $371,073). Up until presently, nearly all of the company's sales have come from its ImmunoCyt test to detect bladder cancer cells in urine.

If accepted, the draft guidance from Roche would expedite the time it takes to bring new tests to market because it eliminates the time needed to conduct clinical trials and have them reviewed by the FDA.

▲ Roche, Gen-Probe, Becton Dickinson Propose, *from page 1*

The draft guidance (see outline below) developed by Roche, Gen-Probe, and Becton Dickinson for creating a new category of tests called IVATs is aimed at eliminating the current uncertainty that IVD manufacturers face today when bringing ASR tests, including DNA-based microarrays, to market.

Meanwhile, David Feigal, Jr., M.D., director at the FDA's Center for Devices and Radiological Health, was a featured speaker at Washington G-2's recent Lab Institute conference in Arlington, Virginia (October 8-11). Feigal did not comment directly on the draft guidance submitted by Roche or the status of the agencies discussions with Roche concerning the marketing of its AmpliChip CYP450 microarray (*see DTTR, September 2003, pp. 1-2*).

However, Feigal did say, "There are many [ASR-labeled] tests being marketed today that are clearly not ASRs," He also observed that there are some 1,000 genetic tests available in the market today and only six or seven have been cleared for commercial sale by the FDA.

IVAT Draft Guidance in Brief

❑ **Definition of IVAT:** An in vitro diagnostic test for which analytical validity has been established. Analytical validity means the ability of a test to measure the property or characteristic that it was designed to measure.

❑ **Premarket Clearance Process:** Involves an abbreviated 510(k) submission that is focused on analytical validation, not clinical utility. For example, the analytical validity of a genetic test defines its ability to measure accurately and reliably the presence of a sequence, a change, or the genotype of interest.

❑ **Labeling:** IVAT manufacturers would not make clinical utility claims (*e.g.*, normal ranges using the assay) in their labeling, advertising, or promotional materials.

❑ **Clearance For Marketing:** Upon submission of an IVAT 510(k), the FDA would make a determination within 60 days.

Source: *DTTR* summation of In Vitro Analytical Tests (IVATs); Draft Guidance for Industry and FDA. To read the entire draft, go to: *www.fda.gov/ohrms/dockets/dailys/03/jul03/072403/03d-0334-gdl0001-vol1.pdf.*

Regarding the fact that the FDA has seemingly looked the other way at the misuse of the ASR label by many manufacturers, Feigal said the FDA simply did not have enough resources to go after all the abusers.

The most common deviations from the intent of the ASR rules include: 1) the bundling of multiple test ingredients into a single package; 2) inappropriate instructions for use; and 3) the sale of tests that require proprietary instruments, according to Feigal. Regarding a timetable for proposed rules, Feigal said, "We're still in a position of consultation. I wouldn't cancel an imminent vacation."

Meanwhile, at a recent investor conference held by UBS Securities in New York City, *DTTR* asked Manfred Baier, Ph.D., Head of German Sales Organization for Roche Diagnostics, for an update on its meetings with the FDA. Baier said that discussions with the FDA were ongoing. "It looks like we will learn product-by-product how they [the FDA] will regulate microarrays," said Baier. Other AmpliChip products that Roche hopes to introduce next year include tests for P53 (cancer), cystic fibrosis, HPV, HIV genotyping, and colorectal cancer risk prediction, according to Baier.

Separately, a spokeswoman for Roche Molecular Diagnostics (Pleasanton, CA) tells *DTTR* that the status of the AmpliChip CYP450 has not changed since the FDA's letter to the company questioning its classification as an ASR. "At his time, the FDA has not prohibited Roche from making the product available as an ASR in the United States," says the spokeswoman.

To date, no laboratories in the United States have actually begun using the AmpliChip for clinical testing, but a spokesman from Quest Diagnostics says the company is evaluating it for use at its Nichols Institute in southern California.

In terms of submitting a 510(k) for AmpliChip CYP450, the Roche spokeswoman says, "We are pleased to have this opportunity to work with the FDA as they determine the appropriate regulatory path for products in this new category. We cannot therefore attach a firm timeline to our application at this time."

But she added that Roche has plans to sponsor a research study intended to support a potential FDA filing that will use AmpliChip CYP450 in homebrew form to evaluate the correlation between 2D6 genotyping and the length, efficacy, and cost of treatment for psychiatric patients being treated for severe mental illness in an inpatient setting. She says the study will soon be announced by the institution conducting it.

Will The Self-Monitoring Blood-Glucose Market Exit Its Slump?

For years the self-monitoring blood-glucose (SMBG) market has been a fast-growing and highly profitable segment for IVD manufacturers. Between 1999 and 2002, for example, the market grew at an average annual rate of approximately 12% to reach $4.5 billion in worldwide revenue, according to *DTTR* estimates. Furthermore, most market analysts had assumed continued double-digit growth rates well into the future. The rosy outlook led one major IVD vendor (*i.e.*, Becton Dickinson) to invest tens of millions to enter the market last year.

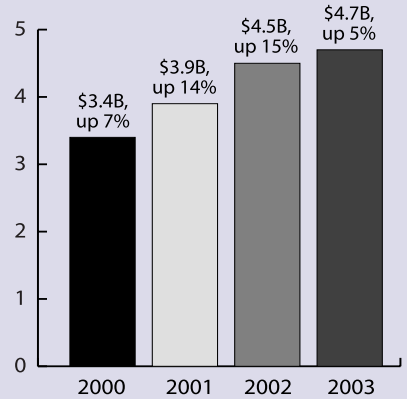
But this year the SMBG market is in a slump. Reported results from the five largest vendors (Roche, Lifescan, Bayer, MediSense, and TheraSense) for the first six months ended June 30, 2003 show combined growth of only 5% year over year. And IVD executives are now wondering whether the deceleration represents a temporary or long-term change for the market.

"We've seen lowered demand all across the world. Payers are making efforts to minimize strip usage. But the slowdown is not a real [long-term] given yet. It's too early to tell," said Manfred Baier, Ph.D., Head of German Sales Organization for Roche Diagnostics, at a recent investor conference in New York City.

In particular, executives at the major SMBG vendors tell *DTTR* that rising deductibles and co-pays at managed care plans are impacting utilization of test strips and driving some health plan members to switch to lower-cost products. In addition, SMBG execs cite a shift in buying away from retail stores toward mail order purchases, where the pricing is more competitive and inventories are leaner.

A rebound in the SMBG market is expected once the U.S. economy improves, but execs are now anticipating an 8% to 10% growth trend rather than the 10% to 15% of prior years.

Annual Growth Rates for Worldwide SMBG Market



Source: *DTTR* estimates

But David Kleff, publisher of *Diabetic Investor* (Buffalo Grove, IL), believes expectations for an 8% to 10% growth rate may still be too high. The biggest threat to the SMBG market is new longer-acting insulin drugs that are reducing the frequency of testing performed by Type I diabetics, according to Kleff. He cites Lantus, made by Adventis Pharmaceuticals (Strasbourg, France), which was launched in the United States in May 2001 and is now being rolled out across the world.

A once-per-day injection of Lantus provides a continuous level of insulin, similar to the slow, steady (basal) secretion of insulin provided by the normal pancreas. As a result, diabetics are able to lower their frequency of blood glucose testing, says Kleff. For example, insulin pump users test themselves about six to twelve times per day. But after initiating Lantus therapy

and eliminating the use of a pump, their average number of tests drops to four to six times per day, according to Kleff (who happens to be an insulin-using diabetic himself).

Even more threatening to the SMBG market is a once-per-month glucose control therapy for Type II diabetics that is being developed by Amylin Pharmaceuticals (San Diego, CA). The drug, Exenatide LAR, utilizes sustained release drug delivery technology developed by Alkermes Inc. (Cambridge, MA). Amylin has submitted an Investigational New Drug application for the drug to the FDA. Kleff believes that Exenatide LAR, if cleared for marketing, could greatly reduce the frequency of blood glucose testing now being performed by Type II diabetics. Late last year, Amylin signed a deal to have pharmaceutical-giant Eli Lilly (Indianapolis, IN) co-develop and co-market the drug.

Below we highlight the latest news at Roche, Bayer, Home Diagnostics Inc., and Hypoguard.

Roche Diagnostics (Basel, Switzerland) reports that revenue from its SMBG business grew 4% in the first half of 2003 to 1.28 billion Swiss franc (US $907 million). After adjustments for currency fluctuations and the recent acquisition of Disetronic, *DTTR* estimates that growth was about 11%. New products fueling growth have included the company's Accu-Chek Compact meter, which features a 17-test drum cartridge with test results provided in less than 10 seconds.

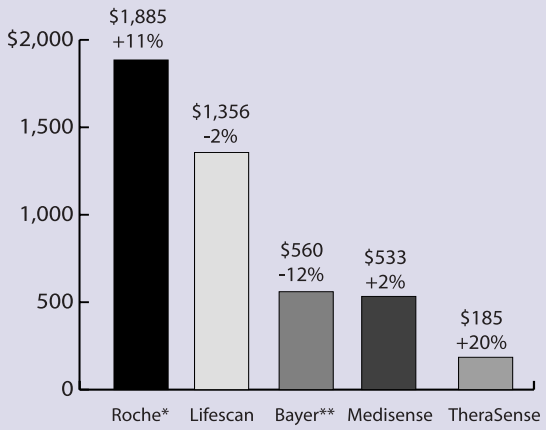
Roche has been able to grow at above-market rates in no small part because of its excellent product placement at retail store shelves and Web sites, according to Don Dumoulin, vice president of sales and marketing for diabetes care at Roche. He says that Roche is the "category captain" for SMBG at nine of the eleven largest retailers in the nation. Category captains assist retailers in understanding specific product niches such as SMBG, explains Dumoulin. In return, category captains often get choice shelf space, says Dumoulin. Of course, Roche also spends a lot on cooperative advertising programs with retailers in return for shelf space, observes *DTTR*.

Meanwhile, the big recent news for Roche's SMBG business has been its acquisition of Disetronic (Burgdorf, Switzerland) in May 2003 for $1.2 billion in cash and stock (*see DTTR, March 2003, p. 3*). Disetronic is the world's second biggest manufacturer of insulin pumps after Medtronic's MiniMed. Don Dumoulin, vice president of sales and marketing for diabetes care at Roche, says the near-term benefits of the acquisition include the ability to cross sell Accu-Chek to Disetronic's insulin pump customers and vice versa.

Longer term, Dumoulin says that the merger will speed Roche's efforts to develop an artificial pancreas which automatically tests patients' glucose levels and then delivers the correct amount of insulin to the body. "We're putting significant research and development resources toward this, but it's a significant challenge. To mimic an organ of the body is a miracle of science," he adds.

Dumoulin says that Roche is making changes at Disetronic's manufacturing plant in Switzerland in response to FDA concerns regarding documentation of

Self-Monitoring Blood Glucose Market Snapshot *(estimated 2003 revenue in millions)*



*Roche figures are based on exchange rate of 1 Swiss franc=$0.74 USD
**Bayer figures are based on exchange rate of 1 euro=$1.14 USD
Source: *DTTR* estimates (growth rates are adjusted for currency fluctuations and acquisitions/divestitures)

the manufacturing processes of the company. As a result of its concerns, the FDA issued an embargo on importation of new Disetronic insulin pumps into the United States in July, which is expected to remain in place until early next year.

On the potential for new drugs for diabetics that could reduce the frequency of testing, Dumoulin believes that only a small number of pump users will switch to Lantus and notes that Exenatide LAR is still roughly three years away from reaching the market.

Bayer Diagnostics (Tarrytown, NY) reports that sales of its Ascensia Elite product line fell 22% in the first half of 2003 to 199 million euros (US $217 million). After adjustments for currency fluctuations, *DTTR* estimates the decline was still a worrisome 12%. The recent sales decline represents an acceleration of the market share losses that Bayer has suffered over the past few years.

Ascensia Elite has been Bayer's primary SMBG product for the past 10 years and a lack of new offerings has hurt the company's market share position. However, Bayer is aiming to reverse course through the introduction of two new products, according to Joe Malta, vice president of sales and marketing for the self-test business. He says Bayer has just launched its Ascensia Breeze monitoring system in the United States. Features include a 10-test disc that eliminates the need for patients to handle individual strips and provides automatic coding.

Malta says a second new product, Ascensia Contour (cleared by the FDA in May 2003), will be launched in the United States in the first quarter of 2004. Contour is a single-strip system that does not require coding or calibration.

Malta says Bayer's SMBG advertising campaigns have focused on direct-to-consumer programs with AARP, reaching out to the Hispanic community through TV commercials on Univision, and physician education campaigns with the American Association of Diabetes Educators. An increase in marketing initiatives is planned for next year, adds Malta.

Over the past two years, **Home Diagnostics Inc.** (HDI—Fort Lauderdale, FL) has restructured its business model away from smaller independent pharmacies and mail order catalogues toward co-branding agreements with big pharmacies and retail store chains. The transition has slowed growth at HDI, which will generate $80 million to $100 million of revenue this year, but is now complete, Dick Damron, chief executive, tells *DTTR*.

Damron says HDI now has co-branding agreements with most big pharmacy and retail stores in the nation, including Walgreen's, Eckerd, CVS, Longs, Duane

Reade, The Medicine Shoppe, Pathmark, Weiss Pharmacy, Kmart, Shop Rite, and Publix.

As consumers become more price conscious due to rising deductibles and co-pays. HDI will ultimately gain a big share of the SMBG market, says HDI's Greg Johnson

Under the HDI model, packaging for the company's Prestige glucose meters and strips includes the retail store's name, and retail prices for the strips are 30% to 40% lower than competing strips from the major SMBG vendors (*see chart*).

Despite the lower price, Greg Johnson, vice president of marketing, claims that retailers earn higher profits by selling Prestige products. For example, he says that HDI sells a 50-count package of Prestige test strips to retailers for about $15, leaving roughly $11 of gross profit to the retailer (i.e., $25.99 minus $15=$10.99 gross profit). The branded strips provide only about $6 to $7 in gross profit per 50-count package to retailers, according to Johnson.

Meanwhile, Damron notes that HDI received FDA clearance to market its new TrueTrack Smart System, which is the company's first meter using biosensor technology, in July. He says HDI is in the process of rolling out TrueTrack to store shelves with a retail price of $28.99 per 50 test strips.

Finally, Damron notes that HDI is seeking to expand in Europe and recently signed a distribution agreement with the German firm Stada Arzneimittel. Stada, which markets generic drugs in Europe, will co-brand, market and distribute Prestige meters and strips in Germany, Austria, France, Belgium, Ireland, Italy, and Spain. Damron adds that HDI has an existing distribution agreement covering the Nordic countries with the Sweden-based specialty pharmaceutical company Meda.

Retail Prices For 50 Test Strips

Bayer Ascensia Elite	$47.99
LifeScan OneTouch Fast Draw	$46.99
Medisense Precision Xtra	$46.99
TheraSense Freestyle	$45.99
Roche Accu-Chek Comfort Curve	$43.99
HDI TrueTrack	$28.99
HDI Prestige	$25.99

Source: Walgreens.com

Hypoguard (Edina, MN), a division of Medisys PLC (London, England), introduced its NewTek Blood Glucose Monitoring system in the United States at the Annual Meeting of the American Association of Diabetes Educators in Salt Lake City in August.

NewTek is the first disposable meter. It contains 100 test strips pre-loaded and pre-calibrated. Hypoguard will market NewTek exclusively through Wal-Mart and Sam's Club under the ReliOn brand, which will continue to include traditional meters and strips made by Medisense.

DTTR has learned that NewTek will first be rolled out in January 2004 at stores in the Southeast, including Florida, Mississippi, Alabama, North Carolina, and Virginia. Specific pricing information for NewTek is not yet available; however, an informed source tells *DTTR* that the product will be priced less than the average $80 to $85 that traditional 100 test strip packages sell for.

The Wal-Mart agreement represents a big push on the part of Hypoguard to break into the retail segment of the SMBG market. Hypoguard currently generates some $50 million in annual revenue from SMBG products in the United States with the majority from sales to long-term care facilities.

Jury Awards $934 Million To Beckman, But Will It Stick?

A southern California jury has ordered Flextronics International (Singapore) to pay $934 million to Beckman Coulter (Fullerton, CA) after finding that the contract manufacturing company had pressured Beckman to pay exorbitant prices for circuit boards.

Beckman had argued that Flextronics, which agreed to a five-year contract in 1997, forced it to pay an extra $650,000 and concealed a $350,000 overpayment for production of a component for its LX20 chemistry analyzer. Attorneys for Beckman said Flextronics pulled out of the contract in May 2000, during booming demand for electronics parts, so it could make cell-phone chips for Motorola.

The jury award, which was affirmed by Orange County Superior Court Judge Gregory Lewis on September 30, includes $3 million in compensatory damages and $931.4 million in punitive damages. The bulk of the punitive damages award is $750 million for economic duress stemming from a charge that Flextronics refused to release inventory parts owned by Beckman unless the company paid for additional parts it did not need.

In a statement, Michael Marks, chief executive of Flextronics, said, "We intend to mount a vigorous challenge of this run-away jury verdict, and are fully confident that this award will be almost entirely eliminated in subsequent legal proceedings....That this irrational verdict could be rendered, even if subsequently corrected, exemplifies the need for reform of a legal system in which juries are allowed to impose absurd punitive damages." Further, Marks said that the award was particularly surprising in light of the testimony by Beckman witnesses that Flextronics did nothing intentionally wrong in the business relationship, which amounted to less than $20 million of revenue over three years. He said that Flextronics will contest the award and ultimately expects to pay no more than $10 million.

Judge Lewis has stayed the enforcement of jury decision pending post trial motions, which are scheduled to be heard on November 25. In addition, lawyers for both sides say they are now in settlement discussions.

FTC Clears The Way For Roche's $1.4 Billion Purchase Of Igen

The Federal Trade Commission has given the green light to Roche's planned acquisition of Igen International (Gaithersburg, MD). The $1.4 billion deal is expected to be completed by year's end.

As previously disclosed (*see DTTR, September 2003, p. 1*), the acquisition will provide Roche with fully paid-up worldwide rights to commercialize Igen's Origen technology, which is the backbone of its Elecsys product line.

Igen shareholders will get $47.25 in cash plus one share of a new spin-off company that will be named BioVeris Corp. for each share of Igen they own. BioVeris will own the Origen technology and be able to market products to the entire clinical diagnostics market, including the hospital, blood bank, reference lab, and physician office markets.

BioVeris at a Glance *($ millions)*

	2003	2002
Revenue	$17.774	$13.243
Cash flow from operations	-33.105	-34.176
Capital expenditures	-3.331	-5.642
Free cash flow	-36.436	-39.818
Net loss	-50.894	-49.150

Source: BioVeris's SEC registration statement

The M1-M Clinical Analyzer for physician-office testing is the first clinical diagnostic system being developed by BioVeris. The initial commercial focus will be to provide cardiac assays that test for heart attack and congestive heart failure. BioVeris also intends to pursue opportunities in the clinical reference laboratory and central hospital laboratory market segments through collaborative arrangements.

In addition, BioVeris will maintain Igen's existing biodefense and life science businesses, where the company's M-Series instruments are already being used by the Department of Defense, pharmaceutical and biotechnology researchers, and scientists at academic and government research institutions.

In the fiscal year ended March 31, 2003, BioVeris generated a net loss of $50.9 million versus a net loss of $49.2 million in the same period a year earlier; revenue increased 34% to $17.8 million. The company, which will trade on the Nasdaq, is currently being valued at $276 million (*i.e.*, Igen's current share price of $57.60 minus $47.25 multiplied by 26.7 million shares=$276 million).

Tm Bioscience To Supply Mayo With P450-2D6 Microarrays

Tm Bioscience Corp. (Toronto, Canada) has signed a two-year agreement to supply Mayo Medical Laboratories (Rochester, MN) with the company's Tag-It P450-2D6 drug metabolism test. Mayo Medical Labs operates one of the top five reference testing businesses in the nation with estimated revenue of $150 million to $200 million per year.

Tm Bioscience's P450-2D6 test is a liquid microarray that runs on the Luminex xMap system. Initially, the test is being marketed on a research-use-only (RUO) basis, according to the company's chief financial officer Jim Pelot. He expects the company to get ISO 13485 and QSR certification by year's end, so that it can offer the test in ASR form.

Pelot says Mayo has already started their internal validation process for the test. He says reagents for P450-2D6 will sell for less than $100 per test mix.

In addition, Tm Bioscience has launched its 40-mutation Tag-It Mutation Detection Kit for Cystic Fibrosis (CF40) and announced it has already sold more than 4,000 CF40 tests. "We expect the CF40 test to be our flagship product for the next several years as this market continues to grow and mature."

In addition, Tm Bioscience has launched its 40-mutation Tag-It Mutation Detection Kit for Cystic Fibrosis (CF40) and announced it has already sold more than 4,000 tests. The test is being marketed on an ASR basis. Industry-wide CF genetic testing volumes (now estimated at more than 1 million per year) have rocketed since the American College of Obstetricians and Gynecologists issued guidelines in October 2001 recommending that all Caucasian women who are pregnant or considering having a baby be screened for CF gene mutations.

IVD Stocks Dip 2% In Latest 4 Weeks; Biosite Crashes 41%

***Roche** non-voting equity shares, which trade on the Zurich stock exchange, are up 16% to 112 Swiss francs so far this year. Shares of **Bayer**, which trade on the German stock exchanges, are down 6% to 19.17 euros.*

The 20 stocks in the G-2 Diagnostic Stock Index fell an unweighted average of 2% in the four weeks ended Sept. 26, 2003, with 12 stocks up in price, two unchanged, and six down. Year to date, the G-2 Index is up 57%, while the S&P 500 Index is up 13% and the Nasdaq is up 34%.

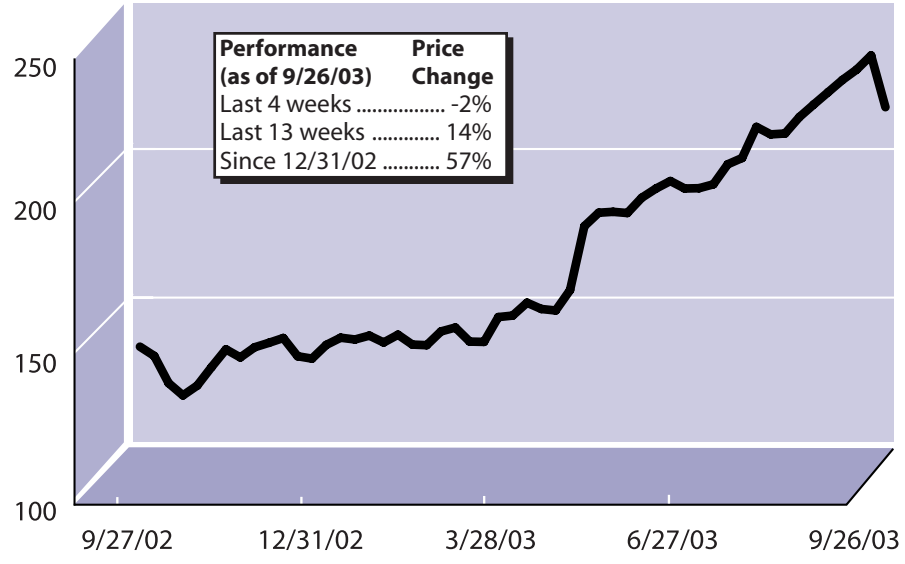
Shares of **Biosite** (San Diego, CA) tumbled 41% to $27.48 per share for a market cap of $459 million. The company recently lowered its revenue projection for 2003 because of a shortfall in sales of its Triage BNP Test, a point-of-care test for diagnosing heart failure. Biosite had anticipated its total revenue would grow 65% to 80% this year to $174 million to $190 million, but now expects growth of 60% to 65% to $168 million to $174 million.

Triage BNP Test sales account for more than half of Biosite's total revenue and had been growing at an annual rate of more than 300% through the first six months of this year. On a Sept. 24 conference call, Kim Blickenstaff, president of Biosite, said increased competition from automated BNP tests made by Roche and Bayer have flattened out the growth in Triage BNP.

Roche launched its proBNP test late last year and Bayer announced FDA clearance for its BNP test on the Advia Centaur system in June 2003. Furthermore, *DTTR* notes that Abbott is aiming to have a BNP test on the U.S. market early next year.

Blickenstaff said the Biosite sales team was spending a lot of time defending existing hospital accounts that were considering moving to the Roche or Bayer product. "So far Bayer and Roche have been reasonably disciplined on price....If absolutely necessary we will move on price," said Blickenstaff. He also noted that Biosite has an agreement with Beckman Coulter to develop an automated BNP test for use on Beckman's immunoassay systems.

G-2 Diagnostic Stock Index



Source: The G-2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 20 IVD companies.

% Price Change, 4 weeks ended 9/26/03

	Price	*% Chg*
UP		
Abbott Labs	$42.35	5%
Beckman Coulter	44.65	1%
Cytyc	14.33	10%
Digene	41.02	8%
Immucor	28.71	15%
Inverness Medical	23.60	3%
i-STAT	13.28	21%
Quidel	6.41	2%
UNCHANGED		
Bio Rad	51.00	0%
DOWN		
Biosite	27.48	-41%
Cholestech	7.91	-13%
Dade Behring	27.69	-1%
Gen-Probe	51.70	-18%
Igen	57.60	-1%
Diagnostic Products	35.65	-6%
Becton Dickinson	35.52	-3%
Johnson & Johnson	49.18	-1%
Meridian	9.87	-6%
TheraSense	12.50	-12%
Ventana	39.58	-2%

G-2 Insider

Effective September 30, Bayer Group (Leverkusen, Germany) says its Healthcare unit, which includes its pharmaceuticals, over-the-counter drugs, and the diagnostic business, is operating as a legally independent corporate unit. The move, which was first announced in late 2001 (*DTTR, January 2002, p. 4*), could facilitate a major overhaul for the conglomerate that could include divestitures, mergers, or joint ventures.

For several years now, investors have been pressuring Bayer to either sell or spin-off its healthcare unit (*DTTR, April 2001, p. 1*), which is still reeling from the withdrawal in August 2001 of its blockbuster cholesterol drug Baycol. And, with the new structure in place, the path is clear for Bayer to act.

Indeed, Bayer has already announced plans to sell its North Carolina-based blood plasma business, which, as part of the company's healthcare unit, posted revenue of 293 million euros (US $344 million) in the first half of this year.

A Bayer spokesman would not comment on any potential plans for the company's healthcare business. However, *DTTR* speculates that a possible scenario could include the sale of Bayer's pharmaceutical business to a bigger competitor (perhaps Britain's GlaxoSmithKline or Germany's Schering AG), followed by a spinoff of the diagnostics unit.

This would not be the first time this type of scenario was played out. For example, Pfizer acquired Pharmacia in April 2003 and has now put Pharmacia Diagnostics up for sale (*see DTTR, August 2003, p. 10*).

Think I'm all wet? You can write me at *labreporter@aol.com*
Jondavid Klipp, managing editor

Company References

Bayer Diagnostics
914-631-8000

Beckman Coulter
714-871-4848

Biosite 858-455-4808

Bostwick Labs 800-214-6628

Diabetic Investor

DiagnoCure 418-527-6100

Home Diagnostics Inc.
954-677-9201

Hypoguard 952-646-3200

Igen 301-869-9800

Roche Diagnostics
317-849-9350

TM Bioscience 416-593-4323

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