Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

Veridex, Immunicon Launch CellSearch For Metastatic Breast Cancer Management

In the last issue of *DTTR*, we highlighted two new exciting breast cancer management tests that are just reaching the market. In this issue, we're highlighting a third, CellSearch, that may even have a stronger chance of hitting it big in the lab industry.

We say this for three reasons: 1) the test has received FDA 510k clearance for metastatic breast cancer; 2) it has a strong distributor: Veridex LLC (Warren, NJ), a Johnson & Johnson subsidiary; and 3) labs are expected to charge payers a reasonable price ($300-$400) for performing the test.

CellSearch has been developed by Immunicon (Huntington Valley, PA), which has spent more than $100 million over the past 10 years on the technology behind the test. Immunicon's CellSearch allows physicians to isolate and quantify circulating tumor cells within blood to help determine whether a particular line of therapy is working or not. Ed Erickson, chief executive, tells *DTTR* that Immunicon has studies underway for CellSearch tests for other forms of cancer, including prostate, colorectal, and lung cancer. For full details, see *Inside the Diagnostics Industry*, pp. 5-8.

Pricing for Various New Breast Cancer Tests

Vendor/Test Name	*Test Price*
Veridex/CellSearch	$350
Genoptix/CancerTrax	$1,495
US Labs/TAM Test	$1,500
Genomic Health/OncotypeDX	$3,460

Source: *DTTR* from companies

Worldwide IVD Sales Growth Accelerating In 2004

Worldwide IVD sales grew by 7% to $12.6 billion (excluding the effect of currency changes) in the six months ended June 30, 2004, according to an exclusive analysis by *DTTR* of financial reports from the 12 largest reagent manufacturers. Our estimate assumes that the 12 largest companies held an 85% share of the market with the remaining 15% held by hundreds of smaller companies. The 7% growth for first-half 2004 marks a significant acceleration from the 5% growth that IVD companies posted for full-year 2003 (see *DTTR*, May 2004, page 10). In the United States, the leading reagent manufacturers have also posted year-to-date growth of 7%. ➥ *p. 2*

▲ **Worldwide IVD Sales Growth Accelerating,** *from page 1*

The fastest-growing major IVD company in first-half 2004 was **Sysmex Corp.** (Kobe, Japan), which grew by 20% to $326.7 million. The company says that domestic sales of its hematology instruments and reagents are exceeding expectations and that sales in Europe and the United States (where the company started direct sales and service in July 2003) are also strong.

The next fastest grower was **Cytyc Corp.** (Boxborough, MA), which grew first-half 2004 worldwide revenue by 16% to $180.2 million (excluding the effect of currency changes and the recent acquisition of Novacept). Cytyc's revenue in the United States was up 17% to an estimated $171 million, or 95% of total sales.

Diagnostic Products (DP—Los Angeles) grew its worldwide revenue by 12% to $216.5 million. DP's revenue in the United States was up 19% to $61 million, representing 29% of the company's total sales.

Johnson & Johnson (New Brunswick, NJ), including Ortho-Clinical Diagnostics and LifeScan, grew its revenue by 10%. J&J also had the biggest turnaround when compared with the moribund 1% growth it posted in full-year 2003. J&J's most vibrant diagnostic segment was LifeScan (Milpitas, CA), which grew its worldwide sales by 16% to $820 million in first-half 2004. J&J's revenue in the United States was up 11% to $756 million.

Top 12 IVD Manufacturers' Worldwide Revenue ($ millions)

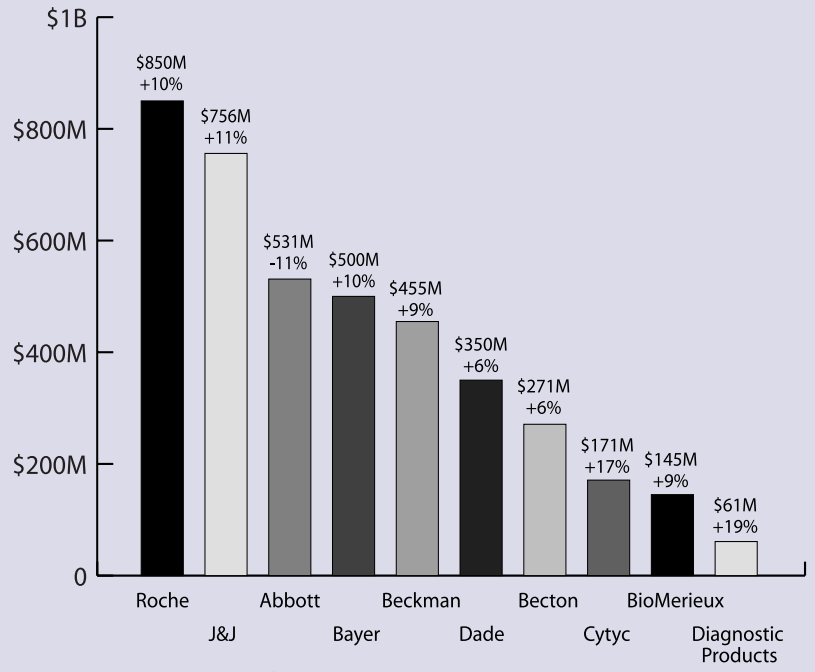
Company	First-Half 2004 Revenue	First-Half 2003 Revenue	Unadjusted % Chg	Adjusted % Chg*	Mid-2004 Market Share
Roche Diagnostics[1]	$2,834	$2,600	9%	9%	22%
Abbott Diagnostics	1,607	1,479	9%	-3%	13%
Johnson & Johnson	1,439	1,259	14%	10%	11%
Bayer Diagnostics[2]	1,154	1,098	5%	7%	9%
Beckman Coulter[3]	816	722	13%	10%	6%
Dade Behring	770	704	9%	4%	6%
Becton Dickinson[4]	565	506	12%	7%	4%
BioMerieux[5]	557	541	3%	7%	4%
Sysmex[6]	327	279	17%	20%	3%
Bio-Rad Labs7	283	253	12%	5%	2%
Diagnostic Products	217	183	18%	12%	2%
Cytyc Corp.	180	149	21%	16%	1%
Top 12 total	10,749	9,774	10%	7%	85%
Other IVD companies	1,897	1,725	10%	7%	15%
Total IVD Market	12,646	11,499	10%	7%	100%

*Excludes effect of currency changes and acquisitions

(1) Roche revenue excludes applied science segment and is based on exchange rate of $1 USD=1.27 Swiss francs. (2) Bayer revenue is based on exchange rate of $1 USD=0.827 euros. (3) Beckman revenue excludes biomedical research segment. (4) Becton Dickinson revenue includes diagnostic systems and flow cytometry. (5) BioM revenue is based on exchange rate of $1 USD=0.827 euros. (6) Sysmex revenue is from company forecast issued on August 3 for the six-month period April 1 to September 30 and is based on an exchange rate of $1 USD=110 Yen. (7) Bio-Rad revenue excludes life science segment.

Source: *DTTR* from company financial reports

U.S. Revenue for 10 Leading IVD Vendors *(First-half 2004)*



Source: *DTTR* estimates and company reports

Beckman Coulter (Fullerton, CA) grew its worldwide clinical diagnostics business by 10% to $816.4 million; sales in the United States increased by an estimated 9% to $455 million.

Roche Diagnostics (Basel, Switzerland) remains the largest IVD company with a 22% market share. The company reported $2.8 billion of revenue in first-half 2004, up 9%. Roche's fastest-growing diagnostics business area was molecular diagnostics, which grew by 13% to $423 million. Roche's slowest-growing division was near-patient testing, which was up 1% to $215 million. In the United States, Roche reported sales growth of 10% to reach approximately $850 million.

The only big IVD company to record declining sales was **Abbott Diagnostics** (Abbott Park, IL), which reported $1.6 billion in revenue, down 3% after adjustments for currency and the effect of the acquisitions of TheraSense and i-Stat. Abbott's sales in the United States fell 11% to $531 million (see *DTTR*, September 2004, pp. 3-4).

Roche's AmpliChip Gets CE Mark

Roche (Basel, Switzerland) has received a CE mark (Conformite Europeene) for its AmpliChip CYP450, making it the first microarray, or DNA chip, to be cleared for clinical diagnostic use in Europe. The test detects genetic variations in the Cytochrome P450 2D6 and 2C19 genes, which play a major role in the metabolism of many widely prescribed drugs. Results can be used by physicians as an aid for selecting drugs and individualizing treatment doses.

AmpliChip CYP450 is run on the GeneChip System 3000Dx, which is made by Affymetrix (Santa Clara, CA). The GeneChip System has also received a CE mark.

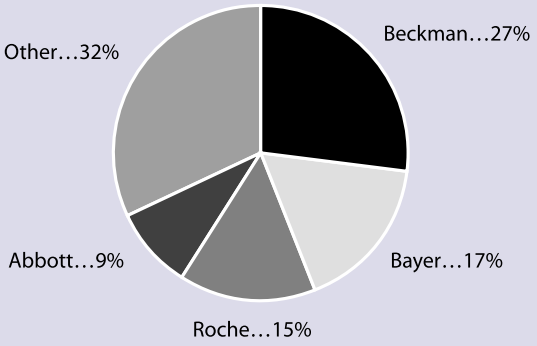
Roche had tried to introduce its AmpliChip CYP450 microarray in the United States last year as an analyte specific reagent (ASR), but the FDA stepped in and has demanded a premarket review (see *DTTR*, September 2003, pp. 1-3). Roche is now expected to submit an application to market the test in the United States under the FDA's de novo classification (more formally known as a Class III desigination).

The designation of Class III status for Roche's AmpliChip CYP450, or a competing product, would mark the first time the FDA has cleared a microarray for sale to the clinical market.

UBS Survey Says Beckman Leads In Automation

A survey of 173 hospitals and independent labs conducted by the investment banking firm UBS (New York City) shows that Beckman Coulter (Fullerton, CA) is likely to lengthen its lead in lab automation placements over the next 12 to 24 months. According to the UBS survey, Beckman ranked first with respondents considering adopting automation, with 27% (36/132) of labs indicating that they were considering a Beckman system. Bayer Diagnostics ranked second with 17% (22/132 respondents), Roche ranked third with 15% (20/132 respondents), and Abbott was fourth with 9% (12/132 respondents).

Potential Automation Placements by Vendor



Source: UBS Laboratory Automation Survey

The UBS survey had 173 respondents, including hospital labs (60%: 104/173), independent labs (15%: 26/173), physician office labs (2%: 3/173), and other labs (23%: 40/173). The other group included pharmaceutical labs, government labs, university hospitals, and 24 respondents that did not indicate their lab type. Average annual volume across all respondents was 3.7 million tests.

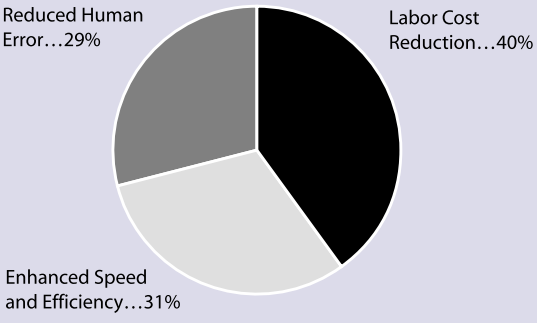
The survey showed that 65% of the respondents who implemented automation rated it at least 4 on a scale of 1-5 in terms of overall satisfaction.

Satisfaction Among Automation Users *(1-5, with 5 Highest)*

Rank	*% Respondents*	*Number of Respondents*
5	16%	8
4	49%	24
3	33%	16
2	2%	1
1	0%	0
Total		49

Source: UBS Laboratory Automation Survey

Drivers of Laboratory Automation



Source: UBS Laboratory Automation Survey

Labor cost reduction was the most important driver of lab automation, when survey respondents were asked to choose among: 1) labor cost reduction (40%); 2) enhanced speed and efficiency (31%); and 3) reduced human error (29%). Other drivers of automation reported by respondents included greater flexibility of systems, declining cost for automation systems, and the ability to more effectively integrate into a lab information system.

Other survey findings showed that 40% (20/50) of those who have implemented automation solutions have 50% or more of their analyzers from their automation vendor. And 83% (135/162) of respondents believe automation is becoming more important in the lab.

CellSearch Poised For Widespread Adoption By Oncologists

Circulating tumor cells have been known to exist since 1869, but CellSearch represents the first tumor cell-counting technology that is fully automated and standardized.

Immunicon's CellSearch system was cleared by the FDA under its *de novo* classification process on Jan. 21, 2004, for use on breast cancer patients to help determine the effectiveness of their treatment. CellSearch helps find cancer cells that have detached from solid tumors and entered the blood stream. These circulating tumor cells (CTCs) are then counted by a pathologist with the aid of Immunicon's CellSpotter Analyzer.

The *New England Journal of Medicine* (*NEJM*—351; 781-791, Aug. 19, 2004) recently published results from a multicenter study that showed that the number of CTCs can predict progression-free and overall survival for women with metastatic breast cancer.

In an editorial published in the same issue of the *NEJM*, Stephen Braun, M.D., and Christian Marth, M.D., of Innsbruck Medical University (Austria), one of Europe's premier medical research institutions, predicted that the CellSearch technique would become a widespread diagnostic tool for treating breast cancer patients. "Measurement of circulating tumor cells predicts a response to treatment much more quickly than our usual clinical practice, which in the best of circumstances permits a treatment evaluation after two to three months," Braun and Marth said.

The timing of the *NEJM* articles couldn't have been better for Immunicon and Veridex, which announced official commercial launch of CellSearch for diagnostic use in metastatic breast cancer patients on August 20. Mark Myslinski, general manager of Veridex, which is distributing the test, tells *DTTR* that initial marketing efforts will be focused on the nation's leading cancer centers (e.g., M.D. Anderson Cancer Center, University of Michigan Comprehensive Cancer Center, etc.) and the leading reference labs like Quest Diagnostics, LabCorp, ARUP Labs, Mayo Labs, and Specialty Labs.

Myslinki would not reveal Veridex's instrument placement goals for CellSearch. But Benner Ulrich, an analyst at UBS Investment Research (New York City) who covers Immunicon, has projected 24 placements by year's end and another 53 placements in 2005.

Edward Erickson, chief executive of Immunicon, which developed the CellSearch technology in collaboration with Veridex, believes the test's relatively low price will help speed adoption. With labs expected to charge $300 to $400 per test, he points out that CellSearch is well below the $500 to $2,000 cost for common imaging procedures (e.g., CT scans, MRIs, and PET scans) used for therapeutic monitoring. It's also well below the $1,495 to $3,460 that some of the newer gene-based breast cancer tests are priced (see table on page 1), notes *DTTR*.

Furthermore, Myslinski says that the CellSearch technology can be applied to other cancers. He says that a CellSearch test for prostate cancer is furthest along in development.

On pages 6-8 we highlight some key points about CellSearch technology, its clinical applications, and the economics behind it all:

Immunocon is in the process of getting FDA approval for its next-generation automated analyzer, which will double the number of test performed per shift to 12 tests.

How Does CellSearch Work?

1) A 7.5-milliliter sample of blood is drawn from a patient and placed in Immunicon's CellSave Preservative Tube—a Class 2 device that contains a preservative that keeps the cancer cells in each sample stable for up to 72 hours.
2) A laboratory receives the specimen and loads it into the CellTracks AutoPrep System.
3) CellTracks treats the specimen with the CellSearch reagents. Tiny, protein-coated magnetic balls mark the cancerous cells. The candidate cells are stained with fluorescent markers for precise identification.
4) The labeled sample is dispensed into a cartridge for analysis.
5) A strong magnetic field is applied to the mixture, causing magnetically marked cells to move to the cartridge surface.
6) The CTCs in the cartridge are then identified by the CellSpotter Analyzer, a semi-automated fluorescence microscope.
7) A pathologist or cytotechnologist rechecks their identification, and CellSpotter tallies the final CTC count.
8) Results are forwarded to the patient's oncologist. The more CTCs in the sample, the less effective the cancer treatment is.

The *New England Journal of Medicine* Article

The study results recently published in the *NEJM* were based on an evaluation of 177 metastatic breast cancer patients at 20 different cancer centers who were about to either start initial therapy or change to a new course of therapy. Patients were tested for a CTC count before therapy and then again at the first follow-up approximately three to four weeks later.

Patients with five or more CTCs per 7.5 milliliter, as compared with the group with fewer than five CTCs, ultimately had a shorter median progression-free survival (2.7 months vs. 7.0 months) and shorter overall survival (10.1 months vs. >18 months).

Further, the study showed that the percentage of patients with more than five CTCs was reduced from 49% (87 women) to just 30% (49 women) at first follow-up—an indication that a number of patients responded to therapy.

"The results showed the presence of circulating tumor cells to be the strongest independent predictor of progression-free and overall survival," said lead author Massimo Cristofanilli, M.D., associate professor in the Department of Breast Medical Oncology at the University of Texas M. D. Anderson Cancer Center in Houston.

Currently patients go through several rounds of treatment before it is known whether or not the therapy is working. According to Daniel Hayes, M.D., clini-

cal director of the Breast Oncology Program at the University of Michigan Comprehensive Cancer Center and the study's senior author, "One of the most problematic aspects of managing cancer is determining the fine lines dividing an effective course of therapy from one that is futile. The CellSearch System may significantly advance our ability to more accurately define those lines and more effectively manage cancer therapy. We are planning further studies to precisely define the role of monitoring CTCs in women with metastatic disease."

The study was funded by Immunicon and several of the company's researchers were involved in the study.

The Economics behind CellSearch

Immunicon has an exclusive worldwide distribution agreement with Veridex Corp. (a J&J subsidiary) for its cancer products. Under the agreement, Veridex is in charge of all sales and marketing of CellSearch, including final labeling and packaging, and Veridex was responsible for guiding CellSearch through the application process with the FDA.

Economics of CellSearch

Lab reagent cost:	$175.00
Veridex gets:	122.50
Immunicon gets:	52.50
Lab charges:	350.00
Gross profit to lab:	$175.00

Source: *DTTR*

Veridex's Myslinski tells *DTTR* that CellSearch reagents and supplies will be sold to laboratories at a list price of $175 per test with little, if any, discounting. Veridex will keep 70% (or $122.50 per test) of net sales, and Immunicon will get 30% ($52.50).

The instrumentation (AutoPrep and CellSpotter) for CellSearch will have a list price of $120,000, and Veridex, which is responsible for placement, will keep 15% ($18,000 per system) of net sales; Immunicon will get 85% ($102,000).

As mentioned earlier, labs are expected to charge in the range of $300 to $400 for each test they perform. CellSearch is not currently covered by the Centers for Medicare and Medicaid Services (CMS) or managed care. Veridex is responsible for securing coverage decisions. Myslinski says CellSearch will need to have more published results and establish national clinical demand before Veridex will seek a coverage decision and individual CPT code for the test.

In the meantime, UBS's Ulrich believes the test can be reimbursed under a collection of codes for morphometric imaging, immunohistochemistry, and immunocytochemistry, for total reimbursement in the range of $200 to $400. But He estimates that it will take several years before CellSearch gains broad third-party reimbursement coverage, which is primarily the responsibility of Veridex.

Reimbursement for CellSearch

Procedure	*CPT Code*	*Amount**
Morphometric imaging	88361	$153.41
Immunohistochemistry	88358, 88342	$174.86
Immunocytochemistry	88342	$92.20

*based on average reimbursement in select sates (CT, NY, FL, AZ, CA)

Source: CMS, UBS estimates

More about Immunicon and Veridex

Mark Myslinski, age 49, general manager of Veridex, was formerly president of Interscope Technologies (Pittsburgh)

Edward Erickson, age 58, became chief executive of Immunicon in March 1999; he had previously served as CEO of DepoTech Corp., a pharmaceutical company.

Immunicon was founded in August 1983 by Paul Liberti, Ph.D., a former professor of biochemistry at Thomas Jefferson Medical College. Since inception, Immunicon has accumulated $77.3 million of losses, including a $13.7 million loss for the six months ended June 30, 2004.

In August 2000, Immunicon entered into a development, license, and supply agreement with Ortho-Clinical Diagnostics, a Johnson & Johnson (J&J) company, which subsequently assigned all rights and obligations under the agreement to Veridex, another J&J company. J&J has invested $11.3 million in Immunicon and holds a 7.8% stake.

Veridex has worldwide commercialization rights to all cancer tests using Immunicon's technology. Immunicon is required to invest 8.5% to 10% of revenues generated from the relationship into cancer-related research and development.

However, Erickson says that Immunicon has retained commercialization rights to all non-cancer applications and is developing tests in the area of cardiovascular disease and fungal disease detection.

Immunicon raised $55 million from an initial public offering in April 2004 of 6.9 million shares priced at $8 per share. The company had $67.6 million of cash on its balance sheet as of June 30, 2004. Through Aug. 30, 2004, Immunicon shares have risen 10% to $8.76.

Separate from its agreement with Immunicon, Myslinski says Veridex is currently working with Johnson & Johnson Pharmaceutical Research & Development (PRD—La Jolla, CA) to develop the company's GeneSearch technology, which will be able to determine such things as the presence and tissue origin of cancer cells. He says several applications for the GeneSearch technology are now under development, including an intra-operative assay for sentinel lymph node testing during breast cancer surgery.

Veridex is also working with PRD to pursue the identification of a profile that specifies which patients with refractory leukemia are more likely to respond to Zarnestra (tipifarnib), under development for the treatment of hematologic malignancies and other cancers.

Immunicon in Brief

Founded:	1983
Headquarters:	Huntington Valley, PA
Chairman and CEO:	Edward Erickson
Chief scientific officer:	Leon Terstappen, M.D., Ph.D.
Employees:	113
Market capitalization (8/30/04):	$192.8M
Accumulated losses (6/30/04):	$77.3M*
Cash holdings (6/30/04):	$67.6M*
Biggest stockholders:	TL Ventures, Caanan Partners, Johnson & Johnson

Source: *DTTR* from Immunicon

BioMerieux Addressing FDA Concerns In Durham

BioMerieux (Marcy l'Etoile, France) is "aggressively" working to resolve issues raised by an FDA inspection of the company's Durham, North Carolina facility this past spring, says Herb Steward, senior vice president for North American commercial operations at BioMerieux.

Following the inspection, the FDA suspended applications for new approvals of Class III products from the Durham site (see *DTTR*, September 2004, pp. 2-3). Steward says the issues relate to process standardization, validation of products, and organizational structure at the facility. BioMerieux manufactures blood culture, hemostasis, and immunodiagnostics products in Durham, where it employs 550 people, but the facility has no Class III products currently in the pipeline that will be affected by the FDA's action, according to Steward.

Separately, Steward tells *DTTR* that BioMerieux's recent initial public offering on the Paris stock exchange will have little impact on the company's North American operations. He says BioMerieux has no immediate plans to raise capital or get listed on the New York Stock Exchange or Nasdaq.

BioMerieux reports that its North American revenue was 120.3 million euros (US $145.8 million) in the six months ended June 30, 2004, up 9% (excluding the effect of currency changes). Steward says that BioMerieux expects long-term growth of 5% to 7% in North America. Key upcoming product launches include the Stellara software system, which will interface BioMerieux's BacT/Alert and Vitek analyzers directly with individual electronic patient records so that clinicians can access test results on a real-time basis, according to Steward.

Finally, BioMerieux says that it has promoted Philippe Sans from the position of president of U.S. operations to senior corporate vice president of North American and Asia/Pacific operations. Eric Bouvier has been named president and chief executive of North American operations and will report to Sans.

BioVeris Settles Lawsuits Against Chief Executive's Son

BioVeris Corp. (Gaithersburg, MD) has announced that it has settled two lawsuits against Jacob Wohlstadter, who is the son of BioVeris CEO Samuel Wohlstadter.

BioVeris had accused Jacob Wohlstadter of spending $7 million from a joint venture named Meso Scale Diagnostics (MSD) to buy luxury cars and a New York City condominium (see *DTTR*, August 2004, p.4).

MSD was set up nine years ago by Jacob Wohlstadter to adapt immunoassay technology developed by his father's company BioVeris (formerly named Igen International) into drug discovery instrument systems for pharmaceutical companies and researchers. BioVeris owns a 31% stake in MSD and has invested $115 million in the joint venture since it was formed in 1995. Jacob Wohlstadter owns the other 69% of MSD.

BioVeris was spun off from Igen International when Igen was purchased by Roche Diagnostics for $1.25 billion earlier this year.

As part of the settlement, BioVeris has paid the joint venture $5 million for various licensing obligations and agreed to sell its stake in the venture to Jacob Wohlstadter for a fair market value less an agreed upon discount. BioVeris expects an appraisal of MSD to be completed by October 2004.

In an August 13 press release, BioVeris said that settlement of the lawsuits will allow the company to "file our annual report, proceed with the sale of our interest in MSD, and avoid the costs and distractions of protracted litigation."

On August 16, BioVeris reported a net loss of $93.3 million for its fiscal year ended March 31, 2004, versus a net loss of $50.9 million in fiscal year 2003; revenue increased to $20 million versus $17.8 million. The fiscal-year 2004 loss included $75.7 million in merger-related costs from its deal with Roche Diagnostics (see *DTTR*, September 2003, page 1) and another $19.6 million was due to BioVeris's share of losses from its stake in MSD.

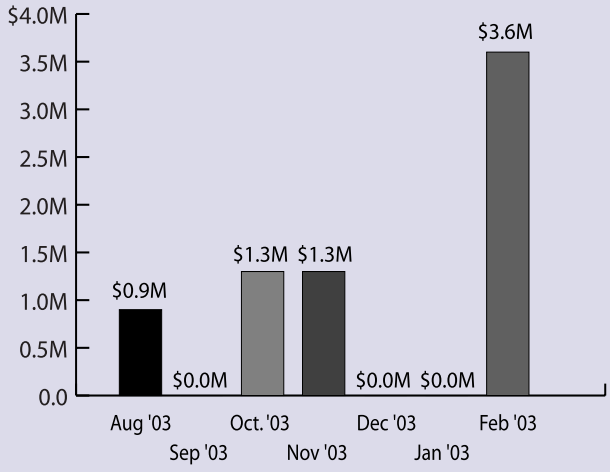
BioVeris's year-end report also showed that Samuel Wohlstadter earned a salary of $422,500 and a bonus of $1.27 million for fiscal 2004.

Diagnostic Products Receives Subpoena

Diagnostic Products (Los Angeles) has received a subpoena from the U.S. Attorney's Office to produce to a Federal Grand Jury documents relating to trading in the company's stock by employees, officers, and directors in early 2004 as well as documents related to the FDA's review of the company's application for a test to detect Chagas.

On March 3, 2004, Diagnostic Products announced that the FDA, based on inspectional findings that included data integrity and procedural issues, had suspended its review of all applications submitted by the company and was deferring the review of any future applications until the issues were resolved (see *DTTR*, April 2004, page 8).

Insider Sales at Diagnostic Products



Source: *DTTR* from EDGAR Online

Insiders at Diagnostic Products sold a total of $3.6 million worth of stock in the company during the month of February 2004, according to EDGAR Online, a financial information company that specializes in regulatory reporting by public companies. The insider selling in February was more than the combined total sold in the previous six months.

Diagnostic Products says it has been in communication, and is cooperating with the U.S. Securities and Exchange Commission (SEC) regarding these matters. An independent committee of its board of directors initiated and conducted an investigation of the trading issues and the company says it is looking forward to presenting its findings to the SEC in the near future.

IVD Stocks Rise 4%; Gen-Probe Up 18%

The 20 stocks in the G-2 Diagnostic Stock Index were up an unweighted average of 4% in the four weeks ending August 30, with 14 stocks up in price, five down, and one unchanged. Year to date, the G-2 Index is up 5%, while the S&P 500 Index is off 1% and the Nasdaq is down 7%.

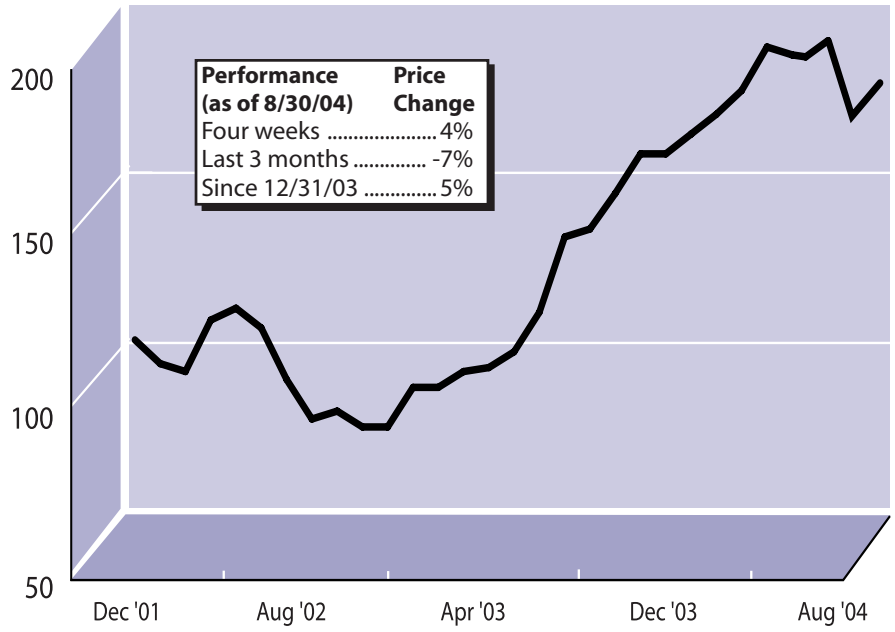
Gen-Probe (San Diego) rose 18% to $36.03 per share for a market cap of $1.8 billion. The company reported stronger-than-expected second-quarter results: earnings came to $11.8 million, or 23 cents per share, up from $8.1 million or 17 cents a share; revenue increased by 21% to $61.2 million. The company also forecast that full-year 2004 revenue would rise to $250 million to $255 million from $207.2 million in 2003.

Digene Corp. (Gaithersburg, MD) fell 20% to $25.28 per share for a market cap of $499 million. The company reported strong growth for its fiscal year ended June 30, 2004, but investors had been anticipating even better performance.

Net income for fiscal-year 2004 was $21.5 million, or $1.04 per share, compared to a net loss of $4.3 million, or $0.24 per share, for fiscal 2003. Net income for fiscal 2004 included benefit from income taxes of $14.3 million, or $0.69 per diluted share. Total revenue for fiscal 2004 increased 43% to $90.2 million from $63.1 million in fiscal 2003. Digene says that more than 300 labs in the United States now offer its HPV test.

For the fiscal year ending June 30, 2005, Digene expects total revenues to be between $125 million and $130 million.

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.

Avg. % Price Change, Four weeks ended 8/30/04

UP		
Abaxis	$14.81	10%
Abbott Labs	41.22	7%
Beckman Coulter	55.20	6%
Becton Dickinson	47.00	1%
Biosite	46.92	9%
Dade Behring	51.16	2%
Diagnostic Products	39.85	6%
Gen-Probe	36.03	18%
Immucor	20.47	11%
Johnson & Johnson	57.54	5%
OraSure	6.25	20%
Quidel	3.40	6%
Third Wave	4.97	3%
Ventana	46.60	5%
UNCHANGED		
Cytyc	22.92	0%
DOWN		
Bio Rad	50.61	-1%
Cholestech	7.32	-2%
Digene	25.28	-20%
Inverness Medical	15.21	-3%
Meridian	11.45	-1%

G-2 Insider

There's still time to register for Washington G-2 Reports' 22nd annual Lab Institute this Sept. 29 to Oct. 2 at the Crystal Gateway Marriott in Arlington, VA. This year's Institute features some of the lab industry's most influential business and government leaders, including:

★ **Randy Scott**, Ph.D., chief executive of Genomic Health, will offer his views on *The Next "Big Bang" in Diagnostic Lab Technology: Implications of Genomic Profiling*

★ **Bud Thompson**, executive vice president, Carilion Health System, who will talk about *Competitive Forces Shaping Hospitals & Health Systems and the Strategic Role of Lab Outreach Testing*

★ The trio of lab entrepreneurs—**James Billington**, president of American Esoteric Laboratories, **Chris Riedel**, president of Hunter Labs, and **Steven Boyd**, president of Southern Diagnostics, will explain *How and Why They Chose To Start Their Lab Companies*

★ **Linda Lebovic**, project officer, office of research, development and information at CMS, will provide an update on where *CMS's Pilot Program for Competitive Bidding Stands*

★ **Louis Wright, Jr.**, M.D., founder of Pathology Services Associates, will provide advice on *The Business of Pathology*

In all, the Lab Institute conference will feature over 35 presentations and panel discussions from more than 50 laboratory experts and government officials. For more details and to sign up go to *www.g2reports.com* or call 202-789-1034.

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