Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

Genomic Health And Arcturus Introduce New Genomic Tests For Breast Cancer Patients

After years of research, two well-financed diagnostic company startups—Genomic Health (Redwood City, CA) and Arcturus Bioscience (Mountain View, CA)—have developed separate technologies to analyze genes from fixed-paraffin embedded tissues allowing them to do large-scale genetic studies on stored biopsies. And the fruits of their labor are now hitting the market in the form of high-priced tests to help physicians make therapy decisions for breast cancer patients.

Genomic Health, which operates a CLIA-certified lab near San Francisco, introduced OncotypeDX at a list price of $3,460 earlier this year. The homebrew test is designed to measure the likelihood that cancer will recur in breast cancer patients. And the company is also developing another test to help physicians prescribe the most effective chemotherapy treatments.

Arcturus has developed technology that its lab partner, US Labs (Irvine, CA), is using to measure the activity of two particular genes in breast cancer tumor tissue that foretell which patients will respond to the drug tamoxifen. US Labs plans to offer the test on a research-use-only (RUO) basis at a list price of $1,500.

For the full story behind Genomic Health, Arcturus, and US Labs and their new breast cancer tests, see *Inside the Diagnostics Industry*, pp. 5-7.

Greenwood To Leave US House To Head BIO

Ironically, Rep. James Greenwood (R-PA), who has led a House Energy and Commerce subcommittee that is investigating conflicts of interest at the National Institutes of Health (NIH), has announced that he will retire at the end of this year to become president of the Biotechnology Industry Organization (BIO-Washington, DC). "Given my seniority in Congress, and my role on the Energy & Commerce Committee, had virtually any other organization approached me, I would have politely declined to interview. However, I passionately believe in the promise of biotechnology to find cures and treatments," Greenwood said in a statement distributed by BIO.

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Rep. James Greenwood (R-PA)

▲ **Greenwood To Head BIO,** *from page 1*

At BIO, Greenwood will lead an organization that represents more than 1,000 companies, including Abbott, Bayer, and Roche. He will oversee a staff of 100 employees and an annual budget of $40 million. IVD-related issues that BIO has lobbied for include the protection of patents on gene-based products.

Consumer watchdog Sidney Wolfe, M.D., head of Public Citizen's Healthcare Research Group (Washington, DC), told Reuters, "Greenwood's move was another example of blurred lines between the government and industry….Washington is reeking with this kind of revolving door."

Greenwood said his decision "is consistent with the high ethical standards that have characterized my 24-year career in elective office." He will replace Carl Feldbaum, who is retiring as BIO's president at the end of the year. According to published reports, Feldbaum earned more than $800,000 in salary and benefits last year, and Greenwood is expected to be paid a similar amount. As a congressman, Greenwood earns $158,100 per year.

BioMerieux IPO Values Company At $1.4 Billion

BioMerieux (Marcy l'Etoile, France) has completed its initial public offering at 30 euros per share, and the shares began trading on the Paris stock exchange on July 7 under the symbol BIM. The offering price was at the high end of the underwriters' expectations of 26.90 euros to 31.25 euros.

The IPO price gives BioMerieux, which now has approximately 39 million shares outstanding, a market value of nearly 1.2 billion euros (US $1.4 billion). This is approximately 21 times the company's net income of 55.1 million euros (US $67 million) in 2003 and 1.3 times its revenue of 914.5 million euros (US $1.1 billion).

The IPO was prompted by the desire of investment firm Wendel Investissement to sell its 34.5% stake. Wendel, which had already sold 5% of BioMerieux to CIC-Banque de Vizille, sold 25.7% through the IPO and could sell its remaining 3.8% if the underwriters exercise their over-allotment option.

Concurrent with the IPO, BioMerieux sold 900,000 shares to its employees at the discounted price of 24 euros per share. Nearly 50% of eligible employees in France purchased shares, and more than 25% of eligible U.S. employees subscribed. BioMerieux raised approximately 22 million euros ($27 million) from the employee offering.

Following the IPO, Alain Merieux, the founder, chairman, and president of BioMerieux, holds a 58% stake in the company. Merieux's stake is valued at nearly 700 million euros (US $850 million). The next biggest shareholders are Groupe Industriel Marcel Dassault SA and CIC-Banque de Vizille, which each own 5%.

In a conference call with the media just prior to the IPO, chief operating officer Benoit Adelus predicted that BioMerieux would increase its net profit by more than

10% annually for the next three years on revenue growth of better than 4% to 5% per year. Chairman Merieux said, "We are very open to possibilities. Becoming a listed company gives us a range of options for launching takeovers or forging partnerships."

FDA Suspends New Class III Applications from BioMerieux in Durham

As chairman Merieux enjoys his new status as a paper billionaire (almost) in Paris, the company's Durham, North Carolina, facility has hit a regulatory bump in the road. During an FDA inspection of BioMerieux's Durham site from April 12-23, 2004, it was found to be out of compliance with the agency's good manufacturing (GMP) regulations.

The FDA is now reviewing BioMerieux's action plans and corrective measures, but in the meantime the agency has suspended applications for new approvals of Class III products from the Durham site. BioMerieux executives in Durham were not available for comment at press time.

Abbott Diagnostics Still Suffering Effects Of Consent Decree

Abbott Diagnostics (Abbott Park, IL), which began bringing back old immunoassays and introducing new ones to the U.S. market this year, is still suffering the after shocks of having this business put in a deep freeze by the FDA between January 2000 and December 2003.

Through acquisitions and the benefit of exchange rate fluctuations, Abbott's worldwide diagnostic business was able to report an 8.6% increase in revenue to $1.607 billion for the six months ended June 30, 2004. But after adjustments for 6.9% positive swing from foreign exchange and about $74 million in added revenue from the acquisitions of TheraSense (closed April 6, 2004) and i-Stat Corp. (closed Jan. 30, 2004), *DTTR* calculates that sales at Abbott's worldwide diagnostics business actually fell by 3.4%.

Abbott's weakest business was U.S. clinical diagnostics, which fell an unadjusted 10.8% and was down 16.1% after taking into account acquired revenue from i-Stat. Abbott's worldwide blood glucose monitoring business posted a 32.2% increase to $339 million, but was actually up only 5.5% after factoring in foreign exchange and the purchase of TheraSense.

Doug Bryant, vice president of global commercial operations at Abbott, tells *DTTR* that Abbott's strategy for winning customers back is relying heavily on new product launches, particularly the Architect CI8200, which integrates immunoassay and clinical chemistry testing onto a single platform. Bryant says Abbott is bringing the system to customers using a demonstration vehicle called Architour, a customized semi-trailer that has a CI8200 on board. The truck started its tour in April and will visit more than 105 cities by the end of the year. Bryant says this method of showing customers the system has been so well received that Abbott has just purchased another truck and started a second tour in Detroit.

In terms of rebuilding its immunoassay menu in the United States, so far this year, Abbott has added five new tests to its AxSym immunoassay system menu, including BNP, anti-Tg, anti-TPO, cortisol, and most recently, an automated hepatitis A assay. Bryant says that key immunoassay launches for the remainder of the year include Architect cardiac markers, AxSym Troponin-I, free and total PSA on both Architect and AxSym, and other AxSym hepatitis markers.

A Closer Look at Abbott Diagnostics' Revenue ($ millions)

	First-half ended 6/30/04	*First-half ended 6/30/03*	*Unadjusted % change*	*Adjusted % change**
U.S clinical diagnostics	$380	$426	-10.8%	-16.1%
International clinical diagnostics	888	797	11.4%	-0.2%
Total clinical diagnostics	1,268	1,223	3.7%	-5.5%
U.S. blood glucose monitoring	151	102	48.0%	1.3%
International blood glucose monitoring	188	154	21.8%	9.1%
Total blood glucose monitoring	339	256	32.2%	5.5%
Worldwide diagnostics	$1,607	$1,479	8.6%	-3.4%

*Excludes impact of foreign exchange fluctuations and adjustments for acquisitions of TheraSense and i-Stat Corp.

Source: Abbott Labs and *DTTR* calculations

Dade Expands Lab Automation Offerings With DPC, Tecan Deals

Dade Behring (Deerfield, IL), which has been behind the curve when it comes to lab automation, has signed two new agreements that should help it catch up. First, Dade and Diagnostic Products Corp. (DPC—Los Angeles) have entered into an agreement in which Dade will offer its StreamLab workcell customers the ability to integrate DPC's Immulite 2000 and Immulite 2500 systems into StreamLab.

All together, Dade's RxL Max and DPC's Immulite analyzers linked to the open-track StreamLab automation system will have a combined menu of more than 150 chemistry and immunoassay tests.

The system was previewed at the recent American Association for Clinical Chemistry (AACC) meeting in Los Angeles. The first installation of the combined system is anticipated to occur by the end of the year.

In addition, Dade recently announced a nonexclusive agreement with Tecan (Zurich, Switzerland) to market Tecan's FE 500 front-end automation system.

Genetic Tests Hold Promise Of Individualized Breast Cancer Therapy

Randy Scott, Ph.D., helped found Genomic Health in August 2000. He previously served 10 years as chief executive at the drug discovery firm Incyte Corp.

Breast cancer is the second-leading cause of cancer death in women (after lung cancer), and 215,990 new cases of breast cancer will be diagnosed in the United States in 2004 alone, according to the American Cancer Society.

Among the challenges physicians face in treating breast cancer patients is deciding on the best treatment approach. Today, physicians rely heavily on three factors: the patient's age; tumor size; and perhaps most importantly, a pathologist's analysis of a biopsy of the tumor.

But the pathologists' report is based on a qualitative analysis and can be highly subjective. "If you ask three different pathologists to analyze a particular biopsy, less than 50% of the time will all three opinions be in concordance," says Randy Scott, Ph.D., chief executive and cofounder of Genomic Health. He says the quantitative gene-based tests that his company has developed are aimed at giving physicians another tool to make cancer patient therapies more individualized.

Genomic Health's OncotypeDX test, which uses PCR to analyze 21 genes associated with breast cancer, first made headlines when the results of an independent validation study were presented at the San Antonio Breast Cancer Symposium in December 2003. The blinded, 668-patient, multi-center trial showed that OncotypeDx can accurately quantify the likelihood of breast cancer recurrence as defined by a recurrence score from 1-100.

OncotypeDX test results are used by physicians to determine whether or not a breast cancer patient should receive chemotherapy. For example, a score of 75 indicates a greater than 30% likelihood that cancer will recur and that the patient has a high risk tumor which should likely be treated aggressively, according to Scott.

The recurrence score was able to accurately assign patients into high- and low-risk groups ($p<0.00001$). In addition, the study showed that the performance of OncotypeDx exceeded the standard measures of patient age, tumor size, and tumor grade in quantifying risk. Scott anticipates that the results of the study will be published in a medical journal sometime this fall.

Genomic Health in Brief

Headquarters/lab:	Redwood City, CA
Chairman and CEO:	Randy Scott, Ph.D.
Chief medical officer:	Steven Shak, M.D.
Employees:	75
Venture capital:	$80 million
Venture backers:	BakerTisch Investments, Versant Ventures, Kleiner Perkins, Texas Pacific Group

Source: *DTTR* from Genomic Health

Scott notes that the study was performed using routinely available fixed-paraffin biopsy tissue, unlike other genome-based assays that require special handling, such as snap freezing in liquid nitrogen. This ability is allowing Genomic Health to go back and analyze thousands of stored fixed-paraffin tissue from as far back as 20 years. And this is speeding the company's ability to complete clinical studies, says Scott. Given initial clinical studies using 447 patients

The American Society of Clinical Oncology (ASCO) recently came out with a recommendation against chemotherapy sensitivity and resistance assays, citing an insufficient evidence base to support their use in oncology practice (see Journal of Clinical Oncology: *Sept. 1, 2004)*

plus the 668-patient validation study, Scott says that OncotypeDx is significantly differentiated from previous tests that have not gone through rigorous clinical validation [*see ASCO sidebar*].

As mentioned earlier, Genomic Health sells OncotypeDX on a homebrew basis at a list price of $3,460, and Scott says there is no discounting. The company received a CLIA certificate for its lab in January and began selling the test shortly thereafter, according to Scott. Turnaround time is 10 to 14 days.

Genomic Health currently has 75 employees, including a direct sales force of 10 people that is calling on pathologists and oncologists. Scott says the company will add more salespeople after its initial study results are published.

But isn't OncotypeDX too expensive? Scott says OncotypeDX is cost effective because chemotherapy treatment costs $15,000 to $20,000 per cycle. "Insurers have been very receptive to the test," he adds.

Scott says that Genomic Health is also studying additional uses for OncotypeDX. In June, the company announced preliminary results of an 89-patient study at the annual meeting of the American Society of Clinical Oncology in New Orleans. The study showed that OncotypeDX not only quantifies the likelihood of breast cancer recurrence but may also provide information on the response to chemotherapy. Patients characterized to have a high risk of recurrence were more likely to respond to chemotherapy, and those categorized as lower risk were less likely to respond. Scott says Genomic Health plans to validate these results in a large-scale trial that will begin by the end of this year.

Arcturus Bioscience & US Labs

Genomic Health isn't the only company that is creating pharmacogenomic tests for breast cancer. Arcturus Bioscience has developed a PCR-based test that measures the expression levels of two genes in breast cancer tissue that can identify tamoxifen-sensitive and tamoxifen-resistant tumors.

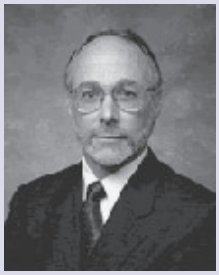
In June 2004, the medical journal *Cancer Cell* published a study performed by researchers from Massachusetts General Hospital (Boston) and Arcturus. By comparing the ratio of activity of the two genes from 20 tamoxifen-treated tumors, researchers were able to predict with 80% accuracy which patients were tamoxifen-resistant and would have a recurrence.

Tamoxifen is an estrogen-blocking drug (made by Astra-Zeneca) that has been used for more than 20 years to treat breast cancer patients. Estrogen promotes the growth of breast cancer cells. As a treatment for breast cancer, tamoxifen slows or stops the growth of

Arcturus Bioscience in Brief

Headquarters:	Mountain View, CA
Chairman and CEO:	Thomas Baer, Ph.D.
Chief scientific officer:	Mark Erlander, Ph.D.
Employees:	95
Venture capital:	$50+ million
Venture backers:	Summit Partners, ABS Capital, Incubic LLC., DynaFund, Onset Ventures

Source: *DTTR* from Arcturus



Thomas Baer, Ph.D., helped found Arcturus in 1996. Prior to Arcturus, Baer was vice president of research at Biometric Imaging, where he led a group developing instrumentation and reagents for AIDS monitoring and blood supply quality control.

cancer cells. As an adjuvant therapy, the drug helps prevent the original breast cancer from returning and also helps prevent the development of new cancers in the other breast.

More than 500,000 U.S. women currently take tamoxifen, making it the most frequently used drug of this class. Seventy percent of women taking tamoxifen respond favorably to the drug, while up to 30% of women on the drug will see no positive benefit, notes Thomas Baer, Ph.D., chief executive and cofounder of Arcturus. He says the test will help doctors make more effective therapy decisions.

US Labs has licensed Arcturus's technology and plans to offer the test on an RUO basis at a price of $1,500 beginning under the name "TAM test" in August or September, according to Ron Forche, director of marketing at US Labs.

As a RUO test, Forche notes that US Labs is not making any performance or clinical claims and will not bill Medicare or other insurance programs for it—hospital clients and patients will be billed directly and will pay US Labs for the test. However, Forche notes that Arcturus is working on categorizing the reagents for the TAM test as an ASR, which would allow US Labs to designate the test as a homebrew and allow for reimbursement from insurance programs.

In addition, Forche says that US Labs plans to begin offering a test that predicts the likelihood of breast cancer recurrence, also using Arcturus technology, by the end of the year. The test will initially be offered on a RUO basis; pricing has not yet been determined.

Forche believes that US Labs' position as one of the largest anatomic pathology labs in the nation will give it a big head start in marketing the test. US Labs generated $53.9 million of revenue last year, and the company is on track to reach $75 million this year. The company has a total of 360 employees, including 42 salespeople, and serves approximately 950 clients throughout the United States, according to Forche.

Separately, Forche notes that US Labs has been offering a DNA chip that analyzes 2,387 genes to pinpoint the source for tumors of unknown origin since the beginning of the year. The chips make use of technology licensed from Arcturus on an exclusive basis until mid-2005; the chips themselves are manufactured by Agilent Technologies. US Labs is offering the test on an RUO basis at a price of $2,000.

Finally, Arcturus's Baer notes that both its PCR-based testing and gene chip technologies can be performed on fixed-paraffin tissue, which will speed its ability to perform large-scale studies.

US Labs in Brief

Headquarters:	Irvine, CA
Chairman and CEO:	Judd Jessup
Senior medical director:	Kenneth Bloom, Ph.D.
Employees:	360
Revenue for 2003:	$53.9M
Venture capital:	$50+ million
Venture backers:	ABS Capital, Highland Capital, Accel Partners, Sage Venture Partners

Source: *DTTR* from US Labs

Bayer Wins Molecular Diagnostics Contract With Novation

Bayer Diagnostics has won a sole-source contract to provide molecular diagnostics systems and supplies to Novation (Irving, TX), the group purchasing organization (GPO) for VHA Inc. and the University HealthSystem Consortium (UHC). The agreement became effective on June 15 and runs through June 14, 2007.

Novation's Lab & Diagnostics Supply Partners

Product Category	*Contracted Vendors*
Blood banking	Immucor, Ortho-Clinical
Blood collection products	Becton Dickinson
Blood gas	Roche, Bayer
Blood glucose monitoring	Roche, J&J/Lifescan
Chemistry	Roche, Olympus, Dade Behring, Ortho-Clinical
Coagulation	Dade Behring
Flow cytometry	Beckman Coulter
Hematology	Sysmex, Bayer, Beckman Coulter
Immunoassay	Roche, Bayer, Dade Behring
Lab automation	Roche, Olympus, Ortho-Clinical, Dade Behring
Microbiology	Becton Dickinson, Dade Behring
Molecular diagnostics	Bayer
Reference laboratory	ARUP Labs, Mayo Medical Labs
Point-of-care analyzers	Abbott Diagnostics (i-Stat)
Specimen collection containers	Samco Scientific, Kendall Healthcare
Urinalysis	Bayer, Cardinal Health

Source: Novation

The contract covers all of Bayer's molecular diagnostics products for infectious disease, including the Versant bDNA assays for hepatitis C and HIV, as well as the TruGene HIV-1 genotyping kits and OpenGene DNA sequencing system.

Novation says the new contract will result in an estimated $4 million to $5 million in annual savings for VHA and UHC members. Assuming an average 25% savings, *DTTR* estimates that the contract is worth more than $12 million per year in revenue to Bayer.

Novation is the largest GPO in the nation. It serves 1,650 hospital members of VHA and UHC and handles $22 billion in annual purchasing volume. A list of all of its contracted lab and diagnostics vendors is provided below.

Biosite And Henry Schein Sign Distribution Deal

Biosite (San Diego) has signed a distribution agreement with Henry Schein Inc. (Melville, NY) under which Henry Schein will distribute Biosite's point-of-care tests to physician office labs (POLs) in the United States. With 9,000 employees and $3.4 billion in annual revenue, Henry Schein is the largest distributor of medical products to physician offices in the combined North American and European markets. Approximately 250 Schein salespeople and 200 telemarketers are expected to promote Biosite's products to POLs.

The Schein agreement is the second POL-distribution agreement that Biosite has signed. PSS World Medical, Inc. has been marketing Biosite's products to POLs since mid-2003.

Biosite's leading product is its Triage BNP Test for congestive heart failure. Triage BNP is the market leader and is currently used by 2,600 hospitals and 300 POLs. In the six months ended June 30, 2004, Biosite's revenue from Triage BNP grew by 59% to $79.6 million.

But competition from automated BNP tests from Roche, Bayer, Abbott, Dade, and OCD is growing. As a result, Biosite needs to increase its penetration of the POL market, thus the deal with Henry Schein. A boost will come if and when Triage BNP gets CLIA waived status; Biosite initially filed an application with the FDA to get the test waived more than 18 months ago.

Abaxis Gets CLIA Waiver For Lipid Panel

The FDA has granted waived status to Abaxis (Union City, CA) for its lipid panel when used in conjunction with the Abaxis's Piccolo point-of-care analyzer. Abaxis had submitted a request to the FDA for CLIA-waiver status for its Piccolo lipid panel in December 2003.

The Piccolo lipid panel is the first test panel for Abaxis to achieve waived status. Clint Severson, chief executive of Abaxis, says the company will next seek a CLIA waiver for Piccolo liver function test panels.

The Piccolo weighs 6.9 kilograms and has a test menu of 11 panels with a combined 25 analytes that have been cleared for use at CLIA-licensed labs. Test results from whole blood are provided in less than 15 minutes.

As of June 30, 2004, Abaxis had placed approximately 350 Piccolo systems with the U.S. military (the initial human diagnostics market for Abaxis). About 200 Piccolos have been placed in non-military sites in the United States—mostly at small hospitals, oncology clinics, and physician offices.

BioVeris Sues To Dissolve Meso Scale Joint Venture

BioVeris Corp. (Gaithersburg, MD) has filed a lawsuit in Delaware state court that seeks to dissolve Meso Scale Diagnostics (MSD-Gaithersburg), a money-losing joint venture, which BioVeris has invested more than $115 million in since 1995.

MSD is run by Jacob Wohlstadter, who is the son of BioVeris's chief executive, Sam Wohlstadter. The younger Wohlstadter is being sued by BioVeris for allegedly using money from the joint venture to buy luxury cars and a New York City condominium (*see DTTR, August 2004, p. 4*).

In the latest lawsuit filed on July 16, BioVeris has asked the Delaware Chancery Court to appoint a trustee to liquidate the joint venture's assets. The lawsuit has accused the younger Wohlstadter of breach of contract and breach of fiduciary duty.

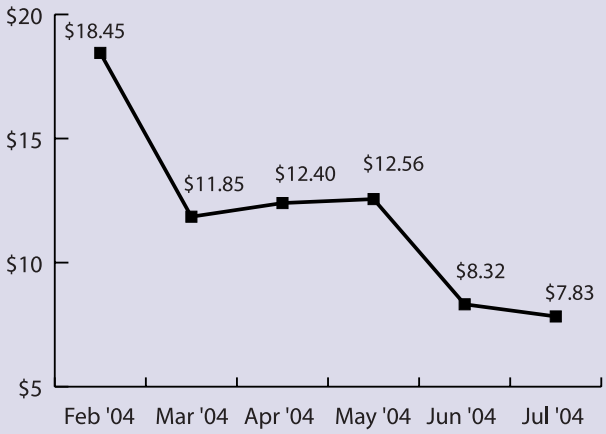
In addition, the Securities and Exchange Commission has informed BioVeris that it has opened an informal inquiry into the joint venture, the company said.

BioVeris had agreed on July 6 to put its initial lawsuit on hold—and avoid filing new actions—while both sides sorted out the information needed to file BioVeris's annual financial results. BioVeris said it terminated the agreement on July 13 after the joint venture did not provide certain information to its auditors. On July 12, BioVeris filed unaudited and incomplete financial results for the year ending March 31. A BioVeris spokesman was not available for comment on the lawsuit.

John Putnam, analyst at Stanford Financial Group (Boca Raton, FL), says the liquidation of MSD would put an end to a "big headache" for BioVeris. BioVeris won't obtain much cash from the liquidation, but it will remove millions of dollars of annual losses from BioVeris's income statement, notes Putnam.

BioVeris was spun out from Igen International when Igen was purchased by Roche Diagnostics for $1.4 billion earlier this year. Under the deal, Roche secured nonexclusive, fully paid-up, worldwide rights to commercialize Igen's Origen technology, which is the backbone of its Elecsys product line. But the BioVeris spinout still owns the Origen technology and can market Origen-based products to the entire clinical diagnostics market, including hospital, blood bank, and reference labs.

BioVeris's Stock Price



Source: *DTTR*

Putnam believes that BioVeris may ultimately be taken over by Roche. By acquiring BioVeris, Roche would slam the door shut on the potential for any new competitor to license the Origen technology to compete in the immunoassay market, he explains.

Since hitting a high of $18.45 per share in February, BioVeris's stock price has plunged by more than 50% to $7.83 per share for a market cap of about $210 million. As of March 31, 2004, BioVeris's unaudited balance sheet showed cash holdings of $148 million (excluding MSD) and no debt, giving the company an enterprise value of just $62 million.

IVD Stocks Drop 14%; OraSure And Quidel Get Trounced

The 20 stocks in the G-2 Diagnostic Stock Index fell an unweighted average of 16% in the five weeks ending August 6, with 17 stocks down in price and only three up. Year to date, the G-2 Index is up 1%, while the S&P 500 Index is off 4% and the Nasdaq is down 11%.

The worst-performing IVD stock in the latest five weeks was **OraSure Technologies** (Bethlehem, PA), which fell 47% to $5.20 per share for a market cap of $233 million. The company recently announced that it may not meet its goal of making a full-year profit. For the first six months of this year, OraSure has reported a net loss of $20,000 on revenue of $25.6 million.

Costs associated with the hiring of a new chief executive, Douglas Michels, were among the factors OraSure listed as cutting into its bottom line. OraSure will be paying the salary and benefits of two CEOs for the next 18 months, company filings with the Securities & Exchange Commission reveal. Michels will earn a base salary of $400,000 plus a minimum bonus of $160,000. Former CEO Mike Gausling, who resigned in June, will continue to collect his $320,000 annual salary through the end of 2005, as well as bonuses and other benefits for the remainder of this year.

In addition, during an August 3 conference call, Michels said the company's OraQuick rapid HIV test had produced an unusually high number of false positives in an ongoing clinical trial. The trial is focused on saliva samples. Similar trials by the U.S. Centers for Disease Control and Prevention in Atlanta found no such problem and were the basis for the FDA's approval of the OraQuick saliva test earlier this year.

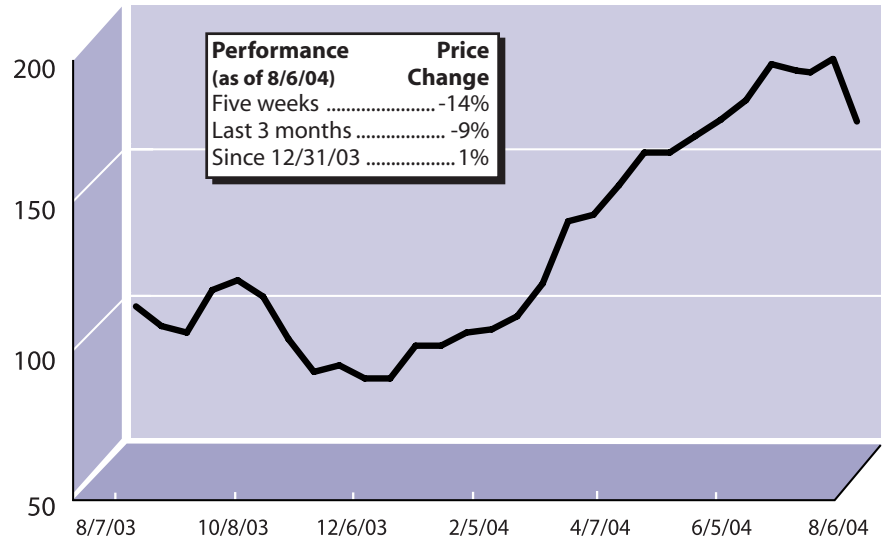
Michels said that sales of the OraQuick saliva test will be postponed until the problem is resolved. He noted that the ongoing trial will have no impact on sales of the OraQuick blood test, which has been on the market for nearly two years without incident.

Shares of **Quidel Corp.** (San Diego) sank 46% to $3.21 per share for a market cap of $100 million after the company reported a surprise loss and disappointing revenue for the second quarter. Quidel, which sells rapid influenza, Strep A, and pregnancy tests, also suspended its financial outlook for the balance of the year.

Quidel reported a second-quarter net loss of $2.3 million on revenue of $14.3 million, compared with a net loss of $367,000 on revenue of $18.9 million a year earlier. The company described these financial results as "disappointing," and said that orders for its Strep A tests were hurt by "unanticipated confusion" created by intellectual property litigation with Inverness Medical Innovations (Waltham, MA). In February, Inverness sued Quidel over patent-infringement issues. A week later, Quidel filed a similar lawsuit against Inverness in federal court in California.

As a result of the bad news and sagging stock price, S. Wayne Kay, president and chief executive, has announced that he is leaving the company. Kay will stay with the company until its board names a successor. "I have accepted the board's decision to make a change given the challenges of the last six months, and I will do everything I can to ensure a smooth transition," said Kay in a press release.

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, 5 weeks ended 8/6/04

	Price	% Chg
UP		
Dade Behring	49.93	5%
Meridian	11.51	4%
Third Wave	4.84	10%
DOWN		
Abaxis	13.48	-29%
Abbott Labs	$38.69	-5%
Beckman Coulter	52.23	-14%
Becton Dickinson	46.62	-10%
Bio Rad	51.00	-13%
Biosite	43.06	-5%
Cholestech	7.50	-8%
Cytyc	23.00	-9%
Diagnostic Products	37.77	-14%
Digene	31.65	-13%
Gen-Probe	30.49	-36%
Immucor	18.36	-15%
Inverness Medical	15.75	-28%
Johnson & Johnson	54.60	-2%
OraSure	5.20	-47%
Quidel	3.21	-46%
Ventana	44.25	-7%

G-2 Insider

Can Correlogic and its lab distribution partners, Quest and LabCorp, market the OvaCheck protein-pattern recognition test for ovarian cancer as a homebrew, or does it first need premarket clearance from the FDA?

Based on the FDA's July 12 letter to Bethesda-based Correlogic, the answer seems to be "yes." In one part, the letter states, "OIVD has determined that the OvaCheck test is subject to FDA regulation." And latter states, "In sum, your software are devices for which premarket approval is required to establish safety and effectiveness."

The need for premarket approval will probably add at least six to twelve more months to the commercial launch of OvaCheck, which Correlogic had originally hoped to have on the market almost a year ago (*see DTTR, July 2003, p. 1*).

But Peter Levine, president of Correlogic, hasn't given up yet. In a July 14 reply to Gutman, Levine said that Correlogic would remove its installed software at Quest and LabCorp, who would then use their own equipment and related software to extract data from patient blood specimens. Quest and LabCorp would then send the data to Correlogic's CLIA-certified lab in Bethesda, Maryland, to be analyzed by Correlogic, which then would provide a written report back to Quest and LabCorp.

How will the FDA respond? My answer: Correlogic and its partners had better start getting a premarket application ready.

Jondavid Klipp, *managing editor*

Company References

Abaxis 510-675-6500

Abbott Labs 847-937-6100

Arcturus 650-962-3020

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