Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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CONTENTS

WASHINGTON G-2 REPORTS

Established 1979

Roche/Affymetrix Alliance Seeks To Bring DNA Chips Into Clinical Diagnostic Use

The sequencing of the human genome, announced on Feb. 12, 2001, by Celera Genomics and the publicly funded Human Genome Project, sparked hope that a wave of new DNA microarrays (DNA chips) would soon be hitting the market, giving doctors the ability to detect predisposition to disease and formulate patient-specific drug treatments. Fast-forward two years later and we find that DNA chip systems have yet to enter the realm of clinical diagnostics in any meaningful way.

But this could all change dramatically now that the IVD industry's 800-pound gorilla, Roche Diagnostics (Basel, Switzerland), has signed a long-term alliance with its counterpart in the DNA chip industry, Affymetrix Inc. (Santa Clara, CA). Under terms of the deal, Roche is paying Affymetrix $70 million in cash plus potential royalty payments in return for a non-exclusive license to use Affymetrix's "GeneChip" technology to develop DNA microarrays for the clinical market.

The first product expected to come out of the new collaboration will be a CYP450 probe array. This test searches for mutations in a set of genes that are involved in the metabolism of several drug classes, including a group of antidepressants, and will help physicians determine which patients are eligible for specific drugs and at what dosage levels. For more on the Roche/Affymetrix deal and CYP450, see *Inside The Diagnostics Industry*, pp. 5-7.

Ontario To Launch Hereditary Breast Cancer Screening Program; Will Defy Myriad's Patents

Ontario's Ministry of Health and Long-Term Care has announced formal plans to perform hereditary breast and ovarian cancer screening tests for high-risk women at seven hospital laboratories in the Canadian province. The decision flies in the face of Myriad Genetics (Salt Lake City, UT), which holds nine U.S. patents and four Canadian patents covering its BRACAnalysis test. The Myriad test analyzes the BRCA1 and BRCA2 genes where mutations indicate a higher risk for developing breast and ovarian cancer. Myriad has threatened to take the Canadian province to court if it moves forward with the screening program.

Continued on p. 2

The challenge from Ontario comes as Myriad's revenue from its genetic testing business, which is dominated by sales of BRACAnalysis, appears to be slowing down

▲ **Breast Cancer Screening Program,** *from page 1*

At a Jan. 6 press conference, Ontario Health Minister Tony Clement said, "We do not accept their [Myriad's] claim and we are disregarding that claim....We will go to the highest court in the land on this."

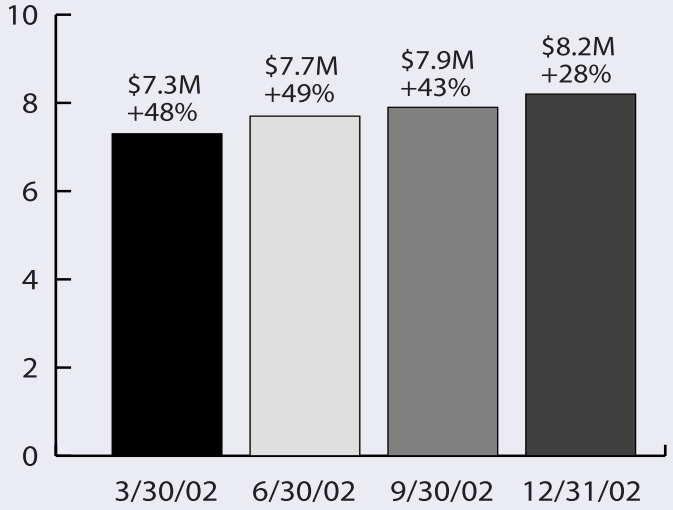
Clement said the Canadian province will provide $1.2 million Canadian (U.S. $790,000) to seven hospitals that will perform the testing: London Health Sciences Centre, McMaster Medical Centre, Credit Valley Hospital, Mount Sinai Hospital, North York General Hospital, Children's Hospital of Eastern Ontario, and Kingston General Hospital. These hospital labs will use a blood test called denaturing high performance liquid chromatography, or DHPLC screening, to search for the gene mutations associated with breast and ovarian cancer. This method of testing will cost Ontario approximately $1,100 Canadian (U.S. $772) per test. Myriad charges $3,850 Canadian (U.S. $2,550) per test and demands that all testing be done at its lab in Salt Lake City.

Clement said that testing for high-risk women, defined as women with a family history or who have had breast or ovarian cancer in the past, is set to begin in April. He anticipates that the province will perform about 600 tests over the next nine months.

For women with a mutation, the risk of developing breast cancer can be as high as 80%, while the risk of developing ovarian cancer can be as high as 40%. Ontario women who test positive for a mutation will be able to have more intensive screening and monitoring procedures to ensure early detection, receive anti-estrogen drug treatments that could reduce risk, or choose preventive surgery such as a mastectomy.

Myriad's Genetic Testing Revenue

Year-over-year revenue growth slowed to 28% in the quarter ended Dec. 31, 2002.



Source: Myriad Genetics

On a Feb. 4 conference call with investors, Peter Meldrum, president of Myriad, said, "Ontario has chosen to thumb its nose at Canadian patent law....We have put the province of Ontario on notice that Myriad intends to vigorously defend its patent rights."

However, although Myriad has made several public statements over the past year threatening to sue Ontario and other Canadian provinces that ignore its patents, the company has not yet filed an actual lawsuit. "We have been threatened by this company with legal action for over a year now," Clement told reporters at the press conference. Clement said that if Myriad's comprehensive claim to patent protection for genes becomes the norm, it would have wide-ranging implications including

restrictions on research. The Canadian federal government has previously washed its hands of the dispute, saying that Ontario and Myriad can fight it out in court if they choose.

Meanwhile, a spokesman from Myriad did not return phone calls from *DTTR* seeking comment. However, the company does appear to be preparing for legal battle. Myriad recently announced the hiring of Richard Marsh as vice president, general counsel and secretary. Marsh's duties will include management of all the company's legal activities, including defense of intellectual property. Previously, Marsh served in various legal counsel positions at the computer technology firm Iomega Corp. (San Diego, CA), including director of intellectual property.

Roche To Expand Glucose Testing Unit With Acquisition Of Disetronic

Roche Holding (Zurich, Switzerland) has announced plans to buy Disetronic Holding (Burgdorf, Switzerland) for 1.6 billion Swiss francs (US $1.18 billion). Roche says it will integrate Disetronic, the world's second-largest maker of insulin pumps for diabetes patients, into the blood glucose monitoring unit of Roche Diagnostics.

On a February 10 conference call, Heino von Prondzynski, head of the diagnostics division, said that the near-term benefits of the merger would include the ability to cross-sell Roche's Accu-Chek glucose test systems to Disetronic's insulin pump customers and vice versa. Longer term, Prondzynski said that the merger would speed each company's efforts to develop an artificial pancreas which automatically tests patient glucose levels and then delivers the correct amount of insulin to the body.

Roche is in a race with Medtronic Inc. (Minneapolis, MN), the world's largest medical-technology company, to bring the first artificial pancreas to market. To this end, Medtronic acquired Disetronic's main rival, MiniMed, in August 2001 (*see DTTR, July 2001, pp. 1-3*). Medtronic says that it has successfully tested its artificial pancreas on animals and can bring such a device to the market in about five years.

Approximately 60,000 people in Europe use a Disetronic insulin pump, giving the company a 70% market share. In the U.S. market, Disetronic has 130,000 pump users for a 17% share, with the remainder held by Medtronic MiniMed.

Terms of the deal call for Roche to offer Disetronic's shareholders two Roche non-voting shares plus 670 francs in cash for each Disetronic share, a premium of 57% over the shares' closing price just prior to announcement of the deal. Following completion of the transaction, Roche says that it will immediately sell the smaller of the company's two units, which makes pharmaceutical injection devices, to Disetronic founder Willy Michel for 425 million Swiss francs (US $311 million). This means that Roche is paying 1.2 billion Swiss francs (US $880 million) for Disetronic's insulin infusion business, or approximately five times its annual revenue of 237 million Swiss francs (US $174 million). This compares with the 10 times annual revenue that Medtronic paid for MiniMed.

Biosite Sets Lofty Goal For 2003 Triage BNP Sales

Testing for B-type natriuretic peptide (BNP) helps doctors determine whether a patient who is short of breath is suffering from congestive heart failure. Biosite's Triage BNP Test was launched in the U.S. market in early 2001 and is currently used by more than 1,350 hospitals

Biosite (San Diego, CA) expects to generate $75 million to $85 million in revenue from its Triage BNP Test this year despite new competition from Roche and impending competition from Bayer and Abbott. Realization of this revenue goal would require Biosite to roughly double the $38.1 million the company generated from Triage BNP in 2002.

On a Jan. 27 conference call, Tom Watlington, senior vice president of commercial operations at Biosite, told investors that Roche's recent entry into the BNP market has so far had little effect. "We are aware of one hospital we lost, but balancing that are two other instances where we won evaluations over [Roche's] NT-proBNP. It's very early in the game, so we expect to feel more pressure as the year goes on. But so far Roche hasn't been a factor," said Watlington.

But, that's not how John Rohe, product manager at Roche, sees things. He tells *DTTR* that Roche is constantly bumping into Biosite in the BNP marketplace, and he claims that Roche has already won $15 million worth of contracts for its NT-proBNP test, excluding a major new contact with Quest's Nichols Institute.

Roche officially launched its NT-proBNP Test, which runs on the company's Elecsys instruments, in January at a list price of $3,500 per 100-test kit, or $35 per test. Rohe says average sales price after discounts is between $17 and $17.50 per test. This compares with an average selling price of $20 to $25 per test for Biosite. Rohe says that Roche's 75-person U.S. salesforce (plus another 25 specialists) is focusing marketing efforts on the 600 customer locations where Roche has already placed Elecsys instruments.

Biosite at a Glance *($000)*

	2001	2002	2003E
Triage BNP sales	$3,417	$38,127	$80,000
Other sales	62,223	67,099	73,000
Total revenue	65,640	105,226	153,000
Net income	6,726	13,394	22,000
Number of Triage BNP hospital customers	249	1,350	NA

E=Estimated
Source: Biosite

Meanwhile, Bayer Diagnostics and Abbott Diagnostics are each aiming to have their BNP tests on the U.S. market by year's end. In addition, Dade Behring recently acquired non-exclusive rights to Roche's NT-proBNP marker. A spokeswoman from Dade tells *DTTR* that the company aims to have its own proBNP test on the U.S. market within one to two years.

In preparation for the onslaught of competition, Biosite says it's working toward getting a CLIA waiver for Triage BNP so that it can be marketed to the tens of thousands of physician office labs (POLs) certified to do waived testing only. In the meantime, Biosite says it's targeting the 22,000 POLs certified to perform CLIA moderately complex tests. The outpatient market for BNP testing got a big boost when the Centers for Medicare and Medicaid Services established a new CPT code for the test (83880) and a reimbursement rate of $47.43.

In addition, Biosite says it's in the process of negotiating with distribution partners for help in penetrating to the POL market. And, the company reports that it is expanding its U.S. salesforce from 31 representatives to 45.

Roche/Affymetrix Deal Could Make DNA Chips A Clinical Reality

Affymetrix's recent licensing agreement with Roche represents a major step toward bringing its GeneChip technology into the clinical diagnostics market. The deal gives Roche non-exclusive rights to Affymetrix's DNA microarray and instrument technologies for a minimum of five years up to 18 years. It will enable Roche to create and market GeneChip laboratory tests for DNA analysis, genotyping, and resequencing applications, as well as for RNA expression analysis. The chips will be manufactured by Affymetrix and branded by Roche under the AmpliChip name.

In addition to a $70 million up-front cash payment, Affymetrix will also receive royalties on sales of diagnostic kits created out of the agreement plus milestone payments for technical and commercial achievements.

Steven Fodor, PhD

"People have been asking us, 'When does this genetic technology get to the doctor's office?' Having one of the world's biggest drug companies behind this technology will drive it into the commercial world sooner," says Steven Fodor, PhD, chief executive of Affymetrix. "We believe the synergies between our GeneChip platform and Roche's PCR technology will establish new standards for genetic clinical testing." Fodor anticipates that the agreement will yield GeneChip tests directed at a broad array of diseases, including cancer, osteoporosis, cardiovascular disease, metabolic disorders, and infectious and diseases.

Thomas Metcalfe

Thomas Metcalfe, senior vice president for genomics business at Roche Diagnostics, expects the worldwide market for DNA microarrays for clinical diagnostics to reach $3 billion to $5 billion annually within the next 10 years. "We want to be at the forefront of building this market," says Metcalfe.

The first product expected to come out of the new collaboration is the GeneChip CYP450 Probe Array, which Roche will brand under the AmpliChip name. CYP450 searches for mutations in two human CYP450 genes (2D6 and 2C19) located in the liver that can affect the metabolism of several commonly prescribed drug classes. Pharmaceutical companies have been testing for CYP450 variations for years to help determine the safety of new drugs they are developing. But the Roche-Affymetrix collaboration will mark the first time that CYP450 testing is brought to the clinical diagnostics market.

Metcalfe says that Roche will begin marketing a CYP450 test as an analyte specific reagent (ASR) in the second quarter. He says the initial target market will be patients on antidepressant and schizophrenia drugs. Metcalfe would not reveal any information regarding potential pricing for CYP450, but *DTTR* speculates that the cost to labs is likely to be well over $100, and the labs will likely charge well over $300 to perform each test.

Although it seems like the first test from the new collaboration has been developed quickly, Affymetrix has actually been working with Roche on CYP450 for the past three years. Affymetrix initially developed CYP450, with access to patents from the National Institutes of Health and Imperial Cancer Research

Technology (London, England), in the mid-1990s and has been selling the test on a research use only (RUO) basis since November 1997.

Walter Koch, PhD

Walter Koch, PhD, director of the department of pharmacogenetics at Roche Diagnostics, tells *DTTR* that Roche has made a number of improvements to the CYP450 chip that double the number of gene variations the chip can detect, thereby making it more useful to the clinical market. These improvements include the ability to detect deletions and duplications of the CYP2D6 gene as well as a number of allelic variations specific to the African and Asian populations.

Koch notes that in any given one-year period, 9.5% of the population, or about 18.8 million American adults, suffer from a depressive illness and that approximately five to six million people seek treatment for clinical depression each year. Today's standard of care includes a prescription for one of the selective serotonin reuptake inhibitors (SSRIs) that fall under brand names like Prozac, Paxil, Zoloft, and Celexa. SSRIs have a wide therapeutic window, low toxicity, and minimal side effects. If a first prescription to an SSRI does not work, a physician will often simply switch a patient to another brand and see if that works. SSRI treatment is successful most of the time.

However, Koch notes that approximately 10% to 25% of patients being treated for clinical depression don't respond to any SSRI. The next line of treatment is often a prescription for one of the tricyclic drugs that fall under names such as amitriptyline (Elavil), imipramine (Tofranil), and nortriptyline (Pamelor). The tricyclics can cause adverse side effects that include drowsiness, anxiety, restlessness, dizziness, muscle twitches, and nausea, and if blood levels rise too high, life-threatening cardiac arrhythmias.

Koch believes that the CYP450 test can reduce some of the adverse effects and risks associated with tricyclic drug prescriptions and consequently lower healthcare costs. Based on each patient's specific metabolic rate as determined by CYP450, a physician could prescribe the appropriate dosage level, thereby eliminating or lowering any potential serious side effects.

What's the next DNA chip that will come to market as a result of the collaboration? Koch says that Roche has active research and development efforts underway for a DNA chip to resequence the P53 tumor suppressor gene. P53 mutations are found in approximately 50% of all cancers, according to Koch. He says Roche and Affymetrix are working on a P53 chip that could help guide radiotherapy and chemotherapy treatment decisions for cancer patients, espe-

A Quick Look At Affymetrix

Affymetrix currently derives nearly all of its $290 million in annual revenue (based on 2002 results) from sales of its DNA microarrays and related instruments (under the brand name GeneChip) to research organizations and pharmaceutical and biotechnology companies for use in developing new drugs.

DNA microarrays, such as Affymetrix's GeneChip products, are half-inch-square glass slides or silicon wafers that carry DNA fragments to screen for certain genes or genetic mutations that can determine a patient's predisposition to a disease or suitability for a particular drug.

Last year, Affymetrix sold 405,000 GeneChips, up 41% from 287,000 chips sold in 2001. The company is currently shipping an average of four of its GeneChip Scanners per week and had placed a total of 800 of these instruments worldwide as of Dec. 31, 2002. Affymetrix's best-selling chips are its U133 Set, which allows researchers to analyze the expression profile of the entire human genome using just two microarrays.

cially once new therapies in development directed toward the P53 pathway become available.

Thomas Metcalfe, senior vice president at Roche, says that one of the key reasons why Roche chose to partner with Affymetrix is the company's highly developed manufacturing capabilities. Affymetrix's microarrays are fabricated at the company's West Sacramento facility using a proprietary photolithographic manufacturing technology adapted from the semiconductor industry. In a nutshell, photolithography allows Affymetrix to manufacture uniform arrays containing more information per microarray at a lower cost. Metcalfe notes that these economies of scale will come in handy if DNA microarrays become as big a factor in clinical diagnostics as Roche thinks they will.

Gentris To Seek FDA Clearance For Its CYP450 Test

Roche isn't the only company working to bring a CYP450 test to the clinical market. David Gessner, vice president of business development at Gentris Corp. (Morrisville, NC), says his company has scheduled a meeting with U.S. Food and Drug Administration officials for later this month (February 2003) to get guidance on how it should proceed with filing an application for its CYP450 test.

Gessner says that Gentris has been performing CYP450 testing on an RUO basis for pharmaceutical companies since early 2001 and has already begun clinical trials in anticipation of filing for commercial kit approval. He says that Gentris has developed CYP450 testing methods that can be utilized on a DNA chip or restricted fragment length polymorphism (RFLP) methods. The company is waiting for guidance from the FDA and then will decide the specifics of its planned commercial test kit, according to Gessner. He is optimistic that Gentris could have a test cleared by the FDA within the next 12 months.

Gessner says that Gentris plans to sell its kit (pending FDA clearance) to the larger reference labs such as Quest Diagnostics, LabCorp, and ARUP Laboratories and will also perform testing at its own lab in Research Triangle Park. He says that Gentris has filed for CLIA certification for its lab. Gessner anticipates that the average selling price for CYP450 tests performed at the Gentris lab will be approximately $250 (including reagents plus lab service).

Gentris is a privately held company that was founded in March 2001 by its chief executive Michael Murphy. The company has raised $2.1 million in venture funds to date; its lead investor is Research Triangle Ventures (Raleigh, NC).

Last year, Gentris, which has 10 employees, generated revenue of approximately $1.2 million from testing services provided to pharmaceutical companies and research organizations. The goal this year is $3.5 million, says Gessner.

Among the many other companies that have active research and development efforts under way for CYP450 testing is Variagenics (Cambridge, MA), which recently merged with Hyseq Pharmaceuticals (Sunnyvale, CA)—*see separate article on page 8*.

OraSure Receives CLIA Waiver For Rapid HIV-1 Test

The U.S. Food & Drug Administration has approved a waiver under the Clinical Laboratory Improve-ments Amendments of 1988 (CLIA) for the OraQuick Rapid HIV-1 Antibody Test made by OraSure Technologies (Bethlehem, PA).

OraQuick is the first FDA-approved rapid, point-of-care test designed to detect antibodies to HIV-1 in finger-stick whole blood within approximately 20 minutes. OraSure received FDA approval of the OraQuick test in November 2002 *(see DTTR, December 2002, p. 3)* for use at laboratories certified under CLIA to perform moderately complex tests. With the CLIA waiver, OraQuick can now be used by a larger number of sites that are generally certified to perform only low-complexity tests such as outreach clinics and physician offices. The test is being distributed by Abbott at prices ranging from $9 to $15 per kit depending on discounts for volume.

Separately, OraSure says that U.S. Navy Military Sealift Command has purchased 10,000 OraQuick tests to screen personnel prior to receiving smallpox vaccinations. The mariners of the Military Sealift Command are civilians who have been directed to receive smallpox immunizations by the U.S. Department of Defense. Individuals who test positive for HIV-1 are at increased risk for complications from the smallpox vaccine.

i-Stat Signs New Distribution Agreement With Fuso Pharmaceutical

i-Stat (East Windsor, NJ) has announced a new agreement with Fuso Pharmaceutical Industries (Osaka, Japan) extending Fuso's rights to distribute the i-Stat system in Japan. As a part of the agreement, Fuso will make a $2 million marketing support payment to i-Stat within 30 days and, in October 2003, will advance $11 million as partial payment against future purchases. The funds provided a welcome boost to i-Stat, which is incurring substantial expenses related to its decision to terminate a distribution agreement with Abbott that covers the U.S. and all international markets except Japan *(see DTTR, Sept. 2002, p. 10)*.

Hyseq And Variagenics Merge To Form Nuvelo

Hyseq Pharmaceuticals (Sunnyvale, CA), a pharmaceutical development company, and Variagenics (Cambridge, MA), which is developing molecular diagnostics, have completed a merger, and the combined companies have changed their name to Nuvelo Inc. Executives at the merged company say the combination will help accelerate development of the most promising products of both companies, which include Alfimeprase, a thrombolytic drug currently in Phase I clinical trials. But, *DTTR* observes that the real reason may be to cut corporate overhead and conserve cash. In the nine months ended Sept. 30, 2002, the combined companies recorded a pro forma net loss of $53.2 million on revenue of $24 million.

Nuvelo At A Glance

For 9 months ended Sept. 30, 2002 ($000)

Revenue	$23,957
Net loss	-53,156
Working capital	45,405
LT debt	6,637
Accumulated deficit	-241,100

Source: Nuvelo

Abbott Sees Resolution Of FDA Consent Decree By Year's End

Abbott Laboratories (Abbott Park, IL) is anticipating a favorable resolution to its consent decree with the U.S. Food & Drug Administration by the end of this year, Richard Gonzalez, president and chief operating officer of Abbott's medical products group, told analysts on a Jan. 16 conference call.

A failure to meet FDA quality system regulations at its Lake Forest diagnostic manufacturing facilities has forced Abbott to suspend sales of roughly 60 immunoassays in the U.S. market since early 2000, including high-volume tests such as vitamin B12, folate, and ferritin. As a result, Abbott customers without backup vendors have been forced to send much of their immunoassay test volume to reference labs at a significant expense. Abbott initially reimbursed many of its customers for this expense, but is no longer doing so. The hassle and expense is leading many Abbott customers to switch to other immunoassay vendors as their contracts with Abbott expire.

Abbott Diagnostics 2002 Revenue Summary *($MM)*

	2002	2001	Change
Worldwide Diagnostic Sales	$2,897	$2,929	-1.1%
U.S. Diagnostics	1,163	1,226	-5.1%
International Diagnostics	1,734	1,703	1.8%
Worldwide MediSense	$494	$456	8.3%
U.S. MediSense	205	190	8.1%
International MediSense	289	266	8.8%

Source: Abbott Laboratories

Gonzalez said Abbott ended 2002 with a 30% share of the U.S. immunoassay market, which is estimated at roughly $2 billion. He anticipates that Abbott's share will decline to 28% to 30% over the course of this year. This compares to estimates of a decline to 20% to 25% by several Wall Street analysts. "We don't expect the erosion rate that many analysts expect," noted Gonzalez.

Meanwhile, overall sales at Abbott Diagnostics continue to deteriorate. Worldwide diagnostics sales fell 1.1% to $2.897 billion in 2002. Abbott says that U.S. diagnostics fell 5.1% to $1.163 billion, while international diagnostics edged up 1.8% to $1.734 billion. Abbott's MediSense glucose monitoring unit generated worldwide revenue growth of 8.3% to $494 million in 2002. For 2003, Gonzalez anticipates that Abbott's worldwide diagnostic sales will increase in the low single-digit percentages, including double-digit growth at MediSense.

Abbott To Discontinue Sale Of Gonorrhea/Chlamydia Assays

Abbott Laboratories has announced that it has discontinued the sale of gonorrhea and chlamydia assays that run on its LCx system because of manufacturing difficulties. Abbott had expected to generate approximately $25 million of revenue from the sale of these tests this year. The decision follows a recall of 1.5 million gonorrhea tests that Abbott was forced to make last year after it learned through routine quality control checks that the kits had lost some of their sensitivity. Several hospital lab managers who had given Abbott the benefit of the doubt in regard to the company's FDA problems tell *DTTR* that Abbott's gonorrhea/chlamydia misadventure was the last straw and they are now planning to switch to another immunoassay vendor.

Dr-Oncall Sues Roche Diagnostics For Trade Secret Infringement

"They [Roche] think we're going to go away, but we're pretty adamant about seeing this thing through to the end," says Papas

Dr-Oncall (Palo Alto, CA), a private company founded by two physicians, is suing Roche Diagnostics for allegedly stealing its business plan for providing Internet-based medical advice and using the plan to establish its MyDoc subsidiary. The suit, filed on Dec. 16, 2002 in Santa Clara Superior Court, seeks compensatory damages as well as an injunction against further operation of the MyDoc.com Internet site.

Gus Papas, MD, a founder of Dr-Oncall, believes that either a venture capital firm or a software company that each had access to the Dr-Oncall business plan may have passed it on to Roche. Before filing the lawsuit, Papas says he contacted Roche to try to get an explanation for the similarities between Dr-Oncall and MyDoc. Papas says that Roche would not provide an explanation of where it got the idea for MyDoc. "I'm not 100% sure exactly how they got our business plan, but there are too many coincidences."

Papas says the Dr-Oncall Internet site is dormant because of a lack of funds. The site was to include an online triage system for patients with minor ailments as well as the opportunity for real-time online chats with physicians.

MyDoc.com was launched in mid-2001 with a $6.5 million investment from Roche. Like Dr-Oncall, the site offers patients online triage and real-time access to a physician; consumers pay $15 per month for the service.

"The suit is without basis or merit. The MyDoc concept was developed as an independent concept and not as a result of any information from or about Dr-Oncall. We anticipate a favorable resolution to the legal challenge," says Joel Reuter, a spokesman for Roche Diagnostics.

Window For Roche, Igen Settlement Closing Fast

On Feb. 24, in Richmond, VA, the U.S. Court of Appeals for the Fourth Circuit heard oral arguments in Roche's appeal of a Maryland district court judge's decision to let a jury award of $505 million to Igen stand. A final decision from the appellate court is expected by mid-year, unless the two companies can reach a settlement first.

Late last year, Sam Wohlstadter, chairman of Igen, had stated that a draft settlement agreement had been reached between the two companies and expressed optimism that a final settlement could be reached soon (*see DTTR, December 2002, pp. 8-9*). However, in a conference call with analysts on Feb. 4, Wohlstadter said that disagreements over "practical implementation issues have delayed the process longer than we might otherwise have anticipated."

He added that both companies were "energetically and expeditiously" working on a solution. But he warned, "If Roche is willing to give up a $400 million to $500 million business that is growing 30% per year, then we expect new partners will be willing to work with us to take it over." A spokeswoman from Roche had no comment on the status of the negotiations.

IVD Stocks Edge Up 2% In Latest 5 Weeks

***Roche** non-voting equity shares, which trade of the Zurich stock exchange, have fallen 3% to 93.85 Swiss francs so far this year. Shares of **Bayer**, which trade on the German stock exchanges, are down 20% at 16.39 euros*

The 21 stocks in the G-2 Diagnostic Stock Index rose an unweighted average of 2% in the five weeks ended Jan. 31, 2003, with 10 stocks up in price, two unchanged, and nine down. Year to date, the S&P 500 Index is down by 5% and the Nasdaq is off by 4%.

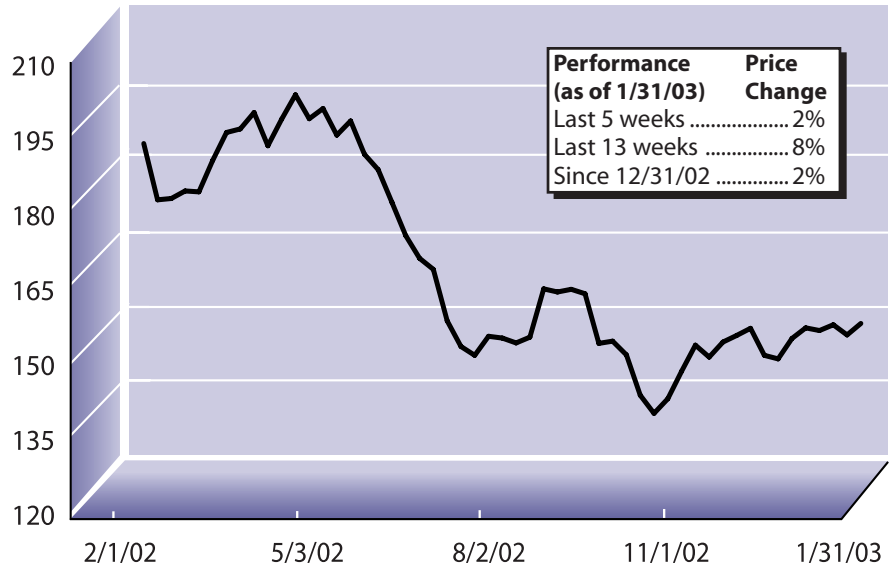
Inverness Medical Innovations (Waltham, MA) was up 23% to $16.24 per share for a market capitalization of $244 million. The company, which makes OTC pregnancy and ovulation tests and nutritional supplements, recently announced that it expects its 2003 earnings to exceed analysts' forecasts of $0.35 per share, or approximately $5.3 million.

Cytyc Corp. (Boxborough, MA) was up 14% to $11.60 per share for a market cap of $1.4 billion. The company recently reported a fourth-quarter profit of $17.9 million, compared with a net loss of $37 million in the same period a year earlier; revenue grew 5% to $66.7 million.

TheraSense (Alameda, CA) was down 14% to $7.15 per share for a market cap of $295 million. The company recently announced that it expects its revenue growth to slow to roughly 18% in 2003 to reach $210 million to $220 million. This compares with a 147% increase in revenue in 2002 to reach $177 million. "The tightening economy is increasing consumers' sensitivity to variations in co-pay among different blood glucose monitoring systems," the company explained in a press release.

Among two recent additions to the G-2 Index, **Dade Behring** (Deerfield, IL) was up 19% to $18.50 per share for a market capitalization of $873 million (based on 47.2 million fully diluted shares); **Gen-Probe** (San Diego, CA) was up 13% to $26.99 for a market capitalization of $650 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 21 diagnostic test and equipment makers.

% price change, 5 weeks ended 1/31/03

UP		
Becton Dickinson	$32.80	7%
Beckman Coulter	32.21	9%
Biosite	35.75	5%
Cholestech	7.10	2%
Cytyc	11.60	14%
Dade Behring	18.50	19%
Gen-Probe	26.99	13%
Inverness Medical	16.24	23%
i-Stat	4.10	2%
Meridian	7.57	10%
UNCHANGED		
Digene	11.47	0%
Johnson & Johnson	53.61	0%
DOWN		
Abbott Labs	$38.12	-5%
Bio Rad	35.40	-9%
Diagnostic Products	35.03	-9%
Diametrics	1.58	-4%
Igen	39.46	-8%
Immucor	18.71	-8%
Quidel	3.43	-1%
TheraSense	7.15	-14%
Ventana	21.52	-7%

G-2 Insider

Roche isn't the only IVD company to forge a significant new partnership aimed at developing pharmacogenomic products (*see pp. 5-7*). Bayer Diagnostics (Tarrytown, NY) recently announced a collaboration with the genomics company Genaissance Pharmaceuticals (New Haven, CT) to identify pharmacogenomic markers of drug safety and efficacy. However, Bayer's expectations for the development of the pharmacogenomics market are a little more subdued than Roche's.

William Wallen, PhD, senior vice president of research at Bayer Diagnostics, says that Bayer will work with Genaissance to identify genetic markers that can be used to match patients with high cholesterol to the most efficacious drugs. However, he notes that development efforts are at the early stages and says it will probably take at least a few years before the collaboration has a diagnostic test available for use at clinical labs.

Market introduction of a new and exciting genetic test does not guarantee commercial success, adds Wallen. "Everyone always underestimates how conservative physicians are and how long it can take for them to integrate new technology into their practice of medicine....The people running the genomics companies are years ahead of practicing physicians," observes Wallen.

He concludes, "Discovery of genomic markers is slowly picking up momentum, but we have few examples yet of even research-based tests which can be used to direct therapy decisions. However, the direction is clear, and the momentum of discovery is increasing rapidly. This will result in a gradual increase in these types of tests coming into routine clinical use over the next five to seven years and will rapidly increase thereafter." ⏏

Company References

Abbott Labs 847-937-6100

Affymetrix 408-731-5000

Bayer Diagnostics 914-631-8000

Biosite 858-455-4808

Gentris 919-465-0100

Igen 301-869-9800

i-Stat 609-443-9300

Myriad Genetics 801-584-3600

Nuvelo 408-524-8100

OraSure 503-641-6115

Roche Diagnostics 317-849-9350

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