

Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

Vol. II, No. 1/September 2001

CONTENTS

TOP OF THE NEWS

Bayer considers sale of healthcare unit..... 1
Horiba tightens reins on unprofitable ABX..... 1

M&A/PARTNERSHIPS

Becton to invest \$25M in TriPath 3-4

INSIDE DIAGNOSTICS INDUSTRY

First-half '01 revenue up 6% at 9 leading IVD firms: Roche, Dade, Abbott, Becton Dickinson, Beckman Coulter, J&J, Diagnostic Products, Bio-Rad, Bayer 5-6
Snapshot of 43 IVD companies 7

TECHNOLOGY

Cytoc's ThinPrep reaches 46% market share 3
Luminex 100 System reaches 678 placements 9

FINANCIAL NEWS

Natus raises \$60.5M from IPO 10
IVD stocks decline 2% 11

G-2 INSIDER

Will glucose test strip margins last long? 12

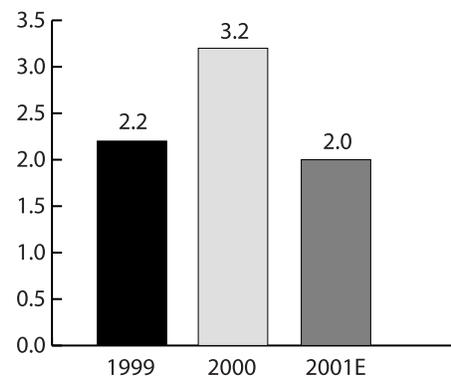


Established 1979

Bayer Reviews Options For Healthcare Unit

Bayer (Leverkusen, Germany) says it is thoroughly reviewing its strategy for its healthcare business (pharmaceuticals, over-the-counter drugs, and diagnostics) following the disastrous withdrawal of its Baycol anti-cholesterol drug in early August. Fifty-two deaths worldwide have been linked with use of cerivastatin, the active ingredient in Baycol. Because of the withdrawal, Bayer says it will miss its previous target for an operating profit in 2001 of three billion euros (US \$2.7 billion), before extraordinary charges. The loss of Baycol, known as Lipobay in Europe, will pull that figure down by 750-800 million euros (US \$684-730 million). *Continued on p. 8*

Bayer Group's Operating Income From Continuing Operations
(in billions of euros)



E=estimated. Source: Bayer and DTTR estimates

In Restructuring Move, Horiba Sacks ABX Chief

In a rare public display of Japanese corporate displeasure, Atsushi Horiba, chairman of Horiba Ltd. (Kyoto), has announced the dismissal of Jean-Edouard Robert, managing director of ABX Diagnostics (Montpellier, France). Horiba owns ABX, which makes hematology analyzers and supplies.

Robert told the French newspaper *Les Echos* (July 3 issue) that the dismissal resulted from differences of opinion over strategy. Atsushi Horiba told the newspaper that ABX is the only one of Horiba's 38 units that is unprofitable. He made it clear that cultural problems did not play a part in his decision. Kozo Ishida, senior managing director at Horiba, will temporarily head ABX until a French recruit is found, according to Atsushi Horiba.

As reported in *Les Echos*, ABX posted a loss of 64 million French francs (US \$9 million) last year on revenue of 580 million French francs (US \$80 million).

Continued on p. 2

▲ **Horiba Sacks ABX Chief**, from page 1

Robert's dismissal follows Horiba's decision to meld ABX's operations with those of Horiba Medical Group (HMG—Kyoto). HMG is a subsidiary of Horiba that has been focused on the Japanese market. It makes blood glucose meters, and theophylline and automatic C-reactive protein meters. The company has also developed a miniaturized sensor for blood cell counters by applying micromachining technology that is normally used to make semiconductor chips. Horiba says it hopes to develop portable blood cell counters using its new sensor within 5-6 years.

Horiba's Diagnostics Segment

(in millions of yen)

Years ended March 20	1999	2000	2001
Revenue	8,159	12,005	12,422
Operating expense	8,798	12,413	12,421
Operating income	-639	-408	1
Assets	10,057	10,516	14,587

Source: Horiba

Horiba originally acquired ABX, which has more than 600 employees worldwide, in June 1996. Until now, Horiba had given French executives at ABX a great deal of autonomy in running the business. Over the past five years, ABX has grown largely from acquisitions, including the purchase of Roche's Cobas Mira business in 1998 and the acquisition of the blood cell counter business of BioChem Immunosystems from BioChem Pharma (Laval, Quebec) in 1999. ABX oper-

ates a U.S. office in Irvine, CA; however, the majority of ABX sales are in Europe. (Note: Executives at the California office did not return phone calls from *DTTR* for comment on this article.)

In a corporate press release announcing the management change at ABX, Atsushi Horiba said, "We will introduce our manufacturing technology into the process of transforming ABX, in order to improve productivity. We promise to deliver products required by customers in a timelier manner than before, and we will upgrade the consumable supply and service system." He noted that except for Robert's removal, ABX's existing employees in development, sales, and service would remain.

In a separate press release issued in the U.S., Horiba indicated that ABX's new tighter association with HMG will enable ABX "to target the rapidly growing point-of-care market in the United States, particularly within the intensive care unit ... Horiba plans to introduce several new and innovative diagnostic analyzers to the U.S. market through ABX Diagnostics over the next few years."

Horiba's diagnostics segment (including ABX, plus Horiba's Japan-based diagnostics business) generated revenue of 12.4 billion yen (US \$104 million) in the fiscal year ended March 20, 2001, up 3% from 12 billion yen (US \$101 million) the previous fiscal year. ABX contributed about 80% of the revenue generated by Horiba's diagnostics segment.

Overall, Horiba Ltd. reported revenue of 77.9 billion yen (US \$652 million) in fiscal 2001, up 10% from 71 billion yen (US \$595 million) in fiscal 2000; net income was 1.4 billion yen (US \$11.7 million) vs. 1.1 billion yen (US \$9.2 million). In addition to diagnostics, Horiba operates businesses in engine measurement instruments, analytical instruments (such as spectrometers), and semiconductor equipment. ▲

Cytc's ThinPrep Reaches 46% Market Share

Cytc Corp. (Boxborough, MA) estimates that its ThinPrep System now performs 46% of all U.S. Pap tests, up from 36% at the end of 2000. "We expect to reach a 50% domestic market conversion by year-end," said Patrick Sullivan, president of Cytc, during a July 25 conference call with analysts. ThinPrep has its greatest penetration in the Northeast and Mid-Atlantic States, he noted, with an estimated 70% share. The situation is nearly reversed on the West Coast, where traditional Pap smear testing still accounts for 65-70% of the market. The single largest health plan that has not yet converted to ThinPrep is Kaiser Permanente (Oakland, CA), which covers approximately eight million HMO members (predominantly in California).

Cytc reported a net profit of \$16.009 million in the second quarter of 2001 vs. \$6.74 million a year earlier; revenue increased 58% to \$52.997 million. During the second quarter, the company sold 84 new instruments at an average \$16,400 per unit. Cytc now has a total of 1,400 instruments in use at labs in the U.S.

The introduction of "mono-layer" testing technologies from Cytc and its competitor TriPath Imaging (Burlington, NC) has been a boon to hospital and commercial labs. Managed care companies and Medicare reimburse labs an average of about \$14-15 for traditional Pap smears, but thin-layer tests are reimbursed at roughly \$25 each.

	2Q01	2Q00	% Chg
Revenue	\$53.0	\$33.5	58
Operating income	20.3	5.8	249
Net income	16.0	6.7	138
Cash holdings	128.1	71.9	78
Long-term debt	0.0	0.0	0

Source: Cytc Corp.

Approximately 50 million Pap tests are performed in the U.S. each year. Quest Diagnostics (Teterboro, NJ) performs about 10 million and reports that 57% of the testing is now done with mono-layer technology. Laboratory Corp. of America (Burlington, NC) says 45-46% of its 7.6 million Pap tests are now performed with mono-layer. Cytc and TriPath collect an average of about \$7-9 in revenue for each mono-layer collection device sold. 🏠

Becton Dickinson To Invest \$25 Million In TriPath

TriPath Imaging (Burlington, NC) has announced an agreement with Becton Dickinson (BD—Franklin Lakes, NJ) to develop and commercialize molecular diagnostic and pharmacogenomic tests for cancer based on validated markers derived from BD's existing strategic alliance with Millennium Pharmaceuticals (Cambridge, MA). In connection with the agreement, BD will purchase 2.5 million newly issued shares in TriPath for \$25 million, making it the second-largest shareholder, after Roche.

Under the arrangement, TriPath will form a new wholly owned subsidiary, TriPath Oncology. BD's molecular oncology diagnostics group and its 25 employees will

become part of TriPath Oncology and relocate their activities to TriPath's North Carolina facilities over the next year. TriPath will be responsible for the development of instruments, based on its existing software and imaging technology, and also will establish an in-house laboratory to facilitate the validation and commercialization of new tests.

Paul Sohmer, MD, chairman of TriPath, says the first resulting test from the partnership will be based on the detection of expression of Melastatin, a gene identified by Millennium to help determine the risk of metastatic melanoma. Sohmer says TriPath will generate revenue from the venture by a combination of direct sales of the new tests and potential royalties on sales made by BD.

In a separate agreement, Millennium and TriPath have entered into a research license for TriPath's evaluation of certain patents in the area of colon cancer, in consideration for which TriPath is issuing to Millennium 400,000 new shares of TriPath common stock. In connection with other aspects of the transaction, TriPath is paying \$1 million to Millennium.

Word of TriPath's new deals with BD and Millennium was released simultaneously with TriPath's second-quarter results for 2001, which showed a decline in revenue to \$6.152 million from \$8.101 million in second-quarter 2000; net loss was \$4.16 million vs. \$5.085 million a year ago.

TriPath attributed the decline to reduced AutoPap-related sales. AutoPap is an automated system for screening Pap tests. The system is currently approved to screen

conventional Pap smears only, but TriPath is seeking approval from the U.S. Food & Drug Administration to use it to screen TriPath's AutoCyte Prep mono-layer Pap slides.

TriPath notes that while AutoPap sales were off, AutoCyte Prep sales were up. The company says it now has 200 AutoCyte Prep customers (predominantly in the U.S.) and a 3% market share of all U.S. Pap tests. 🏠

	2Q01	2Q00	% Chg
Revenue	\$6.152	\$8.101	-24%
Operating loss	-4.351	-4.856	NA
Net loss	-4.160	-5.085	NA
Cash holdings	45.376	15.394	195%
Long-term debt	1.658	5.311	-69%

Source: TriPath

Applied Imaging, DAKO Sign Marketing Agreement

Appplied Imaging (Santa Clara, CA) and DAKO (Carpinteria, CA and Glostrup, Denmark) have signed an agreement for the development and marketing of DAKO assays that can be read on Applied Imaging's MDS automated imaging system for cancer cell analysis. Assays to be added to the MDS menu include DAKO's HercepTest (FDA-cleared for assessing use of Herceptin for breast cancer patients) and ImmunoCyt (FDA-cleared for early detection of recurrent bladder cancer). These assays are expected to become available for use on the MDS imaging platform in early 2002. (Note: ImmunoCyt is licensed by DAKO from DiagnoCure Inc. of Quebec City, Canada). 🏠

inside the diagnostics industry

Revenue Up 6% In First-Half 2001 At Nine Top IVD Firms

Nine of the largest diagnostics manufacturers reported combined worldwide revenue of \$8 billion in the six months ended June 30, 2001, up 6% from \$7.6 billion in the same period a year ago, according to a tally of company financial reports by *Diagnostic Testing & Technology Report*. Growth is being fueled by sales of glucose meters and test strips, molecular diagnostics, and point-of-care testing. After factoring out these high-growth areas, *DTTR* estimates that sales to the core laboratory market (clinical chemistry, hematology, and coagulation) are growing at an annual rate of 2-4%.

Roche's (Basel, Switzerland) diagnostics business reported a 14% increase in operating profit to 498 million Swiss francs (US \$300 million) in the first half of 2001; revenue rose 14% to 3.374 billion Swiss francs (US \$2 billion).

Within diagnostics, Roche's near-patient testing business grew the fastest, with a 36% gain in revenue. This sharp increase was due in part to the recent acquisition of AVL Medical Instruments. Roche's units for molecular diagnostics (PCR-based instruments and tests) and diabetes care each reported growth of 19%; applied science (reagents and systems for research and industry), a 12% growth; and centralized diagnostics, up 8%.

Dade Behring (Deerfield, IL) reported revenue of \$642 million for the first six months of 2001, an increase of 9% from \$589 million in the same period last year. Dade, which is a privately held company, no longer reports its net income figures; however, the company did say that its EBIT (earnings before interest and taxes) for first-half 2001 was \$41 million, up 110% over prior-year levels.

Dade says it has completed its transition to direct distribution of its hemostasis and MicroScan products, effective July 1. This move is expected to generate \$10 million in cost savings per year by eliminating the distributor margin paid to Allegiance. Dade says its bottom-line has also begun to see the benefits of a

cost-cutting program initiated last year and expected to ultimately reduce expenses by \$50 million annually.

Meanwhile, Dade says it continues to work with its banks and bondholders to modify its capital structure. "We are optimistic about the remainder of 2001, although our level of debt continues to present significant challenges," noted Jim Reid-Anderson, president of Dade, in a press release. Dade had total long-term debt

Worldwide Revenue Growth At 9 Big IVD Companies

(\$ in MM)

	First-Half 2001	First-Half 2000	% Chg
Roche Diagnostics	\$2,032	\$1,782	14
Abbott Diagnostics	1,426	1,458	-2
Johnson & Johnson	1,045	984	6
Bayer Diagnostics ¹	940	915	3
Becton Dickinson	885	838	6
Beckman Coulter ²	732	704	4
Dade Behring	642	589	9
Bio-Rad	205	207	-1
Diagnostic Products	140	123	14
Total	\$8,047	\$7,600	6

¹Revenue for Bayer is estimated from partial data from company. ²First-half 2000 revenue for Beckman Coulter excludes a \$16.6M one-time gain from asset sale in Spain.
Source: *DTTR* from company reports

of \$1.4 billion as of Sept. 30, 2000 (the latest reported figure), generating about \$160 million in annual interest expense.

At **Abbott Laboratories** (Abbott Park, IL), the diagnostics division posted a decline of 2% to \$1.426 billion. Operating income for the division was \$181 million in first-half 2001 vs. \$178 million in first-half 2000. (For more on Abbott Diagnostics, see *DTTR*, Aug '01, p. 1).

Becton Dickinson (Franklin Lakes, NJ) reported combined revenue of \$885.4 million from its clinical laboratory and biosciences divisions in the six months ended June 30, 2001, up 6% from \$837.8 million in the same period a year earlier. Becton is seeing its strongest growth from sales of blood collection safety products, ProbeTec nucleic acid testing (NAT) systems (150 placed as of June 30), and immunocytometry systems and reagents.

Beckman Coulter (Fullerton, CA) reported revenue of \$732.4 million from its clinical diagnostics division in the first half of 2001, up 4% from \$703.5 million in the first half of 2000. The division's strongest growth segment was clinical chemistry, up 8% to \$446.3 million; the weakest was hematology, down 4% to \$187.4 million. Geographically, North American sales were up 8% to \$477 million; Europe was down 1% to \$180.8 million; and Asia was down 7% to \$74.6 million.

Beckman overall (including its life science research division) reported net income of \$60.2 million in the first six months of 2001 vs. \$53.4 million in first-half 2000; revenue increased 3% to \$929.1 million.

Johnson & Johnson (New Brunswick, NJ) reported a 6% revenue increase to \$1.045 billion at its combined Lifescan and Ortho-Clinical Diagnostics units. Lifescan was up 9% to \$529 million. Ortho-Clinical Diagnostics was up 4% to \$516 million.

Diagnostic Products (Los Angeles, CA) generated \$140.6 million of revenue in the first six months of this year, up 14% from \$122.8 million in the same period a year ago; net income was \$18.7 million vs. \$13.3 million. The company placed 350 Immulite 2000s in first-half 2001 and now has a total of about 1,500 units placed. Immulite 2000 is a high-volume immunoassay system with a menu of more than 50 FDA-cleared tests.

Bio-Rad Laboratories (Hercules, CA) reported clinical diagnostics sales of \$205.3 million in first-half 2001, down 1% from \$207.4 million in first-half 2000. Separately, the company recently announced the acquisition of Helix Diagnostics Inc., an autoimmune diagnostics test maker based near San Francisco, CA.

Bayer Diagnostics (Tarrytown, NY) increased revenue by 3% to an estimated \$940 million in the six months ended June 30. (For more on Bayer, see lead story, p. 1.)

For a snapshot of 43 of the largest IVD companies ranked by revenue for full-year 2000, see p. 7. 🏠

IVD Companies With \$50+ Million In Annual Revenue

Company	Worldwide Diagnostic Revenue, 2000	Comments
Roche Diagnostics	\$3,750	PCR and Accu-Chek fueling double-digit growth
Abbott Labs	2,924	Still hurting from FDA consent decree
Johnson & Johnson	1,965	Paying 7x revenue for Inverness glucose unit
Bayer Diagnostics	1,824	Parent under pressure to improve healthcare margins
Becton Dickinson	1,652	Seeks to revive topline via molecular diagnostics
Beckman Coulter	1,472	Revenue up 4% led by flow cytometry, automation
Dade Behring	1,184	Goldman Sachs still unable to find a buyer
BioMerieux	525	Organon Teknika purchase adds \$275M to sales
Bio-Rad	409	Recently bought Helix, more acquisitions expected
Arkray*	385	Biggest diagnostics company in Japan
Idexx Laboratories	367	The leader in veterinary diagnostic tests
Sysmex Corp.	310	Buying a majority stake in IRC
Instrumentation Laboratory	300	Launching new POC analyzers for blood gas
Organon Teknika	275	Acquired by BioMerieux in July for \$263M
Pharmacia Diagnostics	265	Market leader in allergy blood testing
Diagnostic Products Corp.	248	Revenue growing by 15%, led by Immulite 2000
Olympus Optical	225	Focused on high-throughput chemistry analyzers
Apogent (formerly Sybron)	210	Drug testing, infectious disease, and pregnancy
Qiagen	204	Bringing DNA prep products to clinical labs
Fujirebio**	200	Recently sold small pharma business to focus on IVD
Radiometer	175	Entered immunoassay market with purchase of Accumetrics
Inverness	170	Selling glucose testing unit to J&J for \$1.3B
Tecan Holding AG	152	Revenue growing by 30+%, led by Genesis FE 500
Eiken Chemical	150	Aims to introduce new gene amplification tech in 2002
Thermo Electron	150	Clinical chemistry and rapid infectious disease tests
Cytec Corp.	142	ThinPrep Pap test quickly replacing traditional smears
Chiron	139	Blood screening collaborations with J&J and Gen-Probe
Gen-Probe	122	Molecular diagnostics; revenue up 14% in 2000
DiaSorin	100	Management-led buyout completed in late 2000
Menarini Diagnostics	100	Part of Menarini, Italy's largest pharma company
Home Diagnostics	85	Sells low-priced, private-label glucose test strips
International Reagents Corp.	83	A leader in coagulation reagents in Japan
ABX	80	Parent Horiba tightening reins after continued losses
Immucor	77	Sales hurt by blood screen performance problems
Sigma-Aldrich	72	Chemistry/coagulation/immunochem; revenue slipping
Ventana Medical	71	Automated instruments/special stains for pathology
Quidel Corp.	68	Rapid tests; sales declining after strong 2000
Nova Biomedical	65	Loss of J&J contract has been a major setback
Genzyme Diagnostics	62	Purchase of Wyntek (POC testing) adds \$25M to sales
Meridian Bioscience	57	Restructuring manufacturing operations per FDA
i-Stat	55	The leader in hand-held blood gas/electrolyte analyzers
Biosite	55	Focused on POC tests; revenue up 28% in 2000
Axis-Shield	50	Top-selling test is POC test for bacterial/viral infections
Total, 43 companies	\$20,974	Annual growth of 4-6%, led by glucose, NAT, and POC

*Revenue estimate includes clinical LIS business. **Revenue excludes divested pharma business.
 Source: Company reports (latest fiscal year); DTTR estimates with help from McEvoy & Farmer (San Francisco, CA) and Biomed Capital Group (Fairfield, NJ).

▲ **Bayer Reviews Options**, from page 1

"We will have to see whether this [the withdrawal of Baycol] has implications for our 'four pillar strategy,' especially the status of the pharmaceutical or healthcare 'pillar' in our portfolio," Manfred Schneider, chairman of Bayer, told shareholders during a press conference at the company's Leverkusen headquarters on Aug. 12. "Our healthcare business segment does, after all, contain the extremely healthy consumer care business [e.g., Bayer Aspirin, Alka-Seltzer, One-A-Day brand vitamins, etc.] as well as diagnostics, which is currently in a positive turnaround situation." He added that Bayer no longer believes it can achieve the 20% operating profit that was its target for the healthcare unit for 2002.

The decision to review the company's "four pillar" strategy comes less than four months after Bayer successfully beat back a shareholder proposal to break up its conglomerate structure (*DTTR*, June '01, p. 1). In an April 27 address to shareholders, Schneider noted: "The related cost and risk [of a breakup] would be considerable. The idea that the value of the independent entities could rise faster than that of the company in its current form is based largely on speculative assumptions about future trends and valuations."

Schneider now says, however, that there are a number of possibilities for the healthcare unit, including a potential sale or joint venture. It is unclear whether Bayer is leaning toward a potential transaction that would include only its pharmaceutical business or its complete healthcare unit (including OTC products and diagnostics). Bayer's strategic review of its operations is likely to be completed within several weeks, according to Schneider. He did note that "two well-known pharmaceutical companies have already phoned us." And analysts are speculating that potential suitors for Bayer's healthcare business (in whole or in part) may include Roche Holding (Basel, Switzerland) and GlaxoSmithKline (Middlesex, England).

Problems at Bayer's pharmaceutical business have taken their toll on the company's stock price. Since the start of the year, shares of Bayer have declined 41% to 33.06 euros per share as of the close of trading on Aug. 17.

Separately, Bayer reported net income of 1.006 billion euros (US \$902 million) for the six months ended June 30 2001, down from 1.033 billion euros (US \$927 million) in the same period last year. Revenue was up 5% to 15.972 billion euros (US \$14.3 billion).

Bayer Group At A Glance (in millions of euros)

	1st-Half 2001	1st-Half 2000	% Chg
Total revenue	15,972	15,238	5
—Healthcare	4,929	4,747	4
—Agriculture	2,092	2,093	0
—Polymers	5,671	5,218	9
—Chemicals	2,496	2,104	19
Operating income	1,671	1,994	-16
Net income	1,006	1,033	-3

Source: Bayer

Operating profit at Bayer's healthcare segment dropped by 37% to 441 million euros (US \$396 million); revenue increased by 4% to 4.929 billion euros (US \$4.4 billion). Within the healthcare segment, the diagnostics business group reported 3% sales growth overall, the largest increases being in Europe, India, and Latin America. Diagnostics comprise about 20% of revenue at Bayer's healthcare segment and about 6% of the company's total revenue. ▲

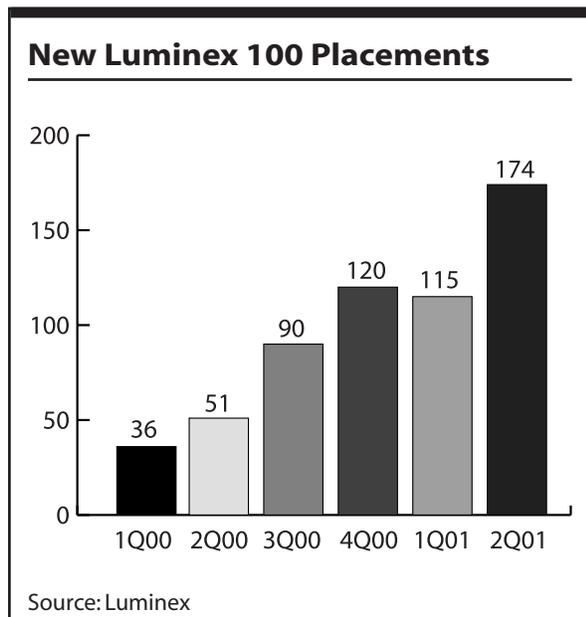
Luminex 100 System Reaches 678 Placements

Luminex Corp. (Austin, TX) reports that it sold 174 of its Luminex 100 systems in the second quarter, giving it a total placement of 678 since sales were initiated in 1999. Average pricing for the Luminex 100 analyzer declined to approximately \$15,500 from \$20,000 in the first quarter. Pricing was affected by a greater percentage of buying from distributors—about 86% of placements were through distributors and 14% from direct sales. Additional purchases from customers with preferential pricing also put pressure on average selling prices. Overall, Luminex reported a net loss of \$4.369 million in the second quarter of 2001 vs. \$3.644 million in the same quarter a year ago; revenue was up 222% to \$4.489 million.

The Luminex 100 is a benchtop analyzer that performs up to 100 tests (including enzymatic, genetic, and immunologic tests) simultaneously on one drop of fluid. The company is working to add cellular, microbial, and related tests, such as complete blood counts (CBC) and bacterial testing capabilities.

The system utilizes Luminex's LabMap (laboratory multi-analyte profile) technology, which makes use of microspheres (microscopic beads of polystyrene) injected with Luminex's proprietary red and infrared dyes. Specific antibodies are attached to these microspheres, which can be combined into a current maximum of 100 discrete tests per panel. The panels are then mixed with a test sample and injected into the Luminex 100 analyzer, where the microspheres pass single-file in a fluid stream through two laser beams.

The first laser excites the internal dyes used to identify the color of the microsphere and the test being performed on the surface of the microsphere. The second laser excites a third fluorescent dye used to quantify the result of the assay being performed. The lasers, combined with high-speed digital signal processing, simultaneously identify the test and measure its result.



Luminex has commercialization (*i.e.*, product development and marketing) partnerships with 30 diagnostics companies, of which 18 are clinical or specialty testing laboratories. On Aug. 1, privately held Inova Diagnostics (San Diego, CA) announced approval from the U.S. Food & Drug Administration for the first clinical diagnostic application based on Luminex's LabMap technology. Inova's new Quanta Plex ENA Profile 4 measures four of the most common autoantibodies (Sm, RNP, SS-A, and SS-B) simultaneously from a single drop of blood. Current ELISA technology requires four separate tests. The markers are used for diagnosis and prognosis of systemic lupus erythematosus, Sjogren's syndrome, and mixed connective tissue disease. Under terms of its agreement with Luminex, Inova will pay Luminex a royalty based on sales of Quanta Plex ENA Profile 4. 🏠

Natus Raises \$60.5 Million From IPO

Natus Medical Inc. (San Carlos, CA), which sells crib-side screening devices for newborns, raised gross proceeds of \$60.5 million from an initial public offering on July 20. The company sold 5.5 million shares (including an over-allotment of 500,000 shares) priced at \$11 per share. The offering was led by Dain Rauscher Wessels and co-managed by First Union Securities and Adams, Harkness & Hill. Investment bankers reaped approximately \$4.2 million in commissions from the IPO, leaving Natus with about \$56 million in net proceeds. As of Aug. 10, Natus had risen 31% above its IPO price to \$14.40 per share.

The company's Co-Stat Analyzer helps screen and monitor for a major factor in neonatal jaundice, the single largest cause for hospital readmission of newborns

Natus has been marketing its ALGO Newborn Hearing Screener for the early detection of hearing loss in babies since 1989. The product delivers sound stimuli to a newborn's ears and analyzes brain wave responses to produce a "pass" or "refer" result. The ALGO Screener is installed in 1,800 birthing and children's hospitals in the U.S. and lists for \$17,500 per device for the high-volume version and \$10,900 for the portable low-volume unit. In 2000, Natus sold disposable supplies (ear muffs and electrodes) to conduct 1.7 million tests. The list price is \$9.75 per disposable kit. Approximately 3.8 million babies are born in the U.S. each year, and impaired hearing affects up to five of every 1,000.

Natus received FDA clearance to market its Co-Stat End Tidal Breath Analyzer in January 2001. The Co-Stat Analyzer enables nurses and pediatricians to screen for and monitor the rate of bilirubin production in babies, a major factor in understanding the disease state of neonatal jaundice, a potentially toxic condition that can cause the skin to turn yellow. Jaundice may be a sign of an abnormally high rate of hemolysis, the process by which red blood cells in the human body are destroyed. Natus' Co-Stat Analyzer measures the rate of hemolysis by detecting the level of carbon dioxide in exhaled breath.

The Co-Stat Analyzer has a list price of \$19,500 per unit. The disposable plastic tubes containing filters (placed at the opening of a baby's nostril) list for \$14 per kit. Key competitors making lab bench analyzers for blood-based antibody and bilirubin tests include Roche Diagnostics and J&J's Ortho-Clinical Diagnostics.

In the three months ended June 30, 2001, Natus recorded a net loss of \$1.1 million vs. a net loss of \$425,000 in the same period a year earlier; revenue increased to \$7.2 million from \$6.1 million. Since Natus was incorporated in May 1987, the company has accumulated net losses of \$22 million.

With 15.3 million shares outstanding at a current price of \$14.40 per share, Natus has a market capitalization of \$220 million. Based on annualized results from the most recent quarter, Natus trades at 7.6 times revenue.

William New, Jr., MD, PhD, is chairman, chief technology officer, and a co-founder of Natus. Following the IPO, New owns 1.025 million shares (including exercisable options), or 7%, of Natus with a current value of about \$15 million. The company's largest stockholders are Trinity Ventures and Delphi Ventures, both in Menlo Park, CA. Each holds a 9% stake. 🏠

IVD Stocks Drop 2% In Latest Five Weeks

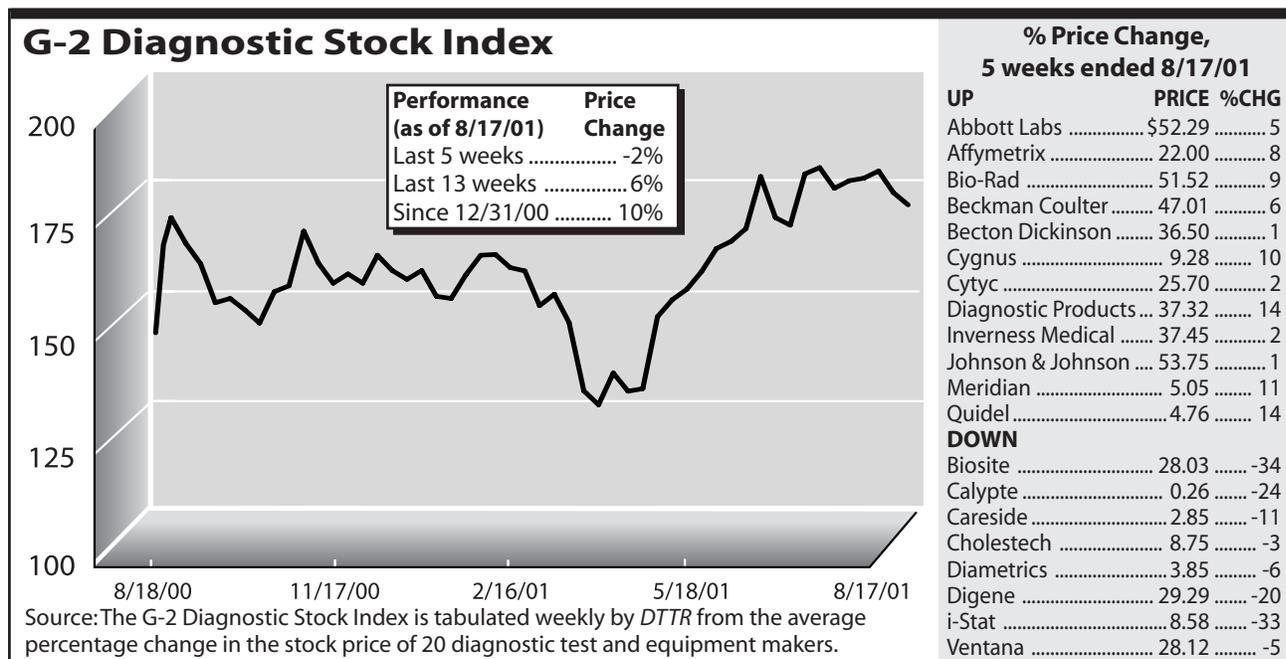
Shares of Bayer, which trade on the German stock exchanges, have fallen 41% so far this year to 33.06 euros per share; Roche non-voting equity shares, which trade on the Zurich Stock Exchange, are down 23% year-to-date to 126 Swiss francs per share

The G-2 Diagnostic Stock Index fell 2% in the five weeks ended Aug. 17. Twelve stocks in the index gained in price, eight fell. Since the start of the year, the index has risen 10%, while the S&P 500 is down 12% and the Nasdaq is down 24%.

Shares of **Biosite** (San Diego, CA) fell 34% to \$28.03 per share for a market capitalization of \$442 million. The company reported higher-than-expected legal expenses of \$473,000 in the second quarter, related to lawsuits with Xoma Ltd. (Berkeley, CA). Overall, Biosite reported net income of \$1.917 million in the second quarter vs. \$1.355 million in the same period a year earlier; revenue was up 21% to \$16.216 million.

Earlier this year, Xoma filed complaints in the U.S. District Court for the Northern District of California alleging that Biosite has exceeded the scope of three license agreements with Xoma signed in January 1999. Two of these licenses relate to the use of Xoma's patented technology for manufacturing genetically-engineered antibodies, which Biosite is using in its antibody development and diagnostic marker discovery business. The third license involves the use of a patented LBP (lipopolysaccharide binding protein) assay for diagnosing infectious complications. Biosite asserts that it is in full compliance with the license agreements and is seeking a preliminary injunction against Xoma.

Shares of **i-Stat** (Santa Clara, CA) were down 33% to \$8.58 per share for a market cap of \$157 million. The company recently announced settlement of patent infringement charges brought by Nova Biomedical Corp. (Waltham, MA) related to Nova's hematocrit testing technology. As part of the settlement, i-Stat will pay Nova \$6.5 million in cash, plus \$3.5 million in a one-year note. Nova has granted i-Stat a worldwide non-exclusive license to manufacture and sell analyzers and cartridges that determine hematocrit using Nova's technology (U.S. Patent No. 4,686,479). In addition, i-Stat will pay Nova a royalty of 4% of the invoice price of products utilizing the licensed method and sold in the U.S., effective Jan. 1, 2001. 🏠



G-2 Insider

The blood glucose self-testing market—with worldwide sales of \$3.5 billion and growth of some 15% per year—has been a boon to all four of the largest IVD manufacturers. Sales of blood glucose meters and strips have pumped up the top and bottom lines at Roche, Abbott, Bayer, and Johnson & Johnson, helping each offset less exciting sales growth in the core laboratory market.

Johnson & Johnson has become so enthralled with this self-testing market that it has agreed to purchase the glucose self-testing business of Inverness (Waltham, MA) for \$1.3 billion (*DTTR*, June '01, p. 1). The deal, expected to close by year's end, values the Inverness unit at roughly seven times its annualized revenue of \$196 million (based on reported second-quarter sales of \$49 million).

Of course, the big question is how long will it be until new competitors force pricing and profit margins in the glucose market lower. Almost certainly, Medtronic's (Minneapolis, MN) entrance into the market through its planned acquisition of MiniMed (Northridge, CA) will heighten competition. In addition, TheraSense (Alameda, CA) is planning to raise more than \$100 million from an IPO—money that can be used for increased marketing of its "Freestyle" meter and strips. Perhaps most ominous for the major IVD companies is Home Diagnostics (Fort Lauderdale, FL), which has clearly stated its strategy of gaining share through price competition (*DTTR*, Aug. '01, p. 1). 🏠

Think I'm all wet? You can write me at labreporter@aol.com

Jondavid Klipp, managing editor

Correction: The issue number for the August *DTTR* should read "12," not "11."

Company References

- Abbott Labs 847-937-6100
- ABX (Irvine, CA) 888-903-5001
- Bayer Diagnostics 914-631-8000
- Beckman Coulter 714-871-4848
- Becton Dickinson 201-847-6800
- Biomed Capital Group
973-244-9559
- Bio-Rad Labs 510-724-7000
- Biosite 858-455-4808
- Cytec Corp. 978-263-8000
- Dade Behring 847-267-5300
- Diagnostic Products
310-645-8200
- i-Stat 609-443-9300
- Johnson & Johnson
732-524-0400
- Luminex 512-219-8020
- McEvoy & Farmer 415-885-6662
- Natus 650-802-0400
- Roche Diagnostics
317-849-9350
- TriPath 336-222-9707

Subscribers are invited to make periodic copies of sections of this newsletter for professional use. Systemic reproduction or routine distribution to others, electronically or in print, is an enforceable breach of intellectual property rights. G2 Reports offers easy and economic alternatives for subscribers who require multiple copies. For further information, contact Randy Cochran at 212-244-0360, ext. 640 (rcochran@ioma.com).

DTTR Subscription Order or Renewal Form

Subscription includes 12 monthly issues, e-mail Alerts, annual company index, newsletter binder, plus exclusive savings on other G-2 publications and programs

YES, enter my subscription at the regular rate of \$379/yr

or

YES, as a current subscriber to the **National Intelligence Report, Laboratory Industry Report, or G-2 Compliance Report**, enter my subscription at the special subscriber rate of \$279/yr

Please Choose One:

Check enclosed (payable to Washington G-2 Reports)

American Express VISA MasterCard

Card # _____ Exp. Date _____

Cardholder's Signature _____

Name As Appears On Card _____

Ordered by:

Name _____

Title _____

Company _____

Address _____

City _____ St _____ Zip _____

Phone _____ Fax _____

e-mail address _____

Return to:

Washington G-2 Reports
29 West 35th Street, 5th Floor
New York, NY 10001-2299
Tel: (212) 629-3679
Website: www.washg2.com

For fastest service:

Call (212) 629-3679
or fax credit card order
to (212) 564-0465

9/01

Note: subscribers outside the U.S. add a \$50 postal surcharge

© 2001 Washington G-2 Reports. All rights reserved. Reproduction in any form prohibited without express permission. Reporting on commercial products is to inform readers only and does not constitute an endorsement.

Diagnostic Testing & Technology Report (ISSN 1531-3786) is published by Washington G-2 Reports, 1111 14th St NW, Ste 500, Washington DC 20005-5663. Tel: 202-789-1034. Fax: 202-289-4062. Order line: 212-629-3679. Website: www.washg2.com

Publisher: Dennis W. Weissman. Editor: D.J. Curren. Managing Editor: Jondavid Klipp, labreporter@aol.com