Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

FDA Finds Abbott In "Substantial Conformity"

The FDA has found Abbott's diagnostic manufacturing operations in suburban Chicago to be in "substantial conformity" with its quality system regulations. The decision clears the way for Abbott to begin returning immunoassays that have been suspended from the U.S. market since January 2000 under the company's consent decree with the FDA. It will also allow Abbott to introduce new immunoassays in the United States after a four-year dry spell.

The question is now: "How fast can Abbott regain the market share it has lost over the past four years?" Echoing the sentiment of other lab executives *DTTR* interviewed, Gary Assarian, D.O., president and medical director of Hospital Consolidated Labs (Southfield, MI), says, "I had to switch assays and systems because of Abbott's problems and I'm not going to renege on contracts that I've made with other vendors that were there for me when I needed them."

Even so, Assarian, who sits on a consumer advisory board for Abbott, notes, "They [Abbott] really didn't lose that much market share. You would have thought their competitors would have buried them. Now Godzilla has been released." Meanwhile, Abbott is aggressively beefing up its glucose monitoring and point-of-care testing businesses with plans to acquire TheraSense and i-Stat, for more details, see *Inside the Diagnostics Industry*, pp. 5-10.

Who Has The Inside Track For Rapid Mad Cow Testing?

On Dec. 30, the United States Department of Agriculture (USDA) announced plans to institute a more comprehensive surveillance system for bovine spongiform encephalopathy (BSE), more commonly known as mad cow disease, that will make use of rapid BSE tests. A widespread screening program, such as those already instituted by governments in Europe and Japan, is not expected to be instituted here in the United States. However, the USDA is in the process of expanding its laboratory facilities in Ames, Iowa to conduct rapid BSE tests targeted at older cattle showing symptoms of the disease. The USDA has not chosen a BSE test vendor yet, but Aaron Geist, analyst at Robert Baird & Co., believes Bio-Rad Laboratories (Hercules, CA) is in the best position to be selected as a major provider. *Continued on p. 2*

Eating meat from cattle infected with mad cow disease has been linked to the form of the disease called variant Creutzfeldt-Jacob disease, a nervous-system disorder that has killed over 150 people over the past several years, mostly in Britain.

▲ **Rapid Mad Cow Testing,** *from page 1*

Other manufacturers of rapid BSE tests include Prionics Corp. (Zurich, Switzerland), whose Prionics-Check test is distributed by Roche. In addition, Enfer Scientific (Tipperary, Ireland) makes a BSE test that is distributed by Abbott.

Geist believes Bio-Rad's Platelia BSE test has the best chances of winning the lion's share of any potential test sales to the USDA because the company is already selling a USDA-approved test for chronic wasting disease, which is similar to mad cow but affects deer and elk, to government agencies in several Midwestern states. In addition, Geist says Bio-Rad is already the market leader in BSE testing with about 50% to 60% of the worldwide market which is estimated at roughly $150 million per year.

The Bio-Rad test is used by 50% of Europe, which performs rapid BSE tests on nearly every cow over 30 months of age (because age is associated with infection) that's headed for the food supply, or some 10 million tests annually. And the Bio-Rad test is used exclusively in Japan, where they test every cow that's slaughtered, or more than 1 million each year. The average selling price for BSE tests ranges from $12 to $18 per test, according to Geist.

The United States slaughters 35 million cattle for the food supply each year, of which about 10 million are over age 30 months. However, the United States tested only a little more than 20,000 cows last year and uses an immunohistochemistry method that can take a week or more to complete.

But the news on December 22 that a cow in Washington state had been detected with mad cow—the nation's first case—has sent the USDA scrambling to assure the public and foreign importers that American beef is safe.

On a December 30 conference call with the media, the USDA's chief veterinarian, Ron DeHaven, D.V.M., said the USDA was not planning on instituting a widespread screening program such as in Europe or Japan. Instead, he said the USDA would be obtaining samples from targeted high-risk cattle—older and showing signs of nervous system disorder—prior to slaughter. These samples will then be sent overnight express to the National Veterinary Services Laboratories in Ames, Iowa, to be received by 10:00 a.m. The rapid tests would be performed at the lab with results reported in the afternoon.

"I would emphasize that this is a surveillance testing system intended not to definitively determine if every animal that goes to slaughter has the disease or not. The surveillance system has been focused on determining, one, if we have the disease, and at what prevalence do we have the disease?" said DeHaven. Under this system, the USDA will get "the greatest bang for your buck," he added.

Under the new plans, rapid BSE testing by the USDA is expected to amount to less than 200,000 tests per year. But if the ban on U.S. beef imports by Japan, Mexico, and South Korea (the top three importers) continues and more cases of mad cow are found in the United States, pressure could mount for a widespread BSE testing program. If this were to happen, *DTTR* estimates that the market for BSE tests in the United States could exceed $100 million per year (*i.e.*, 10 million cows over age 30 months multiplied by $12 per rapid BSE test).

OCD To Market Thermo Electron Automation; Lab InterLink Struggles

Thermo Electron Corp. (Waltham, MA) has signed an agreement naming Ortho-Clinical Diagnostics (OCD—Raritan, NJ) the exclusive marketer of its laboratory automation products in North America.

Thermo Electron's "open" lab automation products are focused on front-end tasks, like centrifugation, decapping, sorting, and aliquoting, and can interface with a variety of analyzers, including OCD's Vitros system. Thermo Electron has been selling its automation line in Europe for several years, and the agreement with OCD will give it access to the North American market.

OCD had previously been the primary distributor of automation systems from Lab InterLink (Omaha, NE). But cash flow problems forced Lab InterLink to lay off nearly all of its employees late last year. The company is now operating with a skeleton crew of eight employees who are struggling to maintain service at the 27 labs (including 23 in the United States) that have installed a Lab InterLink system.

Rodney Markin, M.D., Ph.D., company founder and chairman, tells *DTTR* that he is now trying to raise $10 million from investors or sell the company outright. He says that failure to complete a deal could force Lab InterLink to file for Chapter 11 bankruptcy reorganization.

Alfa Scientific Can Make Money At $18.09 Per iFOBT

Enterix Inc. (Falmouth, ME) says the new Medicare reimbursement rate of $18.09 per immunoassay-based FOBT (iFOBT) is not enough and Beckman Coulter has not made any formal announcements regarding potential relaunch of its FlexSure OBT product. But Alfa Scientific (Poway, CA—just north of San Diego) says $18.09 is enough for it, as well as its distributors and lab customers, to earn a profit on the sale of its Instant-View Fecal Occult Blood Test. The product is one of three iFOBT's that have been cleared by the FDA for marketing—the other two are Enterix's InSure and Beckman's FlexSure. An executive at Alfa Scientific tells *DTTR* that Alfa sells its iFOBT to distributors for about $4 per test. Even after assuming a 100% markup by distributors to $9 per test, this leaves labs with plenty of room to make money on the test, according to the Alfa executive.

Biosite's BNP Test Cleared For Use On Beckman Platforms

Biosite (San Diego) has received FDA clearance to market its Triage BNP Test for Beckman Coulter Immunoassay Systems. As a result, the Biosite test, which is used to help diagnose heart failure, is now available in both a point-of-care and automated format. Under the terms of its agreement with Beckman signed in June 2003, Beckman will manufacture the automated version of the test and Biosite will exclusively sell and market the product. Roche and Bayer already have automated BNP tests on the market in the United States. Abbott plans to introduce both an automated BNP test for its AxSym system and a point-of-care test for the i-Stat analyzer (*see page 10*) within the next several months.

Roche Gets FDA Okay For Genetic Tests For Blood Clots

Although Roche continues to wrangle with the FDA over the proper regulatory path for its AmpliChip products, the company has reached a significant milestone by gaining clearance for two new genetic tests. Roche says the FDA has granted marketing clearance for its Factor V Leiden and Factor II (Prothrombin) G20210A kits for its LightCycler real-time PCR instrument. The products are the first-ever DNA-based genetic disorder tests cleared by the FDA for human testing, according to Roche.

The kits received 510k clearance under an accelerated review/de novo process from the FDA. Both kits were initially introduced to the U.S. market as RUO (research use only) products in 1999.

Both tests allow the detection and genotyping of inherited mutations in the genes that encode the Factor II and Factor V proteins, as an aid to diagnosis in the evaluation of patients with suspected thrombophilia. Inherited thrombophilia predisposes an individual to venous thrombosis (or blood clotting), the third most common cardiovascular disease.

Gen-Probe Gets FDA Clearance For STD Testing On Tigris

Gen-Probe (San Diego) says that its Tigris system has received FDA clearance to run its Aptima Combo 2 assay, a nucleic acid test for simultaneously detecting chlamydia and gonorrhea. Gen-Probe also recently announced FDA clearance for its Aptima Vaginal Swab Specimen Collection Kit, a kit that enables patients to self-collect specimens for the Aptima Combo 2 test.

Tigris is the first commercially available, fully automated, nucleic acid testing system. No manual sample prep is required to initiate a run and generate test results. The system is capable of processing roughly 500 tests in an 8-hour shift and has been in development for more than six years.

But Aptima Combo 2 is the first and only test cleared to run on Tigris. Given its limited menu, analysts at Merrill Lynch estimate that Tigris will generate only about $5 million in revenue for Gen-Probe in 2004. Among other tests that Gen-Probe is developing for Tigris include PCA3 for the detection of prostate cancer through a licensing deal with Diagnocure (*see DTTR, January 2004, p. 3*).

Kaiser To Offer Digene's HPV Test For Screenings

Digene Corp. (Gaithersburg, MD) says that by the spring of this year, its DNA-based HPV test will be offered to all women 30 and older by Kaiser Permanente's Northern California Region along with a traditional Pap test as a "standard of care" for routine cervical cancer screening. The Northern California region is the largest for Kaiser, with nearly 3.2 million members. Prior to rolling out the new initiative, Kaiser first piloted its expanded cervical cancer screening program in Sacramento and Napa/Solano. Since the April 2003 FDA approval of Digene's HPV test for adjunctive cervical cancer screening in women 30 and older, about 90% of the Kaiser members who were offered the test—or 20,000 women—chose to receive it.

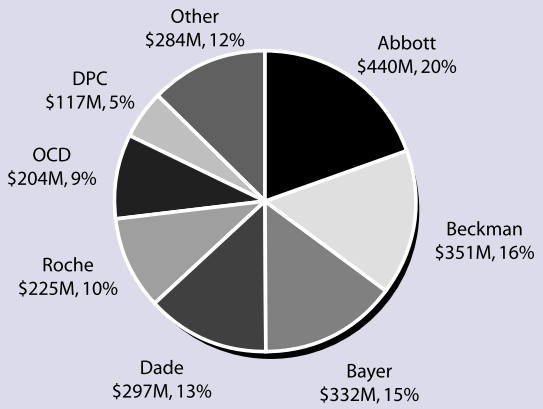
Abbott Will Not Regain Immunoassay Market Share Overnight

Abbott's share of the immunoassay market has shrunk considerably over the past four years due to the company's consent decree with the FDA. That agreement suspended U.S. distribution of more than 60 tests and shut down the company's ability to introduce new immunoassays manufactured at its Lake County, Illinois diagnostics plant. Analysts at SG Cowen have estimated that Abbott's share of the U.S. immunoassay market was cut roughly in half over the past four years to $440 million, or a 20% market share, at year-end 2003.

And the greatest portion of the share losses came after Abbott failed to regain compliance after a follow-up inspection in early 2002. In fact, one industry insider tells *DTTR* that more than 1,000 AxSym analyzers were returned to Abbott in North America in the past 12 months alone.

But with the consent decree lifted, the question is now: "How fast can Abbott win back customers' confidence and business?" *DTTR* interviews with more than 10 lab managers, directors, and consultants suggest that gains will not be made overnight. They say that the three- to five-year contracts they signed with other immunoassay vendors like Beckman, Bayer, Dade, Roche, Ortho-Clinical, and DPC will not be broken. Abbott will need to compete with other vendors as these contracts come due. Thus, even in the best-case scenario, it will take Abbott several years to regain the 40% share it once held in the U.S. immunoassay market, observes *DTTR*.

U.S. Immunoassay Market Share, 2003



Source: SG Cowen and company reports

One thing that everyone agrees on is that Abbott paid its dues. *DTTR* estimates that the whole ordeal has cost Abbott $1.5 billion (see page 6) and has hobbled its research and development budget for diagnostics. "There's no question that Abbott has made some serious changes to improve their processes. In the long run it should result in higher quality products," notes James Westgard, Ph.D., professor of pathology and laboratory medicine at the University of Wisconsin School of Medicine and president of Westgard QC (Madison, WI).

Below we try to answer several other key questions regarding Abbott's comeback attempt.

Where Does Abbott Stand With The FDA?

After the latest inspection, from October 28 to November 13, the FDA sent Abbott a letter (dated December 18) indicating that its Lake County manufacturing processes were "in substantial conformity" with the agency's regulations. As a result, Abbott can bring new and old immunoassays to the market, and will no longer have to pay 16% penalty ($80 million to $100 million per year) to the FDA on "medically necessary" immunoassay sales.

But the consent decree itself has not been terminated. Abbott still needs to take certain follow-up actions, including having its Lake County facility inspected every six months by an independent auditor for the next four years. If Abbott stays in compliance and completes the required follow-ups, it can then request to have the consent decree dissolved.

Will Abbott Cut Prices To Regain Share?

Joe Plandowski, president of Lakewood Consulting Group (Lake Forest, IL), notes that Abbott has historically been a vendor that is reluctant to lower prices. But he thinks Abbott is likely to offer a freeze in its pricing for other diagnostic products if a customer is willing to add the company's immunoassays back to its menu.

Plandowski believes that even after four years, a lot of lab managers are still mad at Abbott for the time and money they incurred in switching to other immunoassay systems. "It was not an easy transition for labs. Revalidating and changing to a new instrument system takes a lot of work. That's why when the FDA initially set the product ban for December 1999, labs protested and got the suspension delayed until January," notes Plandowski. As a result, he anticipates that Abbott will focus its sales efforts at the hospital finance departments rather than the lab directors and managers.

Michael Farmer at the consulting firm McEvoy & Farmer (Seattle, WA) adds that although Abbott has shown pricing discipline in the past, the desire to regain its dominance in the immunoassay market is likely to lead them to try and "buy it back" through aggressive pricing.

Meanwhile, Abbott spokeswoman Rhonda Luniak would not comment on the company's pricing strategies, but she did note that a top goal for Abbott was regaining a contract with Novation (Irving, TX), the nation's largest group purchasing organization (GPO). Novation terminated a sole-source contract it had with Abbott for immunoassay tests in mid-2002 and replaced it with three other vendors, including Bayer, Roche, and Dade.

Which New Immunoassays Will Abbott Introduce This Year?

Abbott is expected to re-introduce tests on a rolling basis this year according to their revenue contribution. Top priorities include vitamin B12, ferritin, and folate tests for the AxSym system, according to Luniak.

Abbott can now also begin introducing new products, and among the first is expected to be the company's Prism system for blood banking. Prism had been scheduled for launch back in 2000, but this was blocked by the consent decree.

Other new products that Abbott is expected to bring to market quickly are AxSym HCV, hepatitis A, hepatitis B surface antigen, total PSA, and free PSA. Dr. Assarian from Hospital Consolidated Labs believes the most compelling of these tests are Abbott's highly sensitive hepatitis tests, which he says could help Abbott "win back market share fairly quickly."

In addition, Abbott's manufacturing partner, Axis-Shield (Dundee, Scotland), submitted a 510k application with the FDA seeking clearance for a B-type natriuretic peptide (BNP) test for use on Abbott's AxSym in December. Abbott is aiming to begin marketing the Axis-Shield BNP test in the United States within the next few months and is already selling it in Europe.

Larry McGrath, publisher of *IVD News* (Grass Valley, CA), says that without some form of pricing concessions, Abbott's best chance of regaining share is by introducing unique markers that are in high demand. So he says Abbott's agreements with Axis-Shield could play a large role in determining its success. In addition to BNP, Axis-Shield is developing AxSym tests for Abbott for testosterone, Lyme disease, homocysteine, and autoimmune disease.

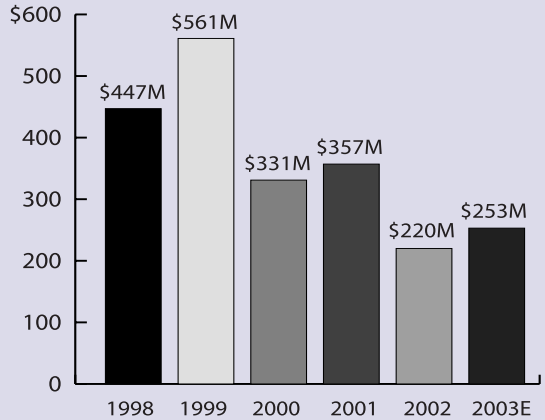
Certainly Abbott has a long way to go toward rebuilding its immunoassay menu. As of year-end 2003, the company's U.S. menu for AxSym totaled 48 tests (including drugs-of-abuse/toxicity tests and therapeutic drug monitoring), while the Architect i2000 was at only 10 tests.

What Was The Financial Cost Of The Consent Decree To Abbott?

In the four years that the consent decree was in effect, 2000 to 2003, operating profits at Abbott's diagnostic division averaged $290 million per year versus the $561 million that the division earned in 1999. That's equal to $271 million in lowered annual profits (i.e., $561 million minus $290 million) or a total of $1.1 billion over the course of the past four years (i.e., $271 x 4 = $1.1 billion).

In addition, Abbott took a $168 million charge in 1999, including a $100 million fine paid to the FDA, when it first signed the consent decree, took another $140 million write-off in mid-2002 when it failed its first attempt to regain compliance, and then took a charge of more than $100 million in late 2002 to restructure its diagnostics division.

Abbott Diagnostics' Operating Earnings



E=estimated based on reported results for nine months ended Sept. 30, 2003
Source: Abbott and *DTTR* estimate for 2003

Add up four years of depressed profits and $400-plus million in write offs and *DTTR* calculates that the whole ordeal has cost Abbott more than $1.5 billion. That's a big number, even for a healthcare conglomerate the size of Abbott.

Finally, Jack Finn, chief executive of Centrex Clinical Labs (New Hartford, NY), notes that the time and money Abbott spent to satisfy the FDA's concerns diverted at least some of its attention away from research and development efforts in key technologies such as lab automation. Finn says that, after an 18-month decision process, Centrex has decided to invest $1.3 million in a robotic system from Bayer that will include the company's Advia Centaur immunoassay system. Centrex is an independent for-profit lab owned by Faxton St. Luke's Healthcare in Utica, New York.

Who Took The Blame?

Miles White, age 48, chairman and chief executive of Abbott, held key management roles at the company's diagnostic division throughout the mid-1990s as he climbed his way toward becoming CEO of the entire company in January 1999. But White has come out of the FDA ordeal unscathed. "He's the Teflon man, but it will be interesting to see if the board renews his employment contract next time it comes due" observes one industry consultant who wishes to remain anonymous.

The fall guy turned out to be Tom Brown, age 55, who "retired" as senior vice president for diagnostics operations in mid-2002 following news that the company's Lake County facility had failed another FDA inspection. In September 2002, Abbott named Joe Nemmers, age 49, as Brown's replacement. Nemmers was formerly vice president of global commercial operations for Abbott Diagnostics.

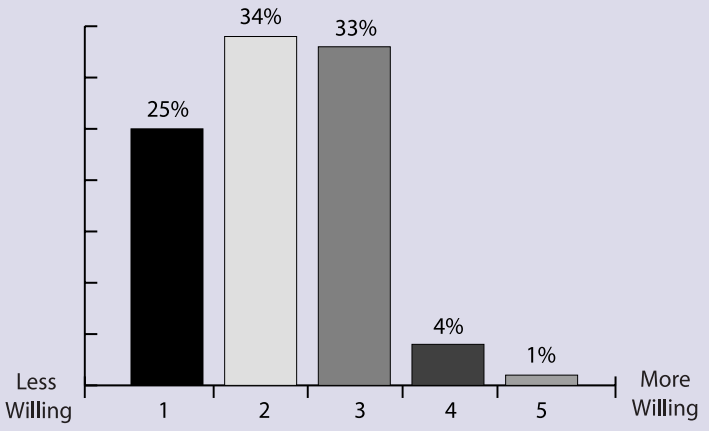
It appears that the saving grace for White has been the relatively strong performance of Abbott's stock price. From Nov. 8, 1999, the day before the initial consent decree was announced, through Dec. 17, 2003, the day before "voluntary compliance" was announced, Abbott's stock price rose from $40.68 to $45.60 for a 12% gain. During the same time frame, for example, Johnson & Johnson was unchanged, Merck fell 39%, and Pfizer fell 13%.

What Does It All Mean For Labs?

Though some of the nation's largest labs had backup immunoassay systems to Abbott or have switched to another vendor, many smaller labs have been forced to send out tests for B12, ferritin, and folate to reference labs at considerable expense over the past four years. So Abbott's plans to return these tests to the market in short order will bring financial relief to smaller labs.

The Abbott debacle has also highlighted the risk of putting all your eggs in one basket. A survey conducted by SG Cowen show that 59% of labs are now less willing to rely on a sole-source supplier for their immunoassay needs. Despite these findings, Barry Portugal, president of Health Care Development Services (Northbrook, IL), says the trend is going the other way. Multi-hospital systems are increasingly moving to standardize their test instrumentation on one vendor to improve consistency and lower costs, according to Portugal.

Willingness To Rely On Sole Supplier *(N=846 labs)*



Source: SG Cowen survey, May 2002

Finally, Westgard says that the Abbott situation underscores the need for labs to use control materials from an independent vendor. "Analytical quality should not be taken for granted," he adds.

Abbott To Acquire TheraSense For $1.2 Billion In Cash

Abbott is paying a steep price to bolster its presence in a market that appears to be slowing down

On January 13, Abbott announced an agreement to purchase all of the shares of TheraSense (Alameda, CA) for $27 per share in cash, or $1.2 billion. On a conference call with analysts, Mark Lortz, chairman and chief executive of TheraSense, said that Abbott plans to keep both its MediSense and TheraSense product lines on the market after the acquisition closes, which is expected by June 30.

David Kliff, publisher of *Diabetic Investor* (Buffalo Grove, IL), says Abbott's MediSense business was quickly becoming an "also-ran" in the blood glucose testing market behind Roche and JNJ's Lifescan. "Abbott needed to make a major acquisition to bolster its position in the marketplace," according to Kliff. "Retailers are increasingly choosing to stock Roche's Accu-Chek, Lifescan, and a generic brand, and MediSense and Bayer have been getting crowded out," he adds.

Kliff believes the two product lines will compliment each other, with MediSense's core market being low-end monitors and strips and TheraSense aimed at the premium market. He says the combination should also help Abbott get better shelf space with retailers.

TheraSense also brings Abbott the technology for a continuous blood glucose monitor—the FreeStyle Navigator. TheraSense submitted a Premarket Approval application for the Navigator in November and clearance from the FDA is expected by late 2004/early 2005. Navigator is designed to provide real-time glucose data, hypo- and hyperglycemic alarms and trend analysis. However, Kliff believes the market for a continuous blood glucose system will be limited because 1) most insulin-using diabetics will be unable to understand the data provided; and 2) it is unclear whether health insurance companies will cover what he assumes will be an expensive product.

Regarding the price for TheraSense, *DTTR* observes that Abbott paid $876 million for MediSense back in August 1996. That price worked out to be five times MediSense's revenue of $173.8 million for the fiscal year ended March 31, 1996 and 26 times its operating income of $33.8 million for the same period.

At $1.2 billion, Abbott is paying six times TheraSense's estimated revenue of roughly $200 million for 2003 and the company is operating at a loss. *DTTR* also observes that back in 1996, the self-monitoring blood glucose market was just beginning to kick into a high gear. It now appears that growth in this market has slowed from 10% to 15% per year to around 5%. "The market is maturing," concludes Kliff.

The Self-Monitoring Blood Glucose Market *($ millions)*

	9 mos. 2003 Revenue	9 mos. 2002 Revenue	% Chg	% Chg after exchange rate adjustments
Roche	1,500	1,430	5%	12%
JNJ/LifeScan	1,040	995	5%	1%
Bayer Diagnostics	475	558	-15%	-5%
Abbott/MediSense	400	366	9%	3%
TheraSense	150	111	35%	30%
Total	3,565	3,460	3%	5%

Source: Company reports and *DTTR* estimates

Abbott To Buy i-Stat For $392 Million In Cash

On December 15, Abbott announced an agreement to purchase all of the shares of i-Stat Corp. (East Windsor, NJ) that it doesn't already own for $15.35 per share in cash, or $392 million. Close of the deal is expected by February.

Abbott had purchased 2 million shares of i-Stat, or 6.6% of the total currently outstanding, in 1998 as part of a five-year agreement to distribute i-Stat's handheld blood analyzer. That distribution agreement was set to expire on Jan. 1, 2004, and i-Stat had planned to bring marketing and distribution of its analyzer in-house.

The acquisition agreement will make i-Stat a stand-alone division at Abbott. On a conference call with shareholders and analysts, Bill Moffitt, chief executive of i-Stat, said that Abbott plans to increase its marketing efforts for the i-Stat analyzer as well as R&D investments to expand its test menu.

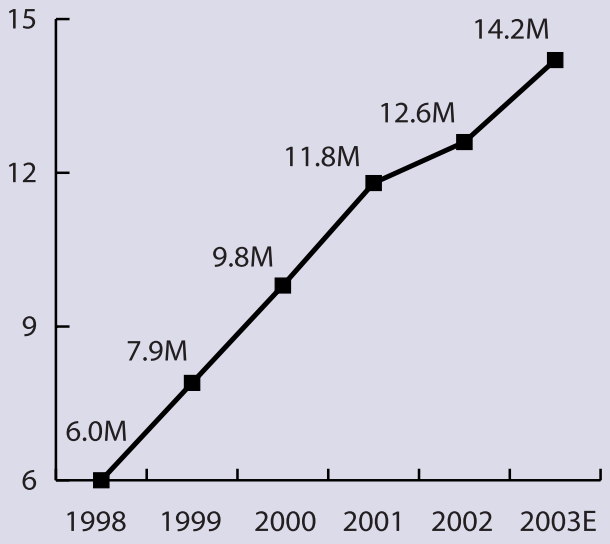
The i-Stat analyzer is cleared by the FDA to perform 16 tests, and it calculates another six parameters (see table). The most recently cleared tests include prothrombin time, troponin I, and kaolin ACT. Test cartridge sales grew by an estimated 13% in 2003 to 14.2 million. New tests being developed include BNP, CRP, PSA, TSH, T3, and T4.

i-Stat's Test Menu

FDA-Cleared Tests	
Celite ACT	PCO_2
Chloride	pH
Creatinine	PO_2
Glucose	Potassium
Hematocrit	Prothrombin time
Ionized calcium	Sodium
Kaolin ACT	Troponin I
Lactate	Urea Nitrogen
Calculated Parameters	
Anion gap	Hemoglobin
Base excess	O_2 saturation
Bicarbonate	Total CO_2

Source: i-Stat

i-Stat: Test Cartridge Sales



E=estimated based on reported results for nine months ended Sept. 30, 2003
Source: i-Stat and *DTTR* estimate

Since its inception in 1983, i-Stat has accumulated losses totaling $288.8 million. But three Wall Street analysts following the company had estimated that it would become profitable in 2004 and earn $0.27 per share, or roughly $6 million, on end-user sales of $100 million. Based on these figures, Abbott is paying more than 50 times expected net income and about four times revenue.

Even so, some investors believe Abbott is getting a bargain because i-Stat is on the cusp of leveraging the 30,000 analyzers it has placed worldwide by expanding its test menu with several important new tests. Furthermore, Abbott has identified point-of-care as strategically important and has estimated that the U.S. market will double over the next five years to $1 billion, largely at the expense of traditional labs.

IVD Stocks Soared 81% In 2003

Twenty-seven IVD stocks jumped an unweighted average of 81% last year versus a 26% gain for the S&P 500 Index and a 50% gain for the Nasdaq.

i-Stat Corp. (East Windsor, NJ) led all IVD companies last year with a stock price gain of 283% to $15.30 per share for a market cap of $309 million. Abbott Labs recently announced plans to acquire all the shares of i-Stat that it doesn't already own for $15.35 per share (*see details on p. 10*).

Digene (Gaithersburg, MD) was up 250% to $40.10 per share for a market cap of $736 million. The company's Hybrid Capture 2 HPV test has become the standard of care for follow-up testing for indeterminate Pap tests. And in March 2003, the test was cleared by the FDA for use in cervical cancer screening in conjunction with a Pap test for any woman age 30 and older.

Other IVD stocks that logged gains of more than 200% last year included **Quidel Corp.** (San Diego), up 211% to $10.77 per share, and **Gen-Probe** (San Diego), up 207% to $24.57 per share. The worst performing IVD stock was **Biosite** (San Diego), which fell 15% to $28.95 per share.

IVD Stock Review for 2003

Company (ticker)	Div. Yield	P/E Ratio	12/31/03 Price	52-Week % Chg
Abbott Labs (ABT)	2.1	30	46.60	17
Apogent (AOT)	0.0	na	23.04	11
Bayer (BAY)	3.3	97	29.41	36
Beckman Coulter (BEC)	0.8	19	50.83	72
Becton Dickinson (BDX)	1.4	20	41.14	34
Bio-Rad Labs (BIO)	0.0	21	57.67	49
Biosite (BSTE)	0.0	19	28.95	-15
Cholestech (CTEC)	0.0	24	7.64	10
Cytyc (CYTC)	0.0	21	13.84	36
Dade Behring (DADE)	0.0	na	35.74	129
Diagnostic Products (DP)	0.5	23	45.91	19
Digene (DIGE)	0.0	na	40.10	250
Exact Sciences (EXAS)	0.0	na	10.12	-7
Gen-Probe (GPRO)	0.0	57	24.57	207
Igen (IGEN)	0.0	na	58.87	37
Immucor (BLUD)	0.0	27	20.39	51
Inverness Medical (IMA)	0.0	25	21.78	66
i-STAT (STAT)	0.0	na	15.30	283
Johnson & Johnson (JNJ)	1.8	23	51.66	-4
Luminex (LMNX)	0.0	na	9.38	128
Meridian (VIVO)	3.4	22	10.44	52
OraSure (OSUR)	0.0	na	7.96	46
Quidel (QDEL)	0.0	na	10.77	211
TheraSense (THER)	0.0	na	20.18	142
Third Wave Tech (WAVE)	0.0	na	4.45	69
TriPath Imaging (TPTH)	0.0	na	7.80	191
Ventana (VMSI)	0.0	56	39.40	71
Unweighted Avg.				81

na=The company has reported a loss in the most recent four quarters or the P/E is 100 or more. Source: *DTTR*

G-2 Insider

It looks like its only a matter of time before **Scott Garrett**, age 54, gains complete control of **Beckman Coulter** (Fullerton, CA) now that he's been promoted to president and chief operating officer. Garrett joined Beckman in August 1999 (*see DTTR, September 2002, p. 12*) as president of the company's clinical diagnostics division, and he will retain that role.

In addition, Garrret will now also have operating responsibility for the company's biomedical research division and supply chain services. Garrett has assumed the operating responsibilities for Beckman from **John Wareham**, 62, who will continue as chairman and CEO with a focus on strategic decisions for the company.

What does this management change mean. We'll, as CEO of Dade back in the mid-1990s, Garrett was the chief architect behind the mergers of the diagnostic businesses of Baxter, DuPont, and Hoechst AG. Only time will tell if Garrett's penchant for deal making will resurface at Beckman.

Reminder: There's still time to sign up for the upcoming conference, ***Achieving Outreach Leadership For Lab & Pathology Services***, in Atlanta, February 5-6. The two-day program will feature presentations from more than 20 executives at some of the nation's biggest outreach labs, including **David Beckwith, Ph.D.**, chief executive of Health Network Laboratories (Allentown, PA); **Wendell O'Neal, Ph.D.**, vice president at Alliance Laboratory Services (Cincinnati); **Steven Harris**, vice president and general manager at Carilion Consolidated Laboratory (Roanoke, VA); and **Michael Bissell, MD**, professor, dept. of pathology, associate dean for applied research at College of Medicine and Public Health, Ohio State University (Columbus, OH). For more info go to *www.g2reports.com*

Company References

Abbott Labs 847-937-6100
Alfa Scientific 858-513-3888
Beckman Coulter 714-871-4848
Bio-Rad 510-724-7000
Diabetic Investor 800-783-3712
Digene 301-944-7000
Fujirebio Diagnostics 877-861-7246
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