Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

IVD Makers Race To Combat Bioterror Dangers

Anxiety over the growing bioterrorism threat is spreading across the U.S. now that more than 12 people in South Florida, New York City, Reno, NV and Washington, DC have tested positive for exposure to anthrax and three have died, as of Oct. 29. Against this backdrop, several IVD companies are pushing hard to develop diagnostic tests to rapidly detect anthrax and other biowarfare agents. One such company is Cepheid (Sunnyvale, CA), which is developing an integrated DNA sample preparation, amplification and testing system (named GeneXpert) that can provide test results in approximately 30 minutes (including sample prep). GeneXpert is being developed under a contract with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). Cepheid president Kurt Petersen, PhD, *Continued on p. 2*

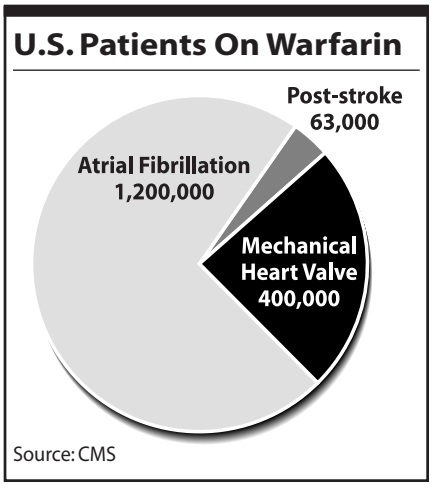
Medicare To Cover Some Home PT Testing

The Centers for Medicare & Medicaid Services (CMS) has announced its intent to issue a national Medicare coverage decision for at-home testing of prothrombin time to monitor dosages of warfarin, a blood-thinning drug better known by the brand name Coumadin (made by DuPont Pharma).

Coverage is expected to be available for patients beginning in early 2002. Medicare plans to cover payment for the disposable test strips; a coverage decision to pay for the hand-held monitor, which can cost upwards of $1,500, was not made.

Medicare's decision applies only to the estimated 400,000 patients who have mechanical heart valves and are using warfarin, according to CMS. For the largest group of warfarin users, the 1.2 million with atrial fibrillation, there is yet no national PT home-testing coverage.

Despite the limited coverage, the potential market size for PT test strip sales for home testing is substantial. Assuming one test per week at $5-$10 for 400,000 patients with mechanical heart valves, the annual market is in the range of $104 million to $208 million. *For more on the PT testing market, see pp. 5-7.*



▲ **IVD Makers,** *from page 1*

tells *Diagnostic Testing & Technology Report* (*DTTR*) that a prototype is expected to be delivered to USAMRIID by year's end.

Anthrax is caused by the bacterium Bacillus anthracis, *which is capable of forming spores that can travel through the air. Infection can result from inhaled, ingested or cutaneous (skin) exposure to spores. Anthrax does not spread from person to person*

The need for rapid tests is underscored by the fact that inhaled anthrax can kill in as little as 2-3 days. Culture-based tests used today at public health laboratories can take more than one day to confirm anthrax exposure. And PCR-based tests used to tell whether an individual has been infected can take up to an additional day. Petersen notes that the GeneXpert system uses a small enough level of power that it could be run off a car battery. This could potentially allow the U.S. armed services to perform DNA tests on military personnel at the point-of-care.

Disposable cartridges under development for GeneXpert will detect bacterial, viral and fungal infections (including anthrax, Q-fever and staph B enterotoxin) in aqueous solutions, as well as in blood and nasal swabs, according to Petersen. Cepheid is developing specific test cartridges for bacterial and fungal infections under a joint venture with Infectio Diagnostic (Sainte-Foy, Quebec). In addition, Cepheid is developing DNA tests for cancer in collaboration with the University of Pittsburgh Medical Center.

Petersen expects GeneXpert to be available for research use in 2002; clearance by the U.S. Food & Drug Administration is expected in 2003. Petersen adds that although interest in Cepheid's products has increased since Sept. 11, it is extremely difficult to predict what the ultimate market may be for bioterrorism testing.

Cepheid has been selling a miniaturized DNA amplification and testing system named Smart Cycler for research use since May 2000. The Smart Cycler, which does not include a sample prep component, is about the size of a suitcase and weighs 65 pounds. USAMRIID has been using three Smart Cycler XC systems at Fort Detrick, MD for the past year. Other federal purchasers of Smart Cycler and Smart Cycler XC include the Centers for Disease Control & Prevention and the FBI.

Through Sept. 30, 2001, Cepheid has sold more than 400 Smart Cyclers and one million disposable reaction tubes. The Smart Cycler has a list price of $27,495; the reaction test tubes, which do not include reagents, sell for $0.55 each. In the nine months ended Sept. 30, Cepheid reported a net loss of $11.319 million vs. a net loss of $30.764 million in the same period a year ago; revenue grew to $8.181 million from $4.428 million.

Vital Living Products To Sell Home Test For Anthrax

Vital Living Products Inc. (Charlotte, NC) says it will have an over-the-counter home anthrax test on the market as early as Thanksgiving. The environmental test, which does not require FDA approval, can detect anthrax in the air, in water and on surfaces and will retail for between $19 and $25, according to chief executive Donald Podrebarac. Vital Living is a small publicly traded company that derives most of its revenue from water testing kits. In the three months ended June 30, 2001, the company reported a net loss of $445,897 vs. a net loss of $148,269 in the same period a year ago; revenue rose to $644,350 from $506,533.

Abbott To Buy Vysis For $355 Million (or 13x Revenue)

Abbott Laboratories (Abbott Park, IL) has agreed to purchase Vysis Inc. (Downers Grove, IL) for $30.50 per share, or approximately $355 million, in a deal expected to close by year's end.

Vysis makes the PathVysion HER-2 DNA Probe Kit, which detects amplification of the HER-2 gene in breast cancer patients and has a maximum Medicare reimbursement of approximately $200 per test, using CPT codes 88271 (x 2), 88274 and 88365. Vysis also makes the UroVysion Bladder Cancer Recurrence Kit, which detects genetic changes in bladder cancer cells found in urine and has a maximum Medicare reimbursement of approximately $230 per test, using CPT codes 88271 (x 3), 88274 and 88365. Additional Vysis products include tests for prenatal testing, chronic myelogenous leukemia, chronic lymphocytic leukemia and bone marrow transplants. Abbott has been marketing Vysis' PathVysion and UroVysion tests under an exclusive agreement signed earlier this year (*DTTR, May '01, p. 1*).

Vysis At A Glance *(in thousands)*

	1st-Half 2001	1st-Half 2000
Revenue	$13,321	$10,513
Operating income	1,826	-2,462
Net income	2,352	-2,314
Cash holdings	12,450	8,365
Long-term debt	0	0

Source: Vysis

In the six months ended June 30, 2001, Vysis reported a net profit of $2.352 million vs. a net loss of $2.314 million in the same period a year ago; revenue was up 27% to $13.321 million. Based on these figures, Abbott is paying 13 times annualized revenue for Vysis and 75 times net income.

Separately, John Thomas, division vice president for investor relations at Abbott, says the company will "launch an unprecedented number of new diagnostics products in 2002." During a third-quarter earnings conference call on Oct. 10, Thomas noted the following:

- ▲ The U.S. Food & Drug Administration will begin a final inspection of Abbott's Lake County, IL manufacturing facility by the end of October. The inspection is expected to take 2-4 weeks. Assuming a successful completion, Abbott will begin re-introducing diagnostics products that have been banned from the marketplace under the company's consent decree with FDA. The first products expected to be re-introduced will include assays for B12, ferritin and folate.
- ▲ Abbott plans to introduce upwards of 20 new assays for its AxSym and other analyzers and plans to launch its Prism system for high-volume blood screening along with six new assays, including FDA pre-approved tests for hepatitis C antibody, hepatitis B surface antigen and HTLV-1 and HTLV-2.

Meanwhile, Abbott reports that worldwide diagnostics sales edged up 2% to $728 million in the third quarter ended Sept. 30, 2001. In the U.S., sales were up 5.9% to $317 million; internationally, sales fell 0.9% to $411 million.

Worldwide third-quarter revenue from the Medisense glucose monitoring unit (part of Abbott's diagnostics division) was up 4.4% to $118 million.

Cytyc To Buy Pro-Duct Health For $180 Million

Cytyc Corp. (Boxborough, MA) has agreed to purchase privately held Pro-Duct Health Inc. (Menlo Park, CA) for five million shares of Cytyc and $38.5 million in cash, or a total of approximately $180 million (based on Cytyc's share price of $28.21 at the end of trading on Oct. 26). The deal is expected to close by year's end.

Pro-Duct recently began marketing an FDA-approved procedure to determine predisposition for developing breast cancer ("ductal lavage") in high-risk women. There are approximately two million breast cancer patients in the U.S. and another three million at high risk for developing the disease, according to Cytyc.

Ductal lavage examines cells from inside the milk ducts, where most breast cancers originate. The minimally invasive procedure takes about 30 minutes at a physician's office and makes use of a proprietary hair-thin catheter developed by Pro-Duct to collect cells from the lining of the milk ducts. The cell specimen is sent to a laboratory for slide preparation using Cytyc's ThinPrep System and is then examined by a cytopathologist. The total cost of the procedure (which has been referred to as a "Pap smear for breasts") ranges between $350 and $700, including the cost of 1-3 catheters at $195 each. Laboratories preparing and analyzing Pro-Duct specimens may be reimbursed up to $48.92 per test by Medicare under CPT code 88108; physician reimbursement for extracting the specimen has not yet been set.

Pro-Duct (formerly named Windy Hill Technology) was co-founded in 1998 by Susan Love, MD, an adjunct professor at the University of California at Los Angeles and medical director of the Susan Love, MD Breast Cancer Foundation, and engineer/entrepreneur Julian Nikolchev.

New Pharma/Diagnostics Company Created: MedPointe

Sale of Carter-Wallace's businesses was completed despite protest from Gabelli Asset Management (Rye, NY), which had claimed that shareholders were being shortchanged in the transactions (DTTR, Oct.'01, p. 1)

Newly formed MedPointe Inc. (Cranbury, NJ) has completed its purchase of Wallace Pharmaceuticals (Cranbury) and Wampole Laboratories (also in Cranbury) from Carter-Wallace (New York City) for $408 million. MedPointe was formed by a group of pharmaceutical and diagnostics executives and received financial backing to complete the transaction from Carlyle Group and the Cypress Group (both in New York City). The acquired units had consolidated revenue of approximately $220 million and 525 full-time employees.

Dr. Anthony Wild, chairman and chief executive of MedPointe, is the former president of the global pharmaceutical sector at Warner-Lambert. James Burns, president and chief operating officer, is a former group vice president at Becton Dickinson. John Bridgen, PhD, will continue as president of Wampole Laboratories, and Thomas Gerstmyer will continue as president of Wallace Pharmaceuticals.

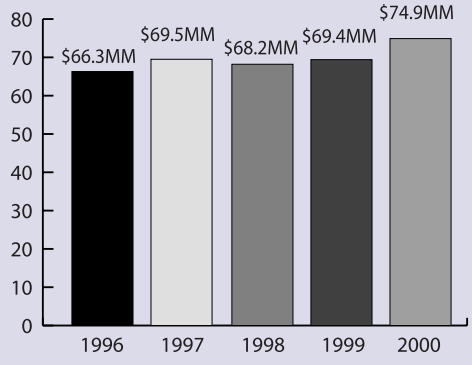
In a separate transaction, Church & Dwight Co. (Princeton, NJ) has completed the acquisition of Carter-Wallace's consumer products business (*e.g.*, Trojan condoms, Nair hair remover and First Response pregnancy test kits—$550 million in annual revenue) for a total purchase price of $739 million.

New Market Avenue Opened For Prothrombin Time Testing

The success of the blood glucose monitoring market indicates that patients who need regular and frequent testing will take advantage of the convenience of doing their own testing at home. Now that Medicare has announced plans for national coverage (starting in early 2002) of prothrombin time self-testing by beneficiaries with mechanical heart values, PT testing is expected to begin shifting out of the laboratory and the physician office just as glucose monitoring has.

PT testing is used by physicians to adjust dosages of warfarin. This blood-thinning drug is most commonly prescribed to patients with mechanical heart valves, and to a lesser extent, post-stroke patients with atrial fibrillation (*i.e.*, abnormal heart beat). Regular testing is needed because eating vitamin K-rich vegetables, drinking alcohol, taking certain over-the-counter medicines and smoking can change warfarin levels in the bloodstream: too much makes blood too thin, causing everything from nosebleeds to bleeding in the brain; too little can increase risk of stroke and blood clot formation.

Medicare Part B Payment For Prothrombin Time



Source: CMS

The overwhelming majority of PT tests are performed on Medicare beneficiaries because the incidence of atrial fibrillation increases as one gets older, from approximately 0.5% for ages 50-59 to nearly 10% for ages 80-89. Last year, 13.8 million PT tests were reimbursed by Part B under CPT code 85610, according to data from the Centers for Medicare & Medicaid Services (CMS). The average allowed charge was $5.42 per test, indicating an overall market of $74.9 million.

But the market potential is significantly higher. That's because thousands of patients who could be on anticoagulation medicine are not, as the table below demonstrates:

Anticoagulants: Indications & Utilization

Primary Indication	*U.S. Population*	*Warfarin Utilization*
Mechanical heart valve	400,000	100%
Atrial fibrillation	2,000,000	60%
Post-stroke	300,000	21%

Source: CMS

One reason why many patients are not being anticoagulated is the narrow therapeutic range of warfarin. Within the context of a busy practice, physicians hesitate to prescribe a drug that can cause lethal bleeding if not carefully monitored.

In addition, most patients taking warfarin are only tested about once every 4-6 weeks, even though numerous studies have indicated the need for more frequent testing. In one study (Horstkotte, 1996) cited by CMS, mechanical heart

valve patients using a home PT testing device were more often in therapeutic range and had fewer bleeding and clot formations:

Patients With Mechanical Heart Valves: *Lab Testing vs. Self-Testing*

	Lab Testing	*Self-Testing*
Number of patients	75	75
Avg. test interval/days	18.9	3.9
Time in therapeutic range	58.8%	92.4%
Stroke/clot formation	3.6%	0.9%
Major bleeding	10.9%	4.5%

Source: Horstkotte, 1996

A separate study (Stroke PORT, 1995) by the Duke Center for Clinical Health Policy Research estimated that prevention of a single stroke saves the health system approximately $250,000. In addition, PT home testing reduces the cost of frequent patient visits to physician offices, which can exceed $100 per visit, including the phlebotomy service, physician consultation and laboratory charge.

To date, the U.S. Food & Drug Administration has approved four PT testing systems for home use with a physician's prescription. Until now, absence of a national Medicare coverage policy and various Medicare carriers' refusal to reimburse suppliers for home testing have limited growth of the market. Based on data from International Technidyne Corp. and Roche Diagnostics, the two leading suppliers of PT home test devices, *DTTR* estimates that less than 1% of all U.S. patients being anticoagulated are testing themselves at home.

Nearly 80% of warfarin patients are managed through physician offices, which either test on-site or send blood samples to an outside laboratory. Test frequency is generally once every 4-6 weeks. This method has the highest adverse event rate (greater than 15%), according to CMS.

Approximately 20% of patients receive their care through anticoagulation clinics, which are often an outgrowth of the cardiology department at larger hospitals. These clinics are frequently managed by the hematology department at a hospital laboratory, with pharmacists doing the actual PT testing and dosage adjustments. Test frequency is about once every 2-3 weeks, with an adverse event rate of less than 8%, according to CMS.

Despite the clinical justification for shifting PT testing to the home, IVD manufacturing executives say several hurdles still remain:

- ▲ Although CMS has announced plans to reimburse some PT home testing, the actual amount has not been determined yet.
- ▲ The recent CMS coverage decision applies only to PT test strips, not to the hand-held monitors. Potential home-test patients may be unwilling to spend upwards of $1,500 to purchase a monitor, and manufacturers tell *DTTR* they cannot afford to give the monitors away.
- ▲ CMS is unlikely to reimburse manufacturers for the cost of training patients to do PT self-testing, and physicians may not have time to spend several hours in training each patient.

Below is an overview of FDA-cleared PT home testing devices (which require a physician's prescription) and their manufacturers.

International Technidyne Corp. (ITC-Edison, NJ), a subsidiary of Thoratec Corp. (Pleasanton, CA), manufactures the ProTime Microcoagulation System, which was the first PT test system approved by FDA for patient self-testing in March 1997. ITC president Larry Cohen tells *DTTR* that approximately 1,000 warfarin patients are currently using ProTime for home testing.

Privately held HemoSense (Milpitas, CA) has a PT home test device called InRatio that it hopes to have on the market next year. Separately, Avocet Medical (San Jose, CA), whose AvoSure PT home test system got FDA approval in 1999, ceased operations earlier this year after failure to gain sales momentum

The ProTime system consists of a small battery-powered instrument and disposable test strips. Approximately one drop of blood (27 uL) is obtained from the patient's finger, using ITC's Tenderlett Plus device, and placed on the ProTime test cartridge which has already been inserted in the instrument. The instrument provides information on the patient's blood levels, expressed in both PT seconds and INR values. The ProTime system includes on-board quality controls to ensure the system is working properly. The controls verify the collection of blood within a prescribed timeframe, the correct sample size and the reagent integrity within the cartridge. The system will not report a result if the controls are out of range.

ITC has contracted with Quality Assured Services (Winter Garden, FL) to distribute ProTime. The list price for each instrument is $1,500; packages of 25 test cartridges with 25 Tenderlett Plus lancets are priced at $250 (or $10 per test).

Roche Diagnostics (Indianapolis, IN) received FDA clearance to market its CoaguChek system for PT self-testing in April 1997. But Roche got tired of waiting for Medicare to establish a reimbursement policy, and in September 2000 announced it would no longer fill prescriptions to new self-testing patients. The company continues to supply test strips to several thousand home-testing patients who had purchased the device prior to September 2000. Now that Medicare has acted, Sunil Hazaray, director of sales and marketing for Roche's point-of-care division, says the company is reviewing a possible re-launch of marketing to the home market.

Roche continues to sell the CoaguChek system for professional use at a list price of approximately $1,300 per instrument and $190 per package of 30 test strips (or $6.33 per test). Roche's Safety Pro lancets cost $60 per package of 200.

Lifescan (Milpitas, CA), a unit of Johnson & Johnson, received FDA clearance to market its Harmony INR Monitoring System for PT testing in doctors' offices and patient self-testing on May 15, 2001. Lifescan plans to kick-off its U.S. marketing campaign for Harmony in the early part of the second quarter of 2002, says Eric Milledge, group chairman for Lifescan. The company has an exclusive U.S. marketing agreement with St. Jude Medical (St. Paul, MN) to promote the Harmony system. St. Jude is the world's leading supplier of mechanical heart valves, with an 80% market share. Milledge notes that St. Jude has 600 sales representatives in the U.S. who will begin marketing the Harmony system to cardiologists and surgeons next year.

Immucor In Nasty Proxy Fight With Venture Group

Kairos Partners (New York City) has commenced a hostile proxy battle to gain three seats on the board at Immucor Inc. (Norcross, GA). Kairos, a healthcare investment fund operated by StoneGate Partners and Aim High Enterprises, owns 841,370 shares of Immucor for an 11.6% stake. Immucor makes blood screening analyzers and supplies used primarily by blood banks and hospitals.

After a disastrous fiscal 2001, Immucor reported greatly improved results in 1Q02 (ended Aug. 31, 2001). Net income was $1.253M vs. a loss of $215,431; revenue rose 9% to $18.64M

According to a proxy statement filed with the U.S. Securities & Exchange Commission, Kairos claims that Immucor "has a dismal track record of poorly integrating acquisitions" and "a crushing debt load." Kairos says its suggestions to Immucor management on how to improve performance "have fallen on deaf ears." These suggestions include a focus on marketing Immucor's automated products, consolidation of product offerings, reduction of manufacturing facilities and excess staffing, and a restructuring of debt.

Kairos wants to replace three of Immucor's six directors, including Edward Gallup, who has served as chairman, president and chief executive of Immucor since its founding in 1982. Kairos' three nominees to Immucor's board include John McGuire, president of Whatman Bioscience (Newton, MA); Ronald Gilcher, MD, president of the Sylvan N. Goldman Center Oklahoma Blood Institute; and Peter White, who worked at Fleet Securities between 1981 and 2001 where he specialized in financing the takeover of businesses by private equity firms.

In a letter to shareholders dated Oct. 3, Immucor's board said it was "disappointed that the Kairos Group has chosen to start a costly and disruptive proxy contest, particularly at a time when Immucor is turning around and expects to set records for revenues and earnings in the current fiscal year." Immucor's turnaround plan includes major price increases and resolution of instrument performance issues, according to the letter. The board nominees will be voted on at Immucor's annual shareholders meeting on Nov. 30.

Immucor At A Glance

(for fiscal years ended May 31—in thousands)

	2001	2000	1999
Revenue	$69,438	$76,541	$59,525
Net income	-8,049	2,812	3,561
Long-term debt	39,738	34,815	31,548

Source: Immucor

In the fiscal year ended May 31, 2001, Immucor reported a net loss of $8.049 million vs. net income of $2.812 million in the previous year; revenue declined 9% to $69.438 million. As of May 31, the company had $3.1 million in cash holdings and long-term debt of $39.738 million. With 7.3 million shares outstanding at $4.76 per share as of Oct. 10, Immucor had a market capitalization of $35 million.

Immucor has suffered from performance issues related to its ABS2000 analyzer, which performs automated ABO grouping, Rh typing, antibody screening and crossmatching for the blood transfusion market. The problems (discovered in mid-2000) caused errors in test results and required Immucor to issue a "safety notification" on the product and the need for customers to do manual back-up testing. A sharp decline in instrument placements and some refunds followed. On Sept. 26 of this year, Immucor announced that, with FDA approval, it had lifted all safety notifications for the instrument and related software.

Visible Genetics HIV-1 Genotyping Test Gets FDA Approval

Visible Genetics Inc. (VGI-Toronto, Canada) has received clearance from the U.S. Food & Drug Administration to market its TruGene HIV-1 test kit and Open Gene DNA Sequencing System for routine clinical use. The TruGene HIV-1 test is the first DNA sequencing technology to be FDA-approved. VGI will charge labs $225 per test kit and begin shipping kits in November, Richard Daly, president of VGI, tells *DTTR*.

Genotype tests, such as VGI's TruGene HIV-1 test, sequence genes of the HIV virus. Physicians use this information to better understand a specific patient's resistance profile and adjust drug therapy accordingly.

Today, most physician offices and laboratories refer their genotype testing to larger reference labs operated by the likes of Quest Diagnostics, Laboratory Corporation of America and Specialty Laboratories. These mega-labs use proprietary "home brew" tests that do not require FDA approval. HIV-1 genotyping has been a lucrative market for the big labs. Medicare covers genotype analysis of HIV-1 under CPT code 87901 at a maximum allowable rate of $355.78 per test. Commercial health plans reimburse such genotyping at between $350 and $550 per test, according to Daly.

Roughly 350,000 AIDS patients are in active treatment in the U.S., and they are changing drug therapy somewhere between one and two times per patient per year, according to Daly. That gives VGI a total potential market of roughly 500,000 tests per year, or annual test kit revenue of some $112.5 million (*i.e.*, 500,000 tests x VGI's charge of $225 per test=$112.5 million).

Anticipating FDA approval, VGI has already installed its OpenGene DNA Sequencing System at 130 labs in the U.S. and has another 170 running outside the U.S. Daly says it costs VGI about $10,000 to manufacture and install the system and train staff at each site. He adds that VGI's cost to manufacture each disposable test kit is about $100-$110 per test, so VGI's sequencers are generating more than $100 in contribution per test. He expects VGI to get FDA clearance for hepatitis C and hepatitis B test kits in 2002.

Embryotech Gets FDA Okay For Male Infertility Home Test

BabyStart test kits are available in Europe and Asia through Embryotech's distributor, Med-Direct International (Dingwall, England), and sell for about $46 per kit

Embryotech Laboratories (Boston, MA) has received FDA approval for over-the-counter sale of its FertilMarq home test for male infertility. FertilMarq, which has a retail price of $39.95 per kit, is the first home-based testing kit for male infertility to obtain FDA clearance. Designed as an initial screening test, FertilMarq provides an assessment of sperm concentration, based on World Health Organization guidelines. Results are provided in about five minutes, according to Embryotech.

The company says FertilMarq will be marketed initially as a "stand-alone" male fertility test and, subsequently after final FDA review, as part of a joint "his-and-hers" fertility test. The "his-and-hers" kit will combine ovulation tests with the FertilMarq test and will be marketed under the name, BabyStart.

TheraSense Raises $114 Million From IPO

TheraSense Inc. (Alameda, CA) raised gross proceeds of $114 million from its initial public offering on Oct. 11. U.S. Bancorp Piper Jaffray was lead underwriter. Six million shares were sold at $19 per share. With a total of 38.1 million shares outstanding, the company has a current market capitalization of $723.9 million.

TheraSense makes the Freestyle blood glucose monitoring system, approved by the U.S. Food & Drug Administration in January 2000. U.S. sales began in June 2000. As of July 31, 2001, more than 390,000 Freestyle meters and more than 79 million test strips have been shipped, the company says. In the six months ended last June 30, TheraSense posted a net loss of $53.716 million on revenue of $25.524 million. Since its inception in 1996, it has accumulated net losses of $89.7 million.

After underwriting commissions to investment bankers, TheraSense received some $100 million in net proceeds from the IPO. The company says it will use approximately $50 million to expand its sales and marketing.

W. Mark Lortz, chairman and chief executive since December 1997, was previously an executive at Lifescan (Milpitas, CA). Last year he earned a salary of $250,000, plus a $25,000 bonus. He owns 784,150 shares in TheraSense for a 2.1% stake currently worth $14.9 million.

Given Imaging Nets $55.8 Million From IPO

Given Imaging Ltd. (Yoqneam, Israel) completed its initial public offering of five million common shares priced at $12 per share on Oct. 3. Given received net proceeds of $55.8 million, after $4.2 million in underwriting commissions. With a total of 25.1 million shares outstanding, Given has a current market capitalization of $301.2 million.

The company has developed the Given System, a wireless imaging system for visual examination of the gastrointestinal tract. It uses a miniaturized video camera contained in a capsule that is about the size of a lima bean. The capsule is swallowed by the patient and delivers high-quality color images in a non-invasive manner to a portable data recorder (about the size of a Sony Walkman) worn on the patient's hip. FDA cleared use of the system over the summer (*for more details, see DTTR, Oct. '01, p. 4*).

In the six months ended June 30, Given reported a net loss of $7.394 million vs. a net loss of $2.574 million in the same period a year ago. The company has not generated any revenue to date. Since its inception in January 1998, Given has incurred $19.453 million in net losses.

Given was founded in 1998 by its president and chief executive, Gavriel Meron, previously chief executive of Applitec Ltd., an Israeli designer and manufacturer of video cameras and systems for the endoscopy market. Meron owns 349,047 shares of Given for a 1.4% stake currently worth about $4.2 million.

IVD Stocks Jump 17% In Latest Six Weeks

The G-2 Diagnostic Stock Index rose 17% in the six weeks ended Oct. 26. Fourteen stocks in our index rose in price, five fell, one was unchanged. Since the start of the year, the index has risen 22%, while the S&P 500 is down 16% and the Nasdaq is down 28%.

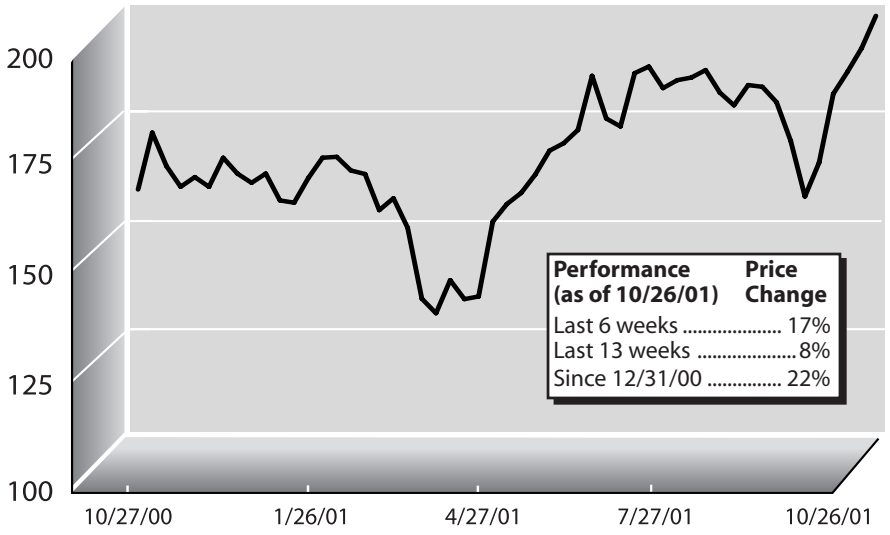
Shares of Bayer, which trade on the German stock exchanges, have fallen 40% so far this year to 33.28 euros per share; Roche non-voting equity shares, which trade on the Zurich Stock Exchange, are down 31% year-to-date to 113.50 Swiss francs per share

Affymetrix (Santa Clara, CA) vaulted 92% to $31.70 per share for a market capitalization of $1.8 billion. The company recently settled its legal dispute with biotech firm Hyseq Inc. (Sunnyvale, CA) over certain patents and licenses owned by each company. In addition, the two companies formed a joint venture to boost the development and commercialization of new opportunities in the DNA array market. Financial terms of the settlement, which is subject to court approval, were not disclosed. Separately, Affymetrix posted a less-than-expected loss of $4.805 million in the three months ended Sept. 30 vs. a net gain of $295,000 in the same period a year ago; revenue was flat at $55.365 million.

Cholestech (Hayward, CA) jumped 62% to $20.02 per share for a market cap of $249 million. Since mid-August, shares of Cholestech have risen 150%. The company recently reported a third-quarter profit of $1.618 million vs. $29,000 in the same period a year ago; revenue was up 39% to $12.139 million. **Quidel** (San Diego, CA) rose 52% to $6.25 per share for a market cap of $176 million. **Digene** (Gaithersburg, MD) rose 42% to $36.19 per share for a market cap of $604 million.

Biosite (San Diego, CA) fell 30% to $16.75 per share for a market cap of $260 million. The company recently warned that a license lawsuit filed against it by Xoma Inc. (Berkeley, CA) has interfered with deliveries to its antibody development and diagnostic marker discovery customers (*DTTR, Sept. '01, p. 11*). In the three months ended Sept. 30, Biosite reported revenue of $17.007 million, up 18% from the same period a year ago; net income was up 5% to $2.13 million.

G-2 Diagnostic Stock Index



Source: The G-2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 20 diagnostic test and equipment makers.

% price change, 6 weeks ended 10/26/01

	Price	% Chg
UP		
Abbott Labs	$54.30	7%
Affymetrix	31.70	92%
Bio-Rad	61.49	26%
Beckman Coulter	43.36	1%
Becton Dickinson	36.70	2%
Cholestech	20.02	62%
Cygnus	6.24	19%
Cytyc	28.21	32%
Diagnostic Products	48.29	19%
Diametrics	4.16	3%
Digene	36.19	42%
Inverness Medical	38.06	3%
Johnson & Johnson	58.67	5%
Quidel	6.25	52%
DOWN		
Biosite	16.75	-30%
Calypte	0.25	-14%
Careside	2.29	-10%
i-Stat	6.48	-4%
Ventana	23.05	-7%
UNCHANGED		
Meridian	4.81	0%

G-2 Insider

Why is Abbott Laboratories willing to pay 13 times revenue for Vysis (*see page 3*)? Well, at Washington G-2's recent Lab Institute in Arlington, VA, James Koziarz, PhD, vice president, diagnostic products, R&D at Abbott Laboratories, provided one reason in his presentation, *Major Trends in Diagnostic Technology*, on Oct. 26.

Koziarz said that Abbott's efforts in molecular diagnostics are aimed at developing or acquiring tests that provide information that physicians can use to make treatment decisions. He noted that Vysis' PathVysion test fits this bill. The PathVysion test detects whether or not there is an overabundance of the HER-2 gene in breast cancer patients and is directly linked to Herceptin drug treatment decisions.

"That's a lot different than, to speak bluntly, the BRAC1 and BRAC2 gene products that were identified a few years ago by Myriad Genetics and that don't have an intervention [*i.e.*, treatment decision] at this point," noted Koziarz.

Abbott is "looking not just at the ability to do the detection because, in effect, that's easy. If you told us to find a gene in a specimen, we could find it. The real key is what to do with that information. The real key is to be able to link it to a diagnostic intervention that has value. And once we do that, I think we've hit the real value of molecular and genomic testing," emphasized Koziarz.

Koziarz also noted that the molecular and genetic testing area is an "intellectual property rich area" in which "everybody owns some intellectual property, but no one company owns all of it." As a result, he expects there will be a lot of collaborations, partnerships and cross-licensing among companies working to bring new tests to the market.

Company References

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