Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

Vol. III, No. 5/January 2003

CONTENTS

WASHINGTON G-2 REPORTS

Established 1979

OUR NEW YEAR'S **Exclusive**

Top IVD Execs Preview Industry Prospects For 2003

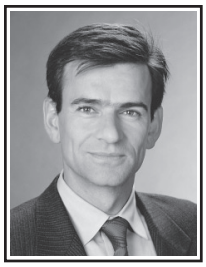
For an inside prognosis of what may be in store for the IVD industry in 2003, Diagnostic Testing & Technology Report (DTTR) *contacted top executives at 10 of the world's leading diagnostics manufacturers. Excerpts of our exclusive interviews begin below and continue through p. 10.*

Heino von Prondzynski

Heino von Prondzynski, head of the diagnostics division at Roche (Basel, Switzerland), anticipates volume growth in the routine chemistry and immunoassay market of about 2%-3% in the U.S. and Europe, but slightly higher in Japan. Reagent pricing pressure continues worldwide and is most severe in Japan, where the government imposed a reimbursement cut of 13% for all clinical diagnostics in early 2002, he notes. Pricing pressure in the U.S. immunoassay market has intensified, he adds, as companies seek to win accounts switching from Abbott because of its ongoing quality system problems with the Food & Drug Administration.

Prospects are much brighter in the $4.4 billion glucose self-testing market, which is being invigorated by TV advertising campaigns. Prondzynski says Roche launched its first TV ad in the U.S. for its Accu-Chek glucose monitors in May 2002, then saw its placement rates soar from a 3%-4% market share to nearly 20%. Roche is developing a second U.S. TV ad campaign and is expanding this form of advertising in Europe, he says. Accu-Chek is now the single largest product line for all of Roche, he points out, and has current annual revenue of about 2.4 billion Swiss francs (US $1.7B) with 15% year-over-year growth.

Prondzynski anticipates continued double-digit growth in the worldwide molecular diagnostics market, estimated at roughly $1.5 billion. He believes the cancer diagnostics market will advance most rapidly in the U.S. because of this country's "clearer reimbursement system," coupled with pressure from patient advocacy groups. Roche's molecular diagnostics division currently generates nearly 1 billion Swiss francs (US $675M) per year, he says, with an annual growth rate of better than 15%. More and more hospitals are adding PCR technology to their labs, and he expects the technology ultimately will spread to all labs, including smaller hospitals and independent labs.



Martin Madaus

Head of Roche's U.S. diagnostic operations. ***Roche Diagnostics*** *(Indianapolis, IN) has 3,500 diagnostics employees in the U.S., where it generates more than $1.5 billion annually.*

DTTR: *How are your settlement negotiations going with Igen International?*

Madaus: We are making progress. We're hopeful we can put this thing to bed sometime soon … Despite our issues with Igen, we continue to gain immunoassay contracts. We are growing 30% annually in immunoassay.

DTTR: *What's the current pricing environment for reagents?*

Madaus: Hospitals are still really focused on lowering their operating costs ... Pricing has become less transparent and harder to compare from vendor to vendor because there is more bundling of instruments, service and automation into reagent contracts … Pricing pressure for routine chemistry reagents has lessened a little bit. But there has been more of a price drop in immunochemistry. Everyone is competing aggressively for the business Abbott is losing.

DTTR: *What are some of the key products Roche has under development?*

Madaus: We should begin clinical trials of our P450 marker next summer. We're developing this test in collaboration with Affymetrix. The test determines how your body metabolizes certain drug classes, and it could become a major test for us … We are also developing a DNA-based human papillomavirus (HPV) test that we hope to have on the U.S. market in home-brew form sometime in 2004 … In the nearer term, we should have a West Nile virus test ready for the blood screening market by next summer.

DTTR: *What is Roche doing to prepare for the loss of its PCR patents in 2004 and 2005?*

Madaus: It's not really that big of a problem because most of the expiring patents are related to our first-generation products. Our TaqMan products have many new patents that won't expire for a long time … We have a huge lead on any potential new competitors. We've got a track record for high quality and automation … PCR-based testing is still largely a home-brew market, and your instruments and reagents have to provide standardized, comparable results. This won't be easy for new competitors to duplicate.

DTTR: *What's the outlook for acquisitions at Roche?*

Madaus: It would be difficult for us to make a major acquisition, but we'll continue to look for smaller acquisitions where we can add a new technology. We'll also continue to seek out licensing agreements for new technologies.

DTTR: *How is the shortage of lab employees affecting the IVD industry?*

Madaus: The shortage has caused more competition for lab employees and higher turnover rates. IVD companies need to provide more service. When a technical problem happens in a lab, we need to be able to help solve it quickly because lab staff are stretched thin. High turnover rates in labs mean that we have to provide more training and service. Quality of service from IVD vendors is becoming more and more important.

DTTR: *What are your thoughts on the future of point-of-care testing?*

Madaus: It will continue to move forward on a test-by-test basis. But I don't anticipate any major shifts in testing back to physician offices anytime soon. I'm doubtful we'll ever get back to the volume of testing in physician offices prior to the CLIA '88 regulations. Physicians are just too overworked as it is.

Ed Michael

Vice president, immunoassay/ clinical chemistry, ***Abbott Diagnostics****. The company, based in Abbott Park, IL, is the world's second largest IVD company, with worldwide annual revenue of $2.9 billion and 16,500 employees.*

DTTR: *What's the latest on Abbott's consent decree with the FDA?*

Michael: Getting our Lake County diagnostics operations back in compliance is our top priority. We've hired two new consulting firms [Bio-Reg and AccuReg] to help us review the latest inspection report from FDA, and we hope to be ready for another inspection by the second or third quarter of 2003. At that point, it will be up to FDA in terms of when they schedule the inspection, how long it will take, and when the agency issues its report.

DTTR: *What are some of the new products Abbott will introduce in 2003?*

Michael: We will introduce three new Architect systems, including the Architect i2000 for mid-volume immunoassays, the Architect c8000 for high-volume clinical chemistry and the Architect ci8200, which integrates both the i2000 and the c8000 instruments onto one platform.

We will also begin distributing an HIV-1 genotyping test developed by Celera Diagnostics and recently cleared by FDA.

Pending the outcome of our next FDA inspection in Lake County, we will launch a number of new products and assays, including our Prism blood banking system, as well as hepatitis C and HIV tests for our AxSym system, and free and total PSA assays for AxSym and Architect.

DTTR: *i-Stat recently announced it would not renew its distribution agreement with Abbott, effective Jan. 1, 2004 (see DTTR, Sept. 02, p. 10). What happened?*

Michael: Well, it was i-Stat's decision. We had been in discussions to extend the agreement and we're still talking to them. If there is a possibility to extend the agreement, then we'd like to. We think the i-Stat products are good products.

DTTR: *What's your outlook on point-of-care testing? Will the majority of central lab testing ever move to the point of care?*

Michael: Certainly point-of-care testing is growing. But 10 years from now, I still believe the majority of lab tests will be performed at hospital and reference labs.

DTTR: *Where is Abbott Diagnostics focusing its research and development efforts?*

Michael: The majority of capital spending remains in the immunochemistry areas. But we're investing an increasing amount in molecular diagnostics and self-testing for blood glucose.

DTTR: *What're some of the barriers that could delay the widely anticipated growth in molecular diagnostics?*

Michael: How widespread it becomes will depend on the value each test provides. Success will be determined on a test-by-test basis. Efficacious tests will command a premium price and will gain market acceptance … Certainly, you should expect more molecular tests to be brought to market in the coming years … Another key factor will be education. Physicians will need to be educated on the use and value of each new test, and this will take some time.

DTTR: *How has the integration of Vysis gone?*

Michael: We've kept Vysis as a wholly owned subsidiary to keep its small-company entrepreneurial spirit alive, though we are forming a single marketing team to sell Abbott's existing molecular diagnostics combined with Vysis' tests.

Scott Garrett

President of Beckman Coulter's clinical diagnostics division. ***Beckman Coulter*** *(Fullerton, CA) ranks among the top six IVD companies, with worldwide annual revenue from clinical diagnostics of approximately $1.4 billion.*

DTTR: *Name a few new products that Beckman will introduce in 2003.*

Garrett: We just began shipping our Synchron LXi system, which combines chemistry and immunoassay testing on a single platform and is aimed at mid-volume labs. And we hope to launch our Unicel DXl immunoassay system for high-volume labs in mid-2003.

We are stepping up our investments to develop new assays, particularly in the area of immunoassays. We've currently got 40 on the market in the U.S. and Canada and a total of 50 in Europe—we want to expand this.

In 2003, we'll introduce test kits for CA 125 [ovarian cancer], CA 15-3 [breast cancer] and CA 19-9 [colon cancer]. We're also introducing an improved CK-MB assay that will compliment our existing troponin I test and have launched a high sensitivity C-reactive protein test.

DTTR: *Are you seeing a greater willingness on the part of hospitals to switch from Abbott, given its problems with the Food & Drug Administration?*

Garrett: All of Abbott's immunoassay competitors have benefited to some degree … I never thought I'd see the day when Abbott's diagnostics division reported flat or declining growth, but it's happened. Still, we're not counting on Abbott being down for the long haul. They'll snap back … Abbott's FDA problems have not distracted it in markets outside the U.S.

DTTR: *What's your view on the pricing situation for routine chemistry and immunoassays?*

Garrett: There is modest pricing pressure in the routine chemistry market, but stronger pricing for new immunoassays is helping to stabilize the overall trend.

DTTR: *What's your outlook for greater adoption of molecular diagnostics in the U.S.? Will Medicare and HMOs open their wallets and pay for these high-priced tests?*

Garrett: Molecular diagnostics is still a small segment of the overall clinical diagnostics market, and clinical diagnostics is a small segment of overall healthcare spending. So, in the short term, expensive molecular diagnostics may be tolerated by payers. But, as molecular testing becomes more widely adopted, the technology and level of automation will have to improve to make it more efficient … Right now, Beckman Coulter does not have a presence in molecular diagnostics for clinical labs, but plans to get more involved in the coming years.

DTTR: *Will the expiration of some of Roche's patents in the next few years open some doors for Beckman Coulter?*

Garrett: We'd love to have access to PCR technology. But I don't think there will be a huge opening for us in 2004 when Roche's patents begin to expire.

DTTR: *Does Beckman Coulter have any plans for significant geographic expansion in 2003?*

Garrett: We're optimistic about the China market. Beckman has been in this market since the 1970s, and by our estimates we're the leading foreign company doing business there. We do some manufacturing in China and we will do more in the future … The economy in China is growing, and as it grows, spending on healthcare is also growing.

Philippe Sans

President of U.S. operations for ***BioMerieux*** *(Marcy-l'Etoile, France), which is focused on the immunoassay and molecular diagnostics markets. The company generated approximately $1 billion in worldwide revenue in 2002. It has approximately 13,000 Vidas immunoassay systems placed worldwide, including about 2,000 in the U.S.*

DTTR: *What's your update on how the integration of the Organon Teknika operations in the U.S. has proceeded?*

Sans: We closed the transaction on June 30, 2001, and completed most of the integration by December 31, 2001. We moved our U.S. headquarters from St. Louis to Organon's headquarters in Durham, NC, and didn't lose a single key executive. The combined management team includes executives from both companies almost equally. The integration was made easier because both companies have European parent companies and similar corporate cultures. This past year we grew U.S. revenue by double digits to about $250 million, exceeding our forecasts. By all measures the integration has been a success.

DTTR: *What are some tests that BioMerieux will introduce in the U.S. in 2003?*

Sans: For our Vidas product line we will have a new D-dimer assay with extended reporting range and a testosterone assay.

We will also introduce a new method for detecting hospital-acquired infections. We're working with MedMined (Birmingham, AL) to launch a product that will analyze patient data to detect nosocomial infection outbreaks.

We are also looking forward to launching Vidas Probe, a dual platform that will allow existing Vidas immunoassay customers to add DNA probe technology and thus perform both immunoassays and molecular diagnostics on a single platform. By adding our AmpStation instrument, existing Vidas customers will enjoy the ease of use for molecular assays that they currently experience with the Vidas immunoassays. The first two Vidas Probe assays that will be available will be chlamydia and gonorrhea.

DTTR: *How have Abbott's problems with the Food & Drug Administration affected the immunoassay marketplace? Are you seeing a greater willingness on the part of hospitals to switch from Abbott?*

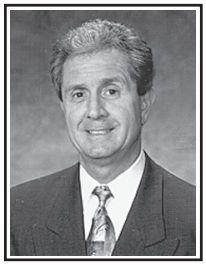
Sans: Certainly, the relationship between FDA and Abbott has, and will continue to have, a negative impact on both its immunoassay and nucleic acid testing sales. Many labs had no choice but to pursue another vendor, if one was available. Our Vidas and miniVidas immunoassay platform has been experiencing double-digit growth in infectious disease and immunochemistry assays.

DTTR: *What's your outlook for greater adoption of molecular diagnostics in the U.S.?*

Sans: This will depend on the cost/benefit ratios and ease-of-use features (real-time, multiplex capability and sample preparation). If customers can make management decisions during a physician shift as a result of molecular testing, the outlook can be very good. We're seeing a definite trend of greater acceptance of analyte-specific reagents for esoterics in university hospitals due to the need for rapid, sensitive results that can affect patient care decisions.

DTTR: *Will Medicare and HMOs open their wallets and pay for these high-priced tests?*

Sans: Higher reimbursement is justified if molecular testing improves patient care, shortens length of stay or reduces other procedures. It's our hope that the reimbursement schedules will reflect the benefits of testing as they pertain to global healthcare costs.



John Hertia

*Clinical diagnostics group operations manager for **Bio-Rad Laboratories**. The company, based in Hercules, CA, generates approximately $450 million annually from clinical diagnostics operations. Its life sciences division generates another $400 million in annual revenue and has been spurred in recent years by sales of its BSE tests for "mad cow" disease in Europe and Japan.*

DTTR: *What are some new clinical products that Bio-Rad will introduce in the U.S. this year?*

Hertia: We've just begun marketing our new PhD automated testing system for autoimmune and serology testing in small and mid-sized labs. And we recently introduced our new automated enzyme immunoassay product, the Evolis System, in Europe and plan to begin marketing it to larger labs in the U.S. in early 2003.

Other new products that we will begin marketing this year include our diabetes monitoring system, the D10, for smaller labs and physician offices. This system will initially perform hemoglobin A1c testing; hemoglobin variance tests will be added to the menu later in the year. Finally, we plan to launch our new quality control data management system, QC On Call, in the third quarter of 2003.

DTTR: *What's your outlook for molecular diagnostics? Will the shift to gene-based diagnostics over the next few years be incremental or rapid?*

Hertia: My guess is that it will be incremental. The spread of molecular diagnostics is dependent on a number of things, including physician education and funding. It also takes time to complete the genotyping studies needed to develop a new test, and it takes time to complete studies demonstrating how a test can be used to improve therapy.

Finally, you must have pretty compelling evidence that demonstrates the cost-effectiveness of a new test. The history of the diagnostics industry shows that it can take awhile before new technologies gain acceptance in the marketplace.

DTTR: *Over the past few years, Bio-Rad has made a number of acquisitions of specialty diagnostics companies. Will this strategy continue?*

Hertia: Our goal is to be the leading supplier of specialty testing. We definitely plan to continue investing in specialty diagnostics. We have no plans to enter the routine diagnostics market.

Bio-Rad is the leading worldwide vendor of BSE ("mad cow") tests—a market that now represents some $90 million to $120 million annually in test kit sales. *For more on this side of Bio-Rad's business, DTTR spoke with treasurer Ron Hutton.*

DTTR: *Is "mad cow" testing a sustainable market? Will the level of testing in Europe and Japan subside in a few years?*

Hutton: The rate of animals being found positive for "mad cow" has not abated. It looks like a sustainable market.

DTTR: *What are the chances of the disease jumping to the U.S.?*

Hutton: The U.S. has been deemed a low risk by FDA.

DTTR: *Bio-Rad has received clearance from the U.S. Department of Agriculture for a rapid test for chronic wasting disease (CWD), a disease that affects deer and elk and is closely related to "mad cow." What's the market potential for CWD testing in the U.S.?*

Hutton: In 2003, we think we might sell 750,000 CWD tests in a price range of $12-$18 per test.

Michael Ziering

*President and CEO of **Diagnostic Products Corp**. (Los Angeles, CA). The company derives nearly 90% of its $300+ million in annual revenue from sales of immunoassay products. It has 7,800 Immulite systems in place worldwide. Annual revenue at DPC is growing by about 15%—outpacing an estimated 5% growth rate for the worldwide immunoassay market.*

DTTR: *Which assays are leading growth this year?*

Ziering: We're seeing strong growth from homocysteine and hepatitis B. More generally, cardiac and infectious disease kits are leading growth … We also recently launched our Immulite 1000, an advanced version of our Immulite 1. The primary improvement is an upgrade to Windows-based software from DOS-based.

DTTR: *Which new assays will you bring to market in 2003?*

Ziering: We should get clearance from the Food & Drug Administration for Epstein Barr and D-dimer assays. We'll also submit an application for a hepatitis A test. We'll also introduce a PAPP-A test for first trimester screenings [initial launch will occur outside the U.S.]. Additional new tests will include Herpes I and II and an oxidized LDL. And we should begin introducing some stool-based assays based on licenses from Alexon Trend (Lenexa, KS). In total, we'll introduce about 10-20 new assays next year … We'd like to introduce a test for BNP (B-type natriuretic peptide), but we can't get the needed licenses.

DTTR: *What's the current pricing environment for immunoassay reagents?*

Ziering: Very competitive!

DTTR: *How has the suspension of Abbott's products changed the marketplace?*

Ziering: It's helped all of Abbott's competitors, including us. There are signs that Abbott customers are becoming impatient with Abbott and are more willing to consider a change. Group purchasing organizations, in particular, have been more willing to make a change. In 1999, for example, we had zero GPO contracts—now we have six.

DTTR: *What's happening with Immulite sales in the international markets?*

Ziering: We sell in about 100 countries, and the international markets comprise about 70% of our total revenue. We're seeing strong growth from developing countries like the Czech Republic and Poland, where we have 100 placed instruments each.

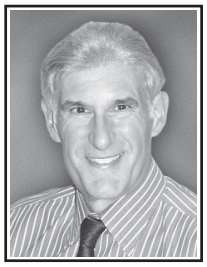
We've also been very successful in China, where we've placed about 200 instruments … We have a direct sales and support team of about 60 people in China. The sales process is political, but it's not too complicated … They [the Chinese government] have made substantial investments in healthcare infrastructure over the past 10 years … My biggest concern about China is the potential for a currency devaluation, but so far they've kept things pretty stable.

DTTR: *Will your company expand into molecular diagnostics?*

Ziering: So far, the technology hasn't taken off, probably because it's not automated as fully as immunoassay … We're waiting for Roche's patents to expire in 2004 and 2005; then we'll get involved in this market.

DTTR: *What's the outlook for consolidation among the larger IVD companies?*

Ziering: There's been talk that Bayer Diagnostics isn't doing so well and that diagnostics has become a drag on Abbott, but I don't know. That's for investment bankers to decide.



Stephen Wasserman

Group vice president for diagnostic systems at ***Olympus America****. Olympus America (Melville, NY) is a unit of Olympus Optical Co. (Tokyo, Japan). It generated approximately $275 million from worldwide diagnostics sales in 2002, including about $100 million from sales in the U.S. The company's focus is on very high-volume chemistry analyzers.*

DTTR: *How has the management style at Olympus changed in recent years?*

Wasserman: When I first started with Olympus a few years ago, decisions at the company were made very slowly and deliberately. But the management-style differences between U.S. and Japanese corporations are narrowing. We [Olympus America] are now making decisions more quickly. Our product cycles are shortening and we're now very attuned to customer demands … We now also report our financials on a quarterly basis, rather than every six months. This keeps you more in touch with changes in the marketplace.

DTTR: *Which new assays will you bring to market in 2003?*

Wasserman: We recently introduced high-sensitivity CRP, colorimetric lithium and direct LDL. Among the new tests we'll introduce in 2003 are hemoglobin A1c, ceruloplasmin and several assays for therapeutic drug monitoring. We're also in the process of rolling out the Olympus OLA2500 system [a front-end automation system]. This system is currently being beta tested in commercial and hospital laboratories.

Also, we just completed an agreement with Lab InterLink to develop a universal lab automation interface. By using Lab InterLink software and mechanical interface we can now connect the Olympus AU analyzers to any track system that meets guidelines of the National Committee for Clinical Laboratory Standards. The first unit will be installed at Albert Einstein Medical Center in Philadelphia, PA.

DTTR: *What's the current trend in reagent pricing in the U.S.?*

Wasserman: Reagent pricing continues to experience a lot of pressure. More companies are competing on price. Some are doing almost anything to place their instruments. They are giving away hardware and using lab automation to lock in long-term reagent contracts.

DTTR: *How will the anticipated shift to more gene-based testing affect the marketplace?*

Wasserman: Molecular testing will be incremental. It won't replace existing testing … It will be used in combination with routine testing to help refine diagnoses and identify the drug(s) most beneficial for each patient.

Olympus has a very large [molecular diagnostics] development program based in Tokyo, and we're just now opening a business unit in the U.S. There's a real push underway to expand our presence in this market.

DTTR: *What's the outlook for consolidation among the larger IVD companies?*

Wasserman: There's no reason why there can't be further consolidation, whether it takes place in 2003 or 2004. There are still six or seven vendors bidding for every contract that comes up. There just aren't enough opportunities for all the [IVD] players.

DTTR: *How fast is the worldwide diagnostics business at Olympus growing?*

Wasserman: We've grown at an average annualized rate of 14% over the past few years and should continue to grow in the double-digits for the next few years.

Patrick Sullivan

Chairman and CEO of Cytyc Corp. (Boxborough, MA). The company, which makes the ThinPrep method for detecting cervical cancer, generates annual revenue of approximately $227 million, with about 6%-8% currently coming from markets outside the U.S.

DTTR: *What's the current penetration of ThinPrep in the U.S.?*

Sullivan: As of September 30, 2002, ThinPrep was being used for about 58% of all Pap tests, and it's growing 3% each quarter. By year-end 2003, we expect ThinPrep to reach a 72% market share. [Approximately 50 million Pap tests are performed in the U.S. each year.]

DTTR: *What's your update on Cytyc's international expansion efforts?*

Sullivan: The biggest immediate opportunities are in Germany and the United Kingdom. Twelve million Pap tests are performed each year in Germany, and we've received favorable reimbursement from the private payer system which covers about 10% of all Pap tests in Germany … In the U.K. a pilot program for thin-layer testing is underway at 11 sites—10 of them use ThinPrep, the other uses TriPath. Results should be reported in August 2003 … We've also got sales efforts underway in Switzerland, Italy, France and Spain. Overall, the European market represents a potential $200 million opportunity for us.

DTTR: *What's the status of your automated ThinPrep Imaging System?*

Sullivan: We expect approval from the Food & Drug Administration in early 2003. The system will increase cytotech productivity by 50% and will also raise reimbursement to labs. Manual ThinPrep Pap testing is currently reimbursed by Medicare at about $28 per slide. New CPT codes have been assigned for automated Pap testing and will take effect on January 1, 2003, with reimbursement of $29.85 [CPT code 88174, thin-layer prep with screening by automated system] and $37.01 [CPT 88175, thin-layer prep with screening by automated system and manual rescreening].

DTTR: *What's the outlook for pricing?*

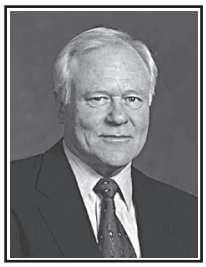
Sullivan: We plan no change in pricing for manual ThinPrep [list price is $11.25 per kit]. But we anticipate charging $3-$4 more [$13.25-$14.25] for ThinPrep testing done with our automated system. This system is adding value, and we should earn a little more.

DTTR: *Why has the ramp-up of your new ductal lavage product for determining predisposition for breast cancer been so slow?*

Sullivan: We're establishing a new standard of care, and this takes time. Ductal lavage revenue was under $10 million for 2002, but this could ultimately be a bigger market for us than ThinPrep. The key is educating the ob/gyns who act as gatekeepers for this procedure. We've currently got 20 salespeople trained on how to sell this procedure, and we plan to train another 120 as well.

DTTR: *Clinical trials for a vaccine against human papillomavirus (HPV), which is the cause of nearly all cervical cancer cases, have shown promise. Will development of a vaccine eliminate the need for Pap testing?*

Sullivan: Not in my lifetime. Even if a vaccine came on the market in a few years, it would potentially be effective only for those women and girls who had not begun having sex. The vaccine would not help any woman or girl already infected with HPV. All women and girls who had begun sexual activity would still need to have periodic Pap tests. So, any potential vaccine would not meaningfully reduce the volume of Pap testing for at least a generation or so.



Warren Pinckert

President and CEO of Cholestech Corp (Hayward, CA). The company makes the LDX Analyzer, a telephone-sized instrument with CLIA-waived test cassettes for total cholesterol, a lipid profile, glucose and alanine aminotransferase (liver function), among other tests. The company's current revenue run rate is approximately $47 million.

DTTR: *How many LDX analyzers are now in use worldwide?*

Pinckert: We've got a worldwide installed base of roughly 16,000, including 10,000 in the U.S. We shipped five million [test] cassettes in 2001 and about six million in 2002. I anticipate continued growth in the 20%-25% range.

DTTR: *What are some new tests you plan to add to the LDX menu?*

Pinckert: We plan to launch a combined lipid profile and ALT cassette in the first half of 2003. We also plan to file a 510(k) with the Food & Drug Administration for a high sensitivity C-reactive protein cassette by the end of 2003. After that, we plan to file a 510(k) for a hemoglobin A1c cassette. Longer-term, I believe the LDX has the sensitivity and specificity to run tests for LP(a) and some other lipoproteins.

DTTR: *What're some of the hurdles you face in gaining physician adoption of your test system?*

Pinckert: We're still a fairly small company, so physician awareness is the first hurdle. The next thing physicians consider is reimbursement. But assuming a physician office performs two lipid profiles per day on the LDX, it can pay off the initial investment in the instrument in about six months. [Note: Cholestech sells the LDX analyzer to distributors for an average of roughly $1,200 each and the list price is $1,995. The average selling price to physician offices is somewhere in between. Cholestech charges about $10 per test cassette for its CLIA-waived panel; Medicare carriers reimburse the panel at an average of roughly $19 each.]

It typically takes three sales calls to a physician office before we close on a sale. Physicians need to learn how to weave it [lipid panel testing] into their practice. Typically, the fingerstick blood sample should be taken when a nurse is taking a patient's weight and other basic information. The test is then run while the patient waits in the exam room. By the time the physician comes in, the test results are ready.

DTTR: *How is your WellCheck business of managing cholesterol screenings at health fairs doing?*

Pinckert: We hit a setback when Pfizer [which sells Lipitor], by far our largest single customer, decided it wouldn't be doing any more national screening programs. We're now trying to better diversify WellCheck's customer base. Over the past 12 months, we've added a number of new customers, including Sankyo Pharma, Forrest Labs, Abbott Labs, Rite Aid drugstores, and Kellogg's, which uses screening to promote its cholesterol-lowering foods.

DTTR: *There's been a lot of talk about the advent of the direct-to-consumer lab testing market. What are your thoughts?*

Pinckert: I think the storefront model of offering testing to walk-in customers has limited potential. The key is to have a technology that is portable and accurate, so you can bring the testing to convenient venues, such as sporting events and health fairs. That will be the successful model.

DTTR: *Any plans to ever introduce a lipid panel for over-the-counter sale?*

Pinckert: Yes, but it wouldn't be with our current technology.

IVD Stocks Down 2% In Latest Five Weeks

*Year-to-date, **Roche** non-voting equity shares, which trade on the Zurich stock exchange, are down 13% to 103 Swiss francs; shares of **Bayer**, which trade on the German stock exchanges, are down 40% at 21.49 euros per share*

The 20 stocks in the G-2 Diagnostic Stock Index were down an unweighted average of 2% in the five weeks ended Dec. 13, 2002, with 11 stocks falling in price, eight rising and one unchanged. Year-to-date, the G-2 Index has fallen 30%, compared with a 23% decline for the S&P 500 and a 31% drop for the Nasdaq.

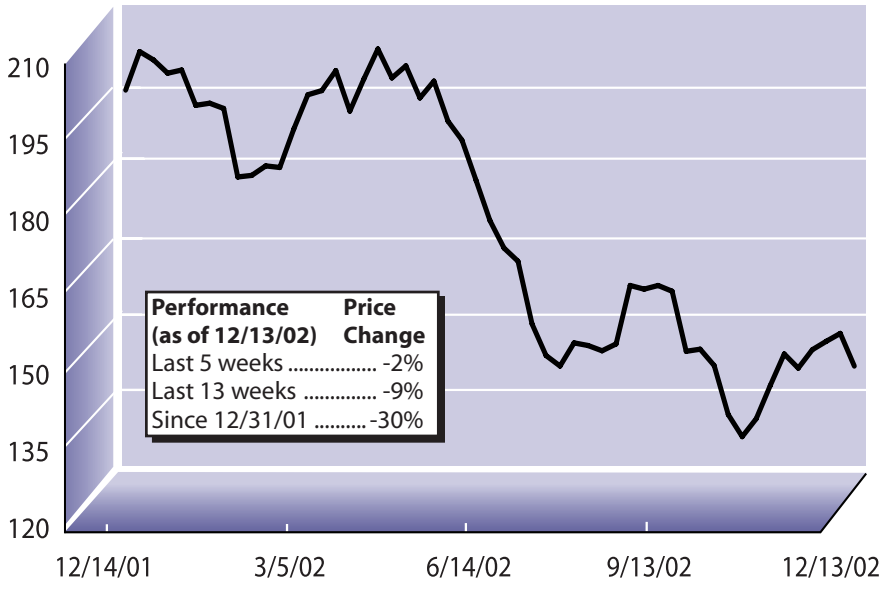
Cygnus Inc. (Redwood City), which makes a non-invasive monitor for self-testing of blood glucose levels, plunged 42% to $0.80 per share for a market capitalization of $31 million. The company reported a third-quarter 2002 net loss of $10.2 million vs. a net loss of $11.6 million in the same period a year earlier; revenue was $1.6 million vs. $418,000. Cash holdings totaled about $25 million as of Sept. 30, 2002.

Meridian Bioscience (Cincinnati, OH) rose 15% to $6.70 per share for a market cap of approximately $100 million. The company recently increased its quarterly cash dividend to $0.09 per share from $0.07. The new annual dividend rate of $0.36 per share is equal to a dividend yield of 5.4%, based on Meridian's current share price. In addition, the company announced a new cash dividend policy whereby it plans to set its dividends between 75% and 85% of each fiscal year's expected net earnings.

Other IVD stocks rising in price included **Quidel** (San Diego, CA), which was up 20% to $3.36 per share for a market cap of $97 million, and **TheraSense** (Alameda, CA), which was up 19% to $9.11 per share for a market cap of $364 million.

Among the latest two IVD companies to get listed in the U.S., but not yet part of the G-2 Diagnostic Stock Index, **Dade Behring** (Deerfield, IL) was up 4% to $15.65 per share in the five weeks ended Dec. 13 for a market cap of about $736 million; **Gen-Probe** (San Diego, CA) rose 17% to $19.65 per share for a market cap of about $552 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, 5 weeks ended 12/13/02

UP	PRICE	% CHG
Biosite	$31.41	+1
Digene	8.14	+4
Igen	41.09	+7
Inverness Medical	12.91	+16
Meridian	6.70	+15
Quidel	3.36	+20
TheraSense	9.11	+19
Ventana	22.00	+9
UNCHANGED		
Becton Dickinson	30.67	0
DOWN		
Abbott Labs	40.48	-12
Bio-Rad	42.25	-5
Beckman Coulter	29.45	-1
Cholestech	5.82	-14
Cygnus	0.80	-42
Cytyc	9.18	-13
Diagnostic Products	36.19	-13
Diametrics	1.74	-13
i-Stat	3.91	-1
Immucor	22.35	-5
Johnson & Johnson	54.91	-9

G-2 Insider

Competition arrives in BNP market. After a year of having the market all to itself, Biosite (San Diego, CA) now has a major competitor in the B-type natriuretic peptide (BNP) test market. Roche Diagnostics (Indianapolis, IN) received FDA clearance for its Elecsys proBNP assay in November, and the nation's largest laboratory, Quest Diagnostics (Teterboro, NJ), has announced plans to use the Roche test at its Nichols Institute esoteric testing laboratory in San Juan Capistrano, CA. "The level of interest from reference labs and hospitals is much higher than we anticipated," says Martin Madaus, PhD, head of Roche's U.S. diagnostics operations. (*For more on the BNP market, see DTTR, Dec. 02, p. 1*).

ZymeTx goes belly up. Unable to raise additional capital to fund ongoing operations, ZymeTx Inc. (Oklahoma City, OK) has filed for Chapter 11 bankruptcy reorganization. The company, which makes point-of-care tests for influenza, says it has been hurt by two straight years of mild flu seasons and a corresponding lack of demand for its tests. Since being formed in 1994, ZymeTx has accumulated net losses totaling more than $40 million, while its annual revenue has never exceeded more than $2 million.

No go for DiaDexus. DiaDexus Inc. (South San Francisco, CA) has withdrawn a planned initial public offering, citing weak stock market conditions. The company had hoped to raise $84-$98 million by selling seven million shares of common stock at an estimated range of $12-$14 per share. DiaDexus was formed in 1997 with SmithKline Beecham and Incyte Genomics as its founders and initial investors. Through year-end 2001, DiaDexus had generated no material revenue and had accumulated net losses of $45.3 million. Its lead product is called the PLAC Test, which measures an individual's risk for coronary heart disease.

Company References

Abbott Labs 847-937-6100
Beckman Coulter 714-871-4848
BioMerieux 800-654-0331
Bio-Rad 510-724-7000
Cholestech 510-732-7200
Cytyc Corp. 978-263-8000
DiaDexus 650-246-6400
Diagnostic Products 310-645-8200
Meridian Bioscience 513-271-3700
Olympus America 631-844-5690
Roche Diagnostics 317-849-9350
ZymeTx 405-271-1314

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.g2reports.com*

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