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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Identifying Future Lab Winners From Losers

TODAY I WOULD LIKE TO DO SOME CRYSTAL BALL-GAZING as a way to make a point about strategic business planning for laboratories. As you will read on pages 15-17, our Editor-In-Chief has analyzed the year-end balance sheets of the two newest publicly-traded laboratory companies.

The purpose of his intelligence briefing is to assess the balance sheet strengths and weaknesses of **Specialty Laboratories, Inc.** and **Dynacare, Inc.**, and provide clients and regular readers of THE DARK REPORT with an understanding of why the business strategies of these two companies will unfold differently in the next couple of years. After all, both companies maintain a high-profile within the lab industry and both companies have differing business strategies with a common theme—each lab company wants to do more business with hospital laboratories.

Many hospital lab administrators and pathologists are personally touched by the business strategies of these two companies. It happens when Dynacare execs show up to discuss joint ventures with the hospital or when sales reps from Specialty Labs call to solicit reference testing business.

Of course, there are other commercial labs and other reference labs calling upon hospitals to pitch lab joint ventures or get more send-out business. Each of these lab competitors has a different mix of strengths and weaknesses–financial, operational, and geographical. But if a hospital lab is going to chose a joint venture partner or a new send-out lab, it wants to be confident that it understands the differing strengths and weaknesses of these potential partners and reference testing sources.

As you read the intelligence briefing on pages 15-17, I hope it gives you new insights about how a balance sheet can help or hinder a laboratory company. The different balance sheets of **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** as of January 1997 partially explain the different business paths each company has followed since that date. The same will hold true for Dynacare and Specialty Laboratories, given their respective balance sheet positions as of December 31, 2000.

Having this type of business knowledge about potential joint venture partners and reference lab sources helps hospital lab directors make better decisions when considering RFPs (request for proposals). It is also a useful way to gain competitive business advantage when trying to sort out which labs will be winners and which labs will be losers in the future. TDR

THE DARK REPORT Honors Lab "Movers & Shakers"

Management leaders who are guiding their laboratories to uncommon success

By Robert Michel

CEO SUMMARY: It's time again to recognize and honor the lab industry's strong leaders in innovative management. These laboratory executives are implementing business strategies designed to position their lab organizations to serve the changing needs of the healthcare system. Their vision and willingness to "stay the course" are traits they hold in common.

IT'S BEEN FIVE YEARS since the first list of lab industry "Movers & Shakers" was announced by THE DARK REPORT.

It was a time when the lab industry's brightest and most innovative leaders were generally unrecognized. It was also a time when the financial fortunes of laboratories throughout the country were ebbing to their lowest point. If ever there was a need for management heroes, it was certainly during the second half of the 1990s.

In creating the "Mover & Shaker" awards, THE DARK REPORT wanted to celebrate *uncommon excellence* in laboratory management. It also hoped to stimulate a higher level of debate about what constituted exceptional laboratory management.

Remember, the mid-1990s was a time when most public lab companies had either gone bankrupt or had merged, eventually forming the three blood brothers. Given the dismal performance of the executives who had run these companies, it could certainly be argued that the public sector of the lab industry lacked a management sophistication common in most industries outside of healthcare.

Within the hospital laboratory sector, one could find precious-little documentation to validate the claimed accomplishments of many high profile lab administrators who frequently spoke at lab industry meetings. Not coincidentally, many laboratorians attending such meetings became skeptical of unvalidated claims made from the podium.

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $10.80 per week in the US, $11.40 per week in Canada, $12.45 per week elsewhere (billed semi-annually).

Recognition Awaits Movers & Shakers

Our 2001 Movers & Shakers will soon be receiving this beautiful award!

That certainly contributed to a lot of healthy skepticism within the lab industry during those years. Then, in January 1997, THE DARK REPORT published its first "Movers & Shakers" honorees. That class of eight individuals set a high standard for others to follow. *(See TDR, January 6, 1997.)*

Included that year were Ken Freeman, Chairman and CEO of a **Quest Diagnostics Incorporated**, as well as Louis D. Wright, Jr., M.D., Chairman of what was then South Carolina-based **Pathology Service Associates** (PSA).

Five Years Of Growth

Since 1997, Freeman's Quest Diagnostics Incorporated has acquired **SmithKline Beecham Clinical Laboratories** and become the world's largest laboratory company, with more than $3 billion in revenues. Dr. Wright's PSA evolved into a near-national pathology business organization, with pathology networks in 13 states serving 80 group practices and 400 pathologists.

Freeman and Wright are just two inspiring examples of how good management leaders, following a sound business strategy, can achieve consistent results. This was even more notable because they did it despite the radical reorganization and widespread financial woes that roiled the lab industry during the second half of the 1990s.

Management Excellence

It's an interesting anomaly that both the lab industry and the pathology profession have never pursued management excellence with the same vigor and enthusiasm as seen within other high-tech industries. In fact, there have been relatively few credible efforts to rigorously identify and study the management methods used by the lab profession's most successful leaders.

That's probably a result of the ample profits earned during the glory years of fee-for-service medicine. Since most labs enjoyed generous profit margins, there was little motivation to identify top-performing lab organizations and learn their management secrets.

If that was once true in the past, it is no longer true in the present. The ever-present economic squeeze on lab testing makes it essential that all labs and pathology group practices acquire and implement successful techniques of high-performance lab management.

It is in this spirit that THE DARK REPORT proudly recognizes this year's list of lab industry "Movers & Shakers." These individuals established high standards for their laboratories. They've accomplished *uncommon results* through their leadership, and vision. The performance of their labs is proof that good management does generate sustained financial stability and prosperity.

Kuo Cheng

Chief Executive Officer

Clinical Laboratories, Inc.
Throop, Pennsylvania

YEARS AHEAD of its independent commercial lab peers, **Clinical Laboratories, Inc.** (CLI) introduced a viable Web-accessed lab test results reporting system to its physician office clients.

By most standards, CLI is a small lab company, serving the area around Scranton, Pennsylvania. But its accomplishments belie its small size.

Under the direction of CEO Kuo Cheng, it developed its own home-grown solution for Web-accessed lab test results reporting—and spent just $70,000! Early in 2000, CLI become one of the first labs in the nation to offer physicians the capability of retrieving their patients' lab test results via wireless PDA units, such as PalmPilots.

As Cheng says, "The Internet levels the playing field and allows us to compete against bigger labs on more equal terms." CLI's willingness to invest in new lab information services is helping attract new physician-clients.

More importantly, under the leadership of Kuo Cheng and with the support of CLI's Board of Directors, the lab company is demonstrating that even small laboratories can be innovative. Such labs, with limited access to capital and human resources, can succeed in implementing bold business strategies!

Marc Grodman, M.D.

President & Chief Executive Officer

Bio-Reference Laboratories, Inc.
Elmwood Park, New Jersey

AT LAST YEAR'S *Executive War College*, there was quite a stir after Marc Grodman, M.D. spoke to senior execs gathered at the Lab CEO SUMMIT.

Dr. Grodman, President and Chief Executive Officer of **Bio-Reference Laboratories, Inc.**, had just declared the most valuable business asset that a clinical lab possesses is its relationship with its office-based physicians. Further, he asserted, this asset was under assault by the multitude of e-health companies which wanted to interpose themselves between lab and doctor.

Under Dr. Grodman's guidance, Bio-Reference is furiously investing to develop an array of information services, rooted in lab test data and utilizing Internet connectivity, to generate additional revenue from physicians, payers, and patients.

Innovation and "out-of-the-box" thinking are alive and well at Bio-Reference. The company is on a growth track and has introduced a number of new services and products to its base of clients.

The jury is still out as to whether or not physicians and payers will embrace these new services. Implementation of these ideas must also be deftly executed. But when compared to other lab organizations, Dr. Grodman and Bio-Reference are certainly blazing a new trail.

Joseph Halligan

President & Chief Executive Officer

PharmChem, Inc.
Menlo Park, California

INTERESTING THINGS ARE AFOOT AT **PharmChem, Inc.** of Menlo Park, California, where President and CEO Joseph Halligan has been challenging conventional management thinking.

During 2000, PharmChem implemented the lab industry's most progressive ASP-system (application service provider) solutions for drugs of abuse test ordering and results reporting. Via Internet access, clients can e-order tests. The system, with little human intervention, will arrange collection sites, ship necessary supplies, notify client and patient, track specimens, cue the medical review, report results, and generate an accurate bill!

Halligan's goal is to use technology and work flow process redesign to eliminate errors and systemic "breakdowns" which affect customers and create waste. In effect, he's moving his people to management tasks that generate higher value while using technology to improve services and reduce expenses.

There's also an interesting twist to the Halligan story. He's no stranger to chemistry laboratories. He was a principal at **Fotomat**, which, in its prime, processed tens of thousands of rolls of film every night. That's one reason why, with his arrival at PharmChem in 1996, the company has enjoyed sustained growth.

David L. Schultz

President

Clinical Pathology Laboratories, Inc.
Austin, Texas

HERE'S A "MOVER & SHAKER" who's not well known on the national scene, but has widespread respect among lab competitors in his home state of Texas.

As President of **Clinical Pathology Laboratories, Inc.** (CPL) of Austin, Texas, David L. Schultz has presided over a solid decade of virtually unbroken growth in specimens, revenues, and net profits.

More importantly, he's been willing to combine commonsense management with a willingness to implement unorthodox business strategies. As a result, CPL has become the major lab player in the Texas Hill Country area and is making steady inroads into nearby metropolitan markets like Dallas, Houston, and San Antonio. It's a tightly-run operation with shrewd marketing programs supporting its sales effort.

By design, both CPL and David Schultz have kept a low profile within the laboratory industry. This is typical of many "Movers & Shakers," since they are intensely focused on the performance of their lab organization.

However, it's no coincidence that CPL not only weathered the turbulent financial storm of the 1990s, but found continuing prosperity. Under Schultz' leadership, CPL's sustained success validates the fact that "good management trumps all cards."

New Cytology Technology Entering Study Phase

AmeriPath signs agreement with Ampersand to develop technology and do clinical studies

CEO SUMMARY: There's a new contestant in the ongoing battle to win the Pap smear technology wars. Ampersand Medical Corporation, by signing a strategic alliance with AmeriPath, Inc., has signaled that it's ready to bring its technology to market. AmeriPath will play a major role in expediting clinical studies and both companies hope to formally start the FDA approval process within the next three or four months.

PATHOLOGY GIANT **AmeriPath, Inc.** announced a strategic alliance with Chicago-based **Ampersand Medical Corporation** on March 27.

This strategic alliance calls for both companies to cooperate in the joint development of several new cytology technologies and products owned by Ampersand. Under terms of the agreement, AmeriPath will "receive an undisclosed amount of equity in Ampersand as compensation for this development work."

AmeriPath will also support Ampersand's research and development by providing laboratory testing support and doing the clinical trials necessary to gather information to support the FDA approval process. Ampersand Medical will pay AmeriPath on "favorable terms" for these services.

New Cytology Products

At least four of Ampersand's new cytology products will be part of this strategic alliance. They are: 1) InPath InCell™ HPV test; 2) InPath CerviPak™, a liquid-based slide preparation system for point-of-care slide creation; 3) InPath CocktailCVX™ & Slide Based Test, a fully automated biomolecular screening system; and 4) InPath e2™, a new type of cervical cell collection device described as "patient friendly."

This strategic alliance is notable for two main reasons. First, it is evidence that a national pathology company considers Ampersand's new biomolecular-based technologies and products to be credible and worthy of further investment. Second, it demonstrates how the national pathology companies are using their size and market influence to gain early access to promising new diagnostic technologies.

AmeriPath confirms this fact. "We built our *Center for Advanced Diagnostics* (CAD) in Orlando specifically to be the vehicle for development work and clinical trials," stated Dennis Smith, Jr., M.D., Senior Vice President and Medical Director at AmeriPath. "All along, the idea was to leverage the resources of CAD and the community-based pathologists of AmeriPath to give

us a prime shot at doing support research and clinical studies for new technologies and products that we think have great potential.

Leaves Cells Undisturbed

"The InPath cervical cancer screening technology is a good example," he continued. "Ampersand has an assay of multiple molecular markers for cervical dysplasia, as well as the E6 and E7 oncogenes of the Human Papillomavirus (HPV). Once the test is completed, it leaves the cells undisturbed. This permits conventional staining and microscopic review by the pathologist, if a review of this specimen using conventional methods is required."

"That's right," agreed Ampersand Chairman and CEO, Peter P. Gombrich. "We think the fact that the cells are *not* destroyed in the testing process is a key benefit in bringing the technology to market, because it allows pathologists to always follow-up with a conventional analysis if required. But there's another advantage to our InPath Cocktail-CVX test. It takes just 20 minutes to get a complete result. In addition, the In-Cell HPV test takes approximately 90 minutes for a result, compared to the hours required to complete HPV tests using DNA-based technologies."

AmeriPath and Ampersand are poised to immediately begin clinical studies of the InPath system. "We expect to have the first important clinical study completed within 90 to 120 days," said Dr. Smith. "After assessing this information, we will begin submitting the necessary information to the FDA to launch the approval process."

Despite the difficulty of accurately predicting how long the FDA will take to approve specific technologies for clinical use, Gombrich believes his company's products offer a unique level of reassurance for FDA regulators. "Remember, after doing tests with our technology, the original cells remain undamaged and can be Pap stained and reviewed by a pathologist in the conventional manner. This is the ultimate quality control for a new product. This fact may encourage regulators to act expeditiously, since there is a way to accumulate clinical data in the early stages of implementation while having a way to constantly check the accuracy of this new assay," noted Gombrich.

From AmeriPath's perspective, Ampersand's technology represents a possible gateway into other diseases besides cervical cancer. "We're excited about the underlying technology which supports Ampersand's cervical cancer diagnostics," noted Dr. Smith. "We think it has potential in non-gynecological applications and will shortly begin to research applications of this technology in urine and sputum specimens."

Non-Exclusive Relationship

Clearly both parties to this strategic alliance have high expectations. "Although this relationship is non-exclusive," explained Gombrich, "AmeriPath will participate in new product development and has the potential to earn royalties from sales generated by these products."

AmeriPath also expects competitive advantage from this alliance. "Since we're conducting the clinical studies, we're in the prime position to evaluate the data and understand, ahead of anyone else, how this technology performs in clinical settings," stated Dr. Smith. "That can position us to be first to introduce the resulting products into the clinical marketplace."

For Ampersand, the active participation of AmeriPath is a strong vote of confidence. Until now, Ampersand's strategy has been to develop its technology as a Pap smear screening system which can be used in laboratories or at the point of care, thus facilitating its use in lesser-developed countries

around the world. It just finished the pilot phase of a study in China involving 200 women. In the next phase, the trial will involve 9,000 women and should be complete in early summer.

AmeriPath's interest in Ampersand was heightened by results of other clinical studies which were published late last year. AmeriPath's willingness to support this technology for applications in the United States encouraged Ampersand to accelerate its plans to seek FDA approval for domestic clinical use of the InPath system.

Important Developments

THE DARK REPORT believes the strategic alliance between Ampersand Medical and AmeriPath represents several important developments in the pathology marketplace.

First, it's a sign that Ampersand's InPath system has reached a point where some credible players believe it can be developed into a product good enough to compete with both the conventional Pap smear, as well as new Pap technologies, including ThinPrep®, PREP®, AutoPap®, and HPV testing. If true, this is another long-term wildcard in the cervical cancer screening market.

Second, the alliance itself demonstrates how national lab and pathology companies will use their size and market influence to get an early look at developing technologies and negotiate competitive advantage as a co-developer and marketer of these technologies.

Third, international applications and international markets will become increasingly important in validating technology. Ampersand's clinical studies in China mirror recent clinical studies of **Digene Corporation's** Hybrid Capture® II HPV test in Costa Rica and South Africa. **TDR**

Contact Dennis Smith, Jr., M.D. at 904-391-1345 and Peter P. Gombrich at 312-222-9550.

High Hopes Surround This Cervical Collection Device

Here is the InPath e²™ cervical cell collection device, developed by Ampersand Medical Corporation of Chicago, Illinois. Made of silicon, it is an anatomically-designed, single-use balloon. The device is placed through a speculum into and against the cervix. Air is introduced into the device, expanding it firmly against the walls of the

entire cervix. Cells adhere to the balloon's surface. The balloon is then placed into a liquid preservative, where the cells float off the balloon, into suspension.

Because of the design of the device, it can do two things better than a conventional cervical brush. One, it can simultaneously collect both endo- and ecto-cervical cells in a single step, from the entire 360-degree dimension of the cervix. Ampersand says this increases both specimen adequacy and the number of cell counts in the vial.

Two, the InPath biomolecular markers for cervical cancer can be applied to the cells while they remain on the collection device. This permits the collection device to act as a cervical "map" and show the precise place on the cervix where cells which test positive for cancer are located.

Perceptive observers will have already noted another benefit to this type of collection device. Because the e² Collector is smooth-surfaced and is not "scraped" across the cervix, it does not irritate the cervix like conventional brushes and spatulas. Thus, women find it more comfortable and do not suffer bleeding, cramping, irritation, or pain as a result of the collection.

Infant Field Expanding Rapidly

Tissue Banking May Be Source Of New Pathology Revenues

CEO SUMMARY: Evidence is accumulating that tissue banking may be where the "rubber meets the road;" where pharma money funds technology enhancements that directly benefit the profession of pathology. Without question, the need by pharma, biotech, and genomic companies to access, analyze and understand the tissue of targeted subpopulations is creating an opportunity for savvy pathologists to make money by aiding in the identification and collection of such tissue specimens.

TISSUE BANKING MIGHT BE RIGHTLY called the new frontier of the anatomic pathology profession. It sits at the convergence point for a variety of medical disciplines, of which genomics and proteomics are only the most publicized.

For local anatomic pathology group practices, tissue banking is now beginning to offer specific, but limited, revenue opportunities. However, during the next decade, tissue banking has the potential to stimulate immense changes to the profession of anatomic pathology.

One pioneering company in the emerging field of tissue banking is **TissueInformatics.Inc**, based in Pittsburgh, Pennsylvania. Founded in 1997, it has attracted investment capital from such credible corporations as **Motorola**. Its mission is comprehensive.

Five Basic Functions

"Think of us as a company organized around five basic functions," stated Peter C. Johnson, M.D., Chairman and CEO of TissueInformatics. "One, we acquire tissue. Two, we develop proprietary imaging technologies. Three, we develop proprietary software to analyze tissue. Four, we build databases from these analyses, and five, we mine that data and can do so with respect to associated genomic and clinical data."

The short term business priority is for TissueInformatics to acquire relevant tissue specimens needed to build its tissue bank. Here is where the business interests of TissueInformatics, hospitals, and local pathology group practices intersect. But more on that later.

In the long term, the demand by customers of tissue banking services will stimulate development of proprietary technologies for tissue imaging and analysis. As a result, anatomic pathologists will be armed with new tools for diagnosing disease. As that happens, pathologists will enjoy increased value and utility to referring clinicians.

This change curve in pathology will parallel that of radiology. Two decades ago, the radiologist's primary role was to read simple X-rays. But in a steady, evolutionary process linked to technologies such as CAT, MRI, and PET, radiologists now enjoy a more complex, interactive relationship with referring clinicians that involves patient diagnosis and ongoing patient monitoring.

Such a "brave new world" for pathology still awaits the future. But basic tissue banking functions are currently expanding in the marketplace. As Dr. Johnson notes, "We are actively working with healthcare institutions to legally and ethically obtain human tissues, which we then microscopically analyze digitally. We use this information to create databases of tissue structure and function."

Two Business Services

Dr. Johnson points out the the current market for tissue banking is divided into two primary business services. One group of organizations banks tissues for human and clinical use; these would include cornea banks, bone banks, and eye banks. The other group of companies primarily wants to acquire tissues: 1) to test for specific gene expression; and/or 2) to use tissues as a platform for biochemical analysis.

TissueInformatics falls into the second group. "We are not a supplier of tissue for therapeutic use," explained Dr. Johnson. "We are not organized to support human use of the tissues. We won't transfer a tissue if it's going to be used for placement in a human.

"Our business is to support pharma, biotech, genomics, and research enterprises," he continued. "We obtain our tissues fresh, preserve them in an appropriate fashion, then take part of the tissue for our own digital analysis while making the remainder available to the pharmaceutical industry for research purposes only."

TissueInformatics' primary customers are pharmaceutical and tissue engineering companies. "These companies want targeted tissue types that may only be available in smaller population areas," explained Dr. Johnson. "That's why local hospitals and pathology groups can be contributors to a tissue banking program."

Outsourcing Arrangement

In its early stages, companies like **Pharmagene** and **LifeSpan** are driving this market. Once these companies acquire tissues, they do biochemical assays and extract DNA, RNA, and proteins. This information is sold to pharmaceutical companies to help them in their drug discovery process. It's an outsourcing type of business arrangement.

"Two things make us different at TissueInformatics," Dr. Johnson stated. One is our emphasis on anatomic pathology. The other is our comprehensive data sets, with the ability to incorporate a wide range of data on individual tissue specimens.

"First, we look at tissues in the same way as pathologists, when they form an opinion about whether the tissue is normal or abnormal. That's the key to understanding our proprietary imaging and analysis technologies," observed Dr. Johnson.

Automate The Analysis

"Second, our software allows researchers to break tissue down into all of its components. It supports the diagnosis by including all of the tissue's mathematical subcomponents," he continued. "This also allows us to automate the analysis and quantitate anything that can be made visible.

"This includes any probe-based assessment of tissue, whether its immunohistochemistry, in situ hybridization, metabolic probes and the like. If it can make the tissue appear different, we can quantitate and develop an information reserve from that," added Dr. Johnson.

"In a literal sense, other companies in this field are grinding up tissues to run biochemical experiments," he added. "In contrast, anything which can be made visible to the pathologist can be digitalized and archived. We can perpetualize the value of that and put the data in a form that lets us leverage associated genomic or clinical data in a quantitative, correlative way.

"We're primarily interested in amassing enough tissue information from distinct subpopulations to allow us to determine the degree of variability in tissue structure and function throughout these subpopulations," observed Dr. Johnson.

Value-Added Bioinformatics

"If we can we extract this information at the same time that genetic information is extracted or proteomic information is accessed, that will yield the most value," he said. "We believe the greatest added-value service in bioinformatics today does not come from expertise exclusively in tissue information, genomics, cellular information, or similar fields. Rather, the greatest added value will come to those companies which build a bridge between these disciplines to create useful knowledge that was previously unavailable."

The need to accumulate tissue specimens from specific subpopulations offers local hospitals and pathology group practices a strategic role in the tissue banking market. "Researchers and pharma companies are interested in looking at subpopulations representative of specific disease states," Dr. Johnson declared. "For example, one study might look at the lung tissue of men who had smoked for 5, 10, 15, or 20 years. Appropriate subjects must be identified at the level of the local hospital."

HOW TISSUE INFORMATICS WAS FORMED

ACTIVITIES IN TISSUE ENGINEERING led to the creation of TissueInformatics.Inc, based in Pittsburgh, Pennsylvania.

It was founded in 1997 by four individuals: Dan Farkas, Ph.D.; Peter Johnson, M.D.; Michael Becich, M.D., Ph.D.; and Mary Del Brady. Dr. Johnson was a reconstructive plastic surgeon at the **University of Pittsburgh Medical Center**. He was an organizer of the *Pittsburgh Tissue Engineering Initiative* and served as its President for two years.

Dr. Johnson left surgical practice in late 1997 and became a full-time employee at TissueInformatics in early 1999. At that time, the company had six employees. It has since grown to 38 employees. During the past four years, TissueInformatics developed five different software analysis packages for tissue analysis, including specific modules for in situ hybridization and high capacity antibody screening.

"All our basic business services are in place," stated Peter C. Johnson, M.D., Chairman and CEO of TissueInformatics. "We have teams ready to do tissue procurement,tissue imaging, and tissue information management. We are actively generating revenues and ramping up our business services. The company is pursuing additional capital and, on two previous rounds of financing, **Motorola Corporation** invested funds.

"Motorola was interested in TissueInformatics because of its activities in bioinformatics," noted Dr. Johnson. "It's developing a biochip system that automates genetic analysis.

"That functionality dovetails with our capacity to automate tissue feature assessment," added Dr. Johnson. "Both companies want to eventually correlate those two unique data sets. That would produce an entirely new dimension of useful information."

Dr. Johnson says that biotech, pharmaceutical, and genomics industries currently need improved methods to perform a high-throughput analysis of multiple tissue images that have either been stained with antibodies for presence of specific proteins or with in situ hybridizations. The goal is to shorten the time and reduce the cost needed for target identification.

This is why the biotech, pharma, and genomics industries are funding the research and development of new technologies that will benefit the pathology profession. But the immediate and primary use of these technologies lies outside general clinical use.

"Technologies under development and refinement at Tissue Informatics are not targeted at replacing pathologists," noted Dr. Johnson. "To the contrary, our efforts are to create new tools which make pathologists both more productive and more valuable.

"We're targeting unique niches, primarily in corporate pathology, where pathologists are faced with the drudgery of looking at thousands of the same kinds of slides over and over," he added. "For example, we're building a package for toxicology that automates the analysis of liver tissue. It will enable a pathologist to spot tiny changes without having to review the entire population for quality control in order to find outliers and classify them outside of what is considered to be the normal database."

Similar Technology Curve

Dr. Johnson points out that a similar technology curve has been under development in cytologic analysis. "Imagine the day when Pap smears can be accurately, speedily, and inexpensively screened by automated systems," he postulated. "When that day arrives, there will be many clinical pathologists who say 'Hooray! The drudgery of

looking at large numbers of specimens each week has been eliminated'."

Dr. Johnson is obviously excited about the future of pathology, given the technologies and methods he's observed under development in his company. "To some extent, I think pathologists are currently tethered to the microscope because automated analysis systems are not yet available to them.

Pathologists Interpret Data

"But I think the day is fast approaching when pathologists are worth far more if they serve as 'meta-pathologists,' where their time is spent, not just doing pattern discrimination work, but interpreting the data," offered Dr. Johnson. "They'll have the capability to aggregate large quantities of clinical and behavioral information and make better projections of patient health on the basis of what's known about the tissue!"

In Dr. Johnson's view, the digitalization of images, combined with software tools that can analyze more information than is present in the image alone, will give pathologists new tools for evaluating specimens. "When such data is networked and available across systems, pathologists will be able to make correlations that were impossible in a 'microscope-only' type of setting," said Dr. Johnson. "It will be a direct consequence of the digital revolution."

Issues Yet To Be Solved

In Dr. Johnson's view, this pathology utopia is probably ten years from becoming reality. "There are a lot of issues yet to solved," he said. "Developing the technology to accomplish this is only the first step. Gaining FDA approval for clinical applications will certainly be challenging, as will liability and subpopulation issues. But this is not pie-in-the-sky. There are compelling reasons why both the research and the clinical markets will embrace these types of enhanced pathology services."

That future will unfold based on trends already under way in today's marketplace. Whereas a company like TissueInformatics has systems to do proprietary tissue analysis and the database capability to store and study that information, it is local hospitals and pathology group practices which have direct and intimate access to patients, the ultimate source of the tissue specimens.

"We have contracts with hospitals that participate in our tissue banking program. Their consent forms cover this kind of procurement," stated Dr. Johnson. "Based on the types of tissues we need to accumulate, the hospital works with the pathologists and the OR teams to identify and obtain consent from the best sources for such tissue. In many instances, such specimens might ordinarily be discarded.

Information Is Shared

"It's not expensive for hospitals and local pathology group practices to work with us," he added. "We support the technicians involved in collecting specimens. There's also a certain amount of money that can aid internal research processes. But most important for the hospital, we share the information we obtain from the tissue it provided.

"This is a critical part of the relationship between TissueInformatics and contributing hospitals," continued Dr. Johnson. "The information we return back to them is available for non-commercial use by their researchers. Because it's been stripped of identifiers, patient confidentiality is protected. That fact helps a non-profit institution deal with the transfer of tissues. It allows them to access the information [from specimens] they need to advance their research, while

answering concerns by patients and the community about disclosure of personal information."

Importance Of Tissue Banks

THE DARK REPORT believes that tissue banking is an emerging field that provides forward-looking pathologists with revenue opportunities in the short term, but may have far-reaching consequences to the entire profession of anatomic pathology in future years.

In the current marketplace, funding for tissue banking activities is coming almost exclusively from pharmaceutical companies, tissue engineering firms, and biotech research companies. The motive is to use a variety of emerging technologies in genomics and proteomics to unlock knowledge on how gene expression affects disease.

However, the ultimate goal is to use this knowledge to develop commercially viable products for diagnosing disease, treating patients, and monitoring their progress. As Dr. Johnson points out, pathology lies at the nexus of matching tissue image analysis with the information generated by various profiling tests.

Molecular And Genetic Path

In fact, it is this type of service mix that academic center labs and companies like **IMPATH, Inc.** now offer to the clinical marketplace. They blend molecular and genetic pathology with the traditional science of anatomic pathology.

From that perspective, the business model of TissueInformatics.Inc. illustrates how the large amount of research dollars funded by pharma, biotech, and genetic-based companies will directly improve the capability of pathologists to make rapid, highly-accurate, and comprehensive diagnoses from a full range of data sets, which include image analysis, genotypic testing and phenotypic testing.

Tissue Engineering Advancing Rapidly

"TISSUE ENGINEERING TECHNOLOGY is making rapid progress, in part because of the research funding by pharma, biotech, and genomics companies," said Peter C. Johnson, M.D., Chairman and CEO of TissueInformatics.Inc.

"If you follow the trajectory curve, we are moving to a point where medical science can manufacture specific tissues tailored to specific individuals," explained Dr. Johnson. "For example, let's say that a patient is going to have surgery that will require skin to be removed and this patient does not want skin for the replacement graft to be removed from another part of his body.

"Technology is taking us to the point where it will be feasible to take a tiny biopsy of skin from this patient and have it histologically analyzed," he continued. "This patient's pattern would be 'fingerprinted' for a subpopulation. Tissue for his skin graft could actually be manufactured to those specifications. Moreover, it would be tested to insure the final product had the proper hue and texture to match the patient's existing skin at the site of the proposed skin graft. In a true sense, it will be 'made-to-order' tissue fabrication!"

Maybe tissue banking is the place where "the rubber meets the road;" where pharma company money stimulates the creation of new technology that directly benefits the pathology profession. If this happened, it would certainly be logical that breakthroughs in therapeutic technologies would also trigger breakthroughs in diagnostic technologies which find widespread application in the field of anatomic pathology. **TDR**

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Dark Index

Specialty Labs and Dynacare Have Balance Sheet Differences

Differing financial strengths and weaknesses will affect each lab's future growth & expansion

SINCE LAST FALL'S SUCCESSFUL IPOS (initial public offering) raised $92 million for **Specialty Laboratories, Inc.** and $50 million for **Dynacare, Inc.**, the financial fortunes of the two lab companies have begun moving in different directions.

Lab administrators and pathologists can better understand the diverging business directions of Specialty Labs and Dynacare by studying each lab's balance sheet. Moreover, balance sheet issues are part of what hinders **American Medical Laboratories, Inc.** from moving forward with its announced IPO. *(See TDR, October 23, 2000.)*

The balance sheet reflects financial strengths and weaknesses for a company. It can directly enhance or inhibit a company's ability to expand and grow. Professional investors understand the importance of a sound balance sheet. For example, balance sheet differences are one reason why Specialty Labs' IPO pulled in almost twice the funds as Dynacare's IPO.

Strong Balance Sheet

Specialty Labs has a particularly strong balance sheet. In contrast, Dynacare's financial structure limits its business options. Both companies' pre- and post-IPO balance sheets are reproduced on page 16 and highlight key differences.

The most basic analysis of a balance sheet can focus on several items: cash and cash equivalents, long term debt, and shareholders' equity. In the case of Specialty Labs and Dynacare, each item will illustrate a fundamental difference.

Increased Cash Holdings

First is cash and cash equivalents. This is the money available to pay bills, service and/or retire debt, and expand business activities. As the two balance sheets show, Specialty Labs' cash holdings increased by $75 million after its IPO. More than 80% of its IPO monies were retained to fund future growth.

In contrast, at Dynacare, cash increased by just $1.8 million. Dynacare used the cash from its IPO differently, as shown by the $61.3 million increase in Dyncare's total assets, from $288.5 million pre-IPO to $349.8 million post-IPO. This increase reflects the value of the lab acquisitions Dynacare completed during 2000.

The telling difference is long term debt. Specialty Labs used its funds to retire 100% of its long term debt. But it's a different story at Dynacare. On annual revenues of $352 million for 2000, it carries about $209 million of long term debt (of which $5.9 million matures during the next 12 months and must be retired). Of course, it must also service the interest payments due on this debt. This diverts cash flow that could be used to fund expansion or to pay stock dividends. Investors recognize this fact and have allowed Dynacare's stock price to fall considerably below its IPO level of $10 per share.

Specialty Laboratories, Inc.

Consolidated Balance Sheets (in thousands)

ASSETS:	FY1999	FY2000
Cash and cash equivalents	$717	$75,604
Net receivables	26,775	32,775
Deferred income taxes	2,680	4,239
Inventory	1,799	1,623
Prepaid exp/other assets	1,276	1,496
Total current assets	$33,247	$115,737
Property and equipment, net	20,272	19,891
Deferred taxes	3,736	2,863
Other assets	2,605	3,514
Total assets	$59,859	$142,005
LIABILITIES AND SHAREHOLDERS' EQUITY:		
Accounts payable	$10,119	$11,921
Accrued liabilities	9,066	10,388
Income tax payable	1,299	4,638
Current portion/long-term debt	9,148	--
Total current liabilities	$29,631	$26,948
Long-term debt-net of current	9,234	--
Other long-term liabilities	2,713	3,260
Total liabilities	$41,578	$30,208
SHAREHOLDERS' EQUITY:		
Capital stock	4,055	89,824
Retained earnings	15,430	24,103
Deferred compensation	(354)	(2,130)
Loan to shareholder	(850)	--
Total shareholders' equity	$18,281	$111,797
Total liabilities & shareholders' equity	$59,859	$142,005

Dynacare Inc.

Consolidated Statements of Financial Position (in thousands $ U.S.)

ASSETS	FY2000	FY1999
Current assets:		
Cash/cash equivalents	$18,099	$16,327
Accounts receivable	62,065	59,562
Prepaid expenses	2,654	5,354
Inventory	7,692	7,059
Deferred income taxes	5,956	2,263
Total current assets	96,466	90,565
Capital assets	45,907	33,846
Licenses and goodwill	166,691	140,124
Other assets	40,784	23,984
	$349,848	$288,519
LIABILITIES		
Current liabilities:		
Bank indebtedness	$00	$1,957
Accnts payable & accrued liabilities	45,867	34,723
Current portion of deferred income taxes	10,961	7,291
Current portion of long term debt	5,913	3,893
Total current liabilities	62,741	47,864
Long term debt	202,287	198,788
Deferred income taxes	29,569	40,221
-	294,597	286,873
SHAREHOLDERS' EQUITY		
Capital stock	98,357	51,158
Deficit	(44,085)	(49,343)
	54,272	1,815
Foreign currency translation adjustment	979	(169)
	55,251	1,646
Total liabilities and shareholders' equity	$349,848	$288,519

• *Financials are taken from public filings and illustrate the comments made in the accompanying story.*

This brings us to a comparison of shareholder equity. At Specialty Labs, total shareholder equity totals $111.7 million and, with liabilities, yields a balance sheet total of $142 million.

Dynacare's shareholder equity, defined as "capital stock" under Canadian accounting rules, totals (after foreign currency adjustment) $55.2 million post-IPO, compared to $1.6 million pre-IPO. This shows how the $50 million raised during the IPO has been absorbed and helped boost "capital stock" from almost zero.

There is one more key difference in the balance sheets of Specialty Labs and Dynacare. Because Spec-ialty had no lab acquisitions in 2000, there is no goodwill on its balance sheet. That is not the case at Dyna-care, which has used lab acquisitions as a major way to boost revenues. It has "licenses and goodwill" of $166.7 million. This is 47.6% of its total assets.

Accounting principles define goodwill as the difference between the purchase price paid for a company and the value of its tangible assets. It is a "paper" accounting entry and is usually amortized over several years.

As a balance sheet item, goodwill affects a company's ability to borrow money, float debt issues, and attract equity investors. If a company were to be liquidated in a bankruptcy action, goodwill frequently has zero value. Obviously, banks and investors want to know that, if liquidated, a company has enough assets to fully cover liabilities and, hopefully, all the stockholder equity.

Lots of goodwill on a balance sheet, without significant amounts of compensating cash, tends to dissuade investors and banks from providing capital on the most favorable terms.

That is a reason why certain lenders and investors would consider, along with other factors, Dynacare's relatively large percentage (47%) of goodwill to be a balance sheet weakness. Subtract the $166.6 million in goodwill from its $349.8 million in total assets, and only $183.2 remains to cover its $294.5 million in total liabilities.

Risk Factors To Consider

Shrewd lenders and investors see this as one risk factor they must consider before extending credit or capital to a company like Dynacare. At the least, it raises the cost of borrowing to the company with a weak balance sheet.

This frames the business challenge facing Dynacare. Investors understand the particular strengths and weaknesses of its balance sheet, revenue stream, and strategic business plan. Both investors and lenders are closely scrutinizing the financial performance of Dynacare to see it can deliver the revenue growth and increased profits it promised in its strategic business plan.

Each quarter, Dynacare must hit ambitious targets for revenue and earnings, otherwise investors will cease to support the stock. There is already evidence that some investors question Dynacare's ability to deliver strong and sustained growth in sales and profits. Since early January, Dyncare's stock price has fallen steadily. It now trades near $5 per share, less than half of its IPO price of $10 in November 2000.

Softening Stock Prices

Although Specialty Labs has a stronger balance sheet than Dynacare, banks and investors are also keeping a close watch on the ability of Specialty Labs' executive team to meet its projections on revenue growth and earnings. That may be one reason why Specialty Lab's stock prices softened considerably in the past 60 days.

As demonstrated in this story, a closer study of the balance sheets of lab companies helps explain some reasons behind the business successes and failures they experience. For example, a less-than-ideal balance sheet, along with other financial factors, at American Medical Laboratories has made it difficult for AML to place an IPO on terms it considers reasonable.

At another time and place, **Quest Diagnostics Incorporated**, when it was spun off from **Corning Corporation**, was able to write off $450 million of intangibles and goodwill from its balance sheet. It started business on January 1, 1997 with a balance sheet that allowed Quest Diagnostics much greater freedom of action than the other two national labs. Did it make a difference? Certainly! Today, the world's largest public clinical lab company is the one which had the strongest balance sheet at the beginning of 1997.

Balance Sheet Analysis

In the pathology world, analyzing the balance sheets of the leading pathology companies like **AmeriPath, Inc.**, **DIANON Systems, Inc.**, and **IMPATH, Inc.** reveals interesting clues to their financial future. For example, AmeriPath, which has relied heavily on acquisitions to fuel its rapid growth, has as much as 79% of its assets comprised of intangibles (goodwill and the like) and hospital contracts (a capitalized value for its pathology group contracts with hospitals).

Obviously, these observations about the balance sheets of the two newest public lab companies don't represent a comprehensive analysis. But this simple assesment does highlight the balance sheet differences of Specialty Labs and Dynacare. It helps lab execs and pathologists understand the different financial resources available at each company to support each lab's business strategies. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There's another commercial laboratory working toward its ISO-9001 certification. CEO Roy Trucks of **Doctors Laboratory, Inc.** in Valdosta, Georgia reports that implementation of ISO-mandated procedures is going well. The goal is to pass the audit and receive the ISO-9001 certificate by October 2001. Trucks also indicates that the new management methods have already begun boosting productivity in the lab while reducing system-generated errors.

LABCORP ACQUIRES NEW HAMPSHIRE-BASED PATH LAB, INC.

Probably the nation's best existing example of a commercial lab with long-standing hospital joint venture relationships has been purchased by **Laboratory Corporation of America**. It was announced on March 26 that LabCorp would acquire **Path Lab, Inc.** in a deal expected to close within 30 days. Path Lab President Thomas Hirsch will stay on, along with his management team. Path Lab has been discreetly shopping for a buyer for some time.

MEDPLUS FOUNDERS FINANCIALLY—QUEST TO THE RESCUE?

It's been an increasingly-tough market for **MedPlus, Inc.**, a company developing products to support an electronic medical record. Operating losses and weak investor interest in e-health companies have taken their toll. As March 26, **Quest Diagnostics Incorporated** offered to buy the remaining stake in MedPlus that it doesn't already own for $17.3 million, subject to proper due diligence. As of press time, Quest Diagnostics had not confirmed that it would proceed with the MedPlus acquisition.

MORE ON: MEDPLUS

MedPlus is a relatively small company. It claims to have contracts with 125 hospitals, and its annual revenues totaled only $11.5 million for fiscal year ending January 31, 1999. It's net loss for that year was $8.5 million. During 2000, Quest Diagnostics paid almost $10 million to acquire an 18% equity interest in MedPlus. As part of that agreement, Quest Diagnostics agreed to jointly market MedPlus' ChartMaxx and E.Maxx patient record systems. These systems are designed to integrate clinical data, including lab test results, from hospitals, laboratories, and physicians' offices.

PHARMCHEM ESCAPES CALIFORNIA

Located in Menlo Park, California, **PharmChem, Inc.** has endured the employee shortages and escalating business costs that come from its location in the famed "Silicon Valley." But apparently California's energy crisis is the "straw that broke the camel's back." Company officials announced plans to close all operations in California. PharmChem will move its headquarters and testing now done in California to an existing laboratory in Fort Worth, Texas. PharmChem's Menlo Park laboratory was recently reclassified by **PG&E** to an "interruptible power supply." This means the lab is subject to shut-down by rolling power blackouts.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 30, 2001.

PREVIEW #4

EXECUTIVE WAR COLLEGE

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Topic: Nation's Largest Hospital Lab Consolidation

Learn about the challenges of combining two consolidated hospital lab systems into a unified lab management arrangement. Aurora Health Systems of Milwaukee joined its 12-hospital lab system with the 10-hospital lab system of Advocate Health Care in Chicago. Here's the biggest consolidation project in the U.S.! Discover the surprising secrets that generated improved productivity and additional lab testing services.

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- ***Pathology Meets the Internet: Early-Adopter Pathologists Report Significant Success.***
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