



*From the Desk of R. Lewis Dark...*

# THE **RD** DARK REPORT

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

*R. Lewis Dark:*

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## COMMENTARY & OPINION by...

*R. Lewis Dark*  
Founder & Publisher



### Oncologists Cut Into Pathologists' Revenue Pie

EVENTS NOW UNFOLDING IN DALLAS, TEXAS, SIGNAL A DIFFERENT DIRECTION for pathology and clinical laboratory testing. As you will read on pages 3-9, in May, just weeks from now, a new laboratory company, funded with \$40 million from an unlikely combination of four partners, is about to become operational.

The primary business objective of the new partnership between **Pathologists Bio-Medical Laboratories**, **Baylor Health Care**, **Texas Oncology**, and **US Oncology** is to build a state-of-the-art reference and esoteric laboratory, to be known as **MedFusion**. First the partnership will offer this testing to hospitals and other clients in the Dallas area, before expanding across Texas and into other parts of the United States.

I want to focus on another intriguing aspect of the new business relationship among these four unexpected bedfellows. Within the same building where MedFusion's laboratory is located, US Oncology is building its own laboratory that will focus on providing oncology testing for its 1,300 oncologists who practice in Texas and in 38 other states across the country.

Because it currently serves about 720,000 cancer patients per year in this country, US Oncology has the ability to refer a huge volume of biopsies and cancer tests to its new laboratory, currently under construction in Dallas. At the same time, the pathologist-owners of Pathologists Biomedical Laboratories (PBL) in Dallas have positioned themselves to become the primary and preferred source of pathology subspecialty expertise to analyze and diagnose these specimens.

The obvious conclusion is that US Oncology represents the first wave of oncologists ready to cut into the pathologists' revenue pie, just as dermatologists, urologists, and gastroenterologists have done during the past two decades. I think that conclusion—even if true—is rather simplistic and misses a more subtle and important insight.

Personalized medicine and companion diagnostics are making the diagnosis and treatment of cancer and other diseases more complex. I believe the Dallas pathologists at PBL have their sights on a much more valuable prize. They are positioning themselves to become an essential part of the cancer care team. In coming years, this means that they evolve into necessary consultants on every case of cancer, from diagnosis to selection of therapies and monitoring the patients' progress. As that happens, I predict these Dallas pathologists will earn more compensation by providing services that have significant value to patients and their care teams. **TDRE**

# Baylor Pathologists Form Lab with US Oncology

➤ Four partners prepare to open two sizable new laboratory businesses to be based in Dallas

➤➤ **CEO SUMMARY:** *In Dallas, Pathologists Bio-Medical Laboratories is part of a new laboratory partnership that includes Baylor Health Care System, Texas Oncology, and US Oncology. The four partners ponied up a total of \$40 million in cash and debt to build a state-of-the art laboratory in a 172,000 square foot building. To be called "MedFusion," the laboratory partnership expects to provide reference and esoteric testing to Baylor Health, hospitals, other clients, and to clinical trial service organizations.*

**I**N RECENT WEEKS, organizers of a comprehensive new clinical laboratory enterprise based in Dallas, Texas, took the wraps off their business plans.

Four partners, including a large pathology group, are preparing to open a \$40 million clinical laboratory complex by May 2010. This new laboratory venture will be a major presence in the Dallas market and has ambitions to deliver a unique mix of laboratory testing services.

**MedFusion** is the name of the new laboratory company. MedFusion is a four-way partnership between **Pathologists Bio-Medical Laboratories** of Dallas; **Baylor Health Care System**; **Texas Oncology**; and **US Oncology**. The four groups are equal partners in MedFusion. Each partner is providing roughly one quarter of the \$40 million the capital required to finance the construction and initial operations of MedFusion.

The new company leased 172,000 square feet of space in the Dallas suburb of Lewisville. Construction of the new laboratory facility began in October, 2009. The laboratory facility will become operational as early as this May.

MedFusion's CEO, Keith Laughman, says that reference and esoteric testing will be the main emphasis. "The day we open our doors we'll have a robust test menu of about 1,200 orderables," noted Laughman. "We will have a broad range of tests. MedFusion's menu will include many tests that Baylor Health Care and other Dallas hospitals currently send out of state."

A second laboratory will be opened within the same building as MedFusion's laboratory. This second laboratory will be owned by US Oncology. It will provide histology, technical component, and other laboratory services in support of cancer testing

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for cases referred by the physicians at US Oncology, Texas Oncology, and other oncology clients.

“MedFusion’s laboratory will focus on clinical pathology and clinical trials,” stated Laughman. “The US Oncology laboratory—in conjunction with Pathologists Bio-Medical—will focus on anatomic pathology (AP). It will offer a wide range of tests that are part of AP services to create a deep and robust service offering.

“This cancer testing laboratory will draw upon the consortium,” he continued. “MedFusion’s laboratory will work with US Oncology as they serve their target markets in oncology. With the US Oncology laboratory located in the same facility as the MedFusion lab, it allows us to support their testing needs with the range of clinical pathology tests that complement histology-based testing for cancer.”

### ► Integration of CP and AP

“As we move forward, there will be more integration of clinical pathology into an anatomic pathology report,” commented Laughman. “MedFusion will be there with the sophisticated information technology needed to support this integration.

“Further, as MedFusion’s clients are interested in getting anatomic pathology second opinions, the US Oncology and Pathologists Bio-Medical consortium will be there for us. Operationally, we expect the two laboratories will be very tightly integrated,” he predicted.

“Although the two laboratories will have separate ownership and different CLIA licenses,” explained Laughman, “there are pre-analytical processes that we can share, and we’ll have an integrated information system so that we can generate extremely sophisticated reports.”

The creation of two separate laboratory facilities within the same building is intentional and recognizes several important trends now unfolding in healthcare. “The significant focus on oncology is

because this medical field is experiencing a rapid transformation,” said Laughman. “New technologies for diagnosis and treatment of cancer mean that the standard of care is advancing rapidly. In turn, these advances promise better outcomes for cancer patients because of faster, more exact diagnostics and more precise information about which treatments would most benefit the patient.”

### ► Two Markets For Lab Testing

For its part, MedFusion has its eye on serving two market segments. One is the hospital/health system market. The other is the clinical trials market. MedFusion’s immediate geographical focus will be the Dallas–Fort Worth metropolitan area. As service levels allow, it intends to expand outward to other Texas cities.

“As a source of reference and esoteric testing for hospitals and health systems, we will perform at least 95% of the laboratory testing that is typically sent out by a hospital,” he explained. “We will also provide other low volume tests that hospitals must generally perform internally in order to meet clinical service requirements.

“We expect that, as a local provider of reference and esoteric testing, MedFusion’s turnaround time will allow these hospitals to preserve service levels even as they refer out those tests at a lower unit cost than their current production costs,” added Laughman.

### ► Rapid Growth Expected

The four partners are planning for MedFusion to become a sizeable enterprise. “When the laboratory opens in May, it will employ about 150 people,” noted Laughman. “As the business grows, there may be as many as 900 employees within the next five years.

“In that group of 900 will be employees to provide a variety of services beyond the lab testing services,” he said. “For example, on the clinical trials side, we’ll have site management organization support and eventually CRO [contract

## Four Partners Come Together and Design New Lab Company to Support Integrated Care



venture called MedFusion by its four partners. It is the first large-scale business venture that brings together a regional pathology

**THERE WILL BE AT** least one first for the Dallas, Texas-based laboratory

supergroup, a multi-billion dollar health system, and a Fortune 500 specialty medical company to form a stand-alone reference and esoteric testing laboratory. It is actively building a new lab facility in a 172,000 square foot building and projects employing as many as 900 people in coming years.

### MedFusion's Four Partners:



#### Baylor Health Care System

- \$3.1 billion revenue
- 2,995 beds in the system
- 23 owned, leased, affiliated and short-stay hospitals
- 109,991 admissions
- 2,886 physicians, active staff
- 17 ambulatory surgery centers
- 88 primary care centers, specialty care centers, senior health centers



#### US Oncology

- \$3.3 billion revenue
- 493 locations in 39 states
- 1,310 physicians
- 720,000 patients served in 2008
- Rank 646 on Fortune 1,000



Pathologists Bio-Medical Laboratories, L.L.R.

#### Pathologists Bio-Medical Laboratories

- Pathologist-owned independent pathology laboratory
- 28 pathologists
- Serves hospitals of Baylor Health Care and other hospitals in Greater Dallas Area



#### Texas Oncology

(Division of US Oncology)

- 100 service sites in Texas
- 300 physicians
- 68,000 patients served in 2008

research organization] types of specialty services. These will be in addition to the clinical pathology services.”

MedFusion's four partners believe that opportunities in the clinical trials sector will be substantial, for an interesting reason. “In response to advances in molecular diagnostics, clinical trials and clinical practice will merge,” predicted Laughman. “That is not true today. They are very separate clinical activities.

“However, as molecular diagnostics help identify patient populations in a more exact way, this will trigger closer

interaction with clinical trials activity,” he explained. “This will happen because of several developments.

### ▶ Large Amounts Of Lab Data

“First, the immense amount of data generated by the multi-variant assessments used by next-generation diagnostics will be very similar to the data handling capabilities associated with clinical trials,” he explained. “In support of clinical trial researchers, these enriched and fuller sets of lab data will represent key patient inclusion criteria for studies. These data

will span the clinically relevant period of time, further adding to their value.

“We anticipate that, moving into the future, clinical studies will involve smaller populations,” he said. “We can already see examples of how the use of molecular diagnostics moves treatment away from the pharmaceutical blockbuster model and toward more targeted therapies. These examples point the way toward wider use of personalized medicine and companion diagnostics.

### ► Clinical Trials Integration

“This integration of clinical practice and clinical trials will become broader and more pervasive,” observed Laughman. “Today, pharma companies conduct large-scale trials and studies to support a particular blockbuster drug. In the future, pharmaceutical companies will likely conduct a larger number of trials to appropriately categorize the different cohorts of patients. This knowledge will be used to develop more targeted therapies appropriate for each patient cohort.”

Because MedFusion is starting with a brand new facility and no legacy systems, says Laughman, they are able to build with this future in mind. “Our infrastructure is designed to deliver on this integration of care,” he noted. “Our laboratory does not have to break down legacy systems and transition old ways of doing things into new systems. We’re able, in a green field sort of mind set, to build it the way we want it to be. We expect that to be an advantage.

### ► Patient Data And Information

“MedFusion is establishing systems that will offer a more holistic view of the patient’s data and information,” explained Laughman. “All laboratories are in the information business. MedFusion will provide that information as efficiently and rapidly as possible. Electronic connectivity is key and we are designing a robust IT system.”

“This will take some re-invention,” he added. “There are excellent LIS systems and

CRM (customer relationship management) systems available today. But too often, these and other IT systems are fragmented in a laboratory.

“MedFusion is integrating and operationalizing those systems at a higher level in its IT architecture,” said Laughman. “Similarly, our goal is to integrate lab test results and clinical data to help clinicians get a more complete picture of the results for a particular patient.

“As a laboratory service provider, MedFusion will benefit from its relationships with Baylor Health Care—which is building a new cancer center; Texas Oncology; and US Oncology,” he stated. “That will be true for two reasons. First, the needs of these physicians and MedFusion’s access to them will drive the introduction of new tests. Second, physicians affiliated with MedFusion’s partners represent an extremely committed focus group helping to ensure that the services offered will provide outstanding clinical utility.”

### ► Unique Combination

MedFusion represents a unique combination of partners for a lab testing business. There is no obvious precedent where a major healthcare system and its pathology group have formed a large laboratory company in partnership with a major specialty physician company such as US Oncology and its Texas Oncology business. These two medical groups combined represent about 1,300 doctors.

However, with the four partners contributing about \$40 million to launch the new laboratory, MedFusion certainly has adequate funding to build a state-of-the-art facility. This lab facility, designed from the ground up, will incorporate the latest generation lab testing technology. It is also designed to accommodate next-generation diagnostic technologies, thus giving it the potential to become a unique provider of patient-oriented laboratory testing services in Dallas and North Texas.

**TDR**

—by Karen Branz

# Two New Pathology Models Will Soon Be Tried in Dallas

➤ **Goal is to deeply integrate laboratory testing into healthcare continuum in ways that add value**

➤➤ **CEO SUMMARY:** *There are notable aspects to how and why four unlikely partners are banding together to invest \$40 million and create the nation's newest reference and esoteric testing laboratory. It was the pathologists at Baylor University Hospital in Dallas, Texas, who originated the vision and initiated conversations with the other three partners. This new business shows how pathologists can leverage their knowledge and play a greater role in advancing personalized medicine.*

**M**AKE NO MISTAKE! Pathologists are the visionaries and initiators of the newly-created laboratory testing partnership in Dallas, Texas, that is expected to become operational this May.

Inside sources tell THE DARK REPORT that it was the pathologist leaders at **Pathologists Bio-Medical Laboratories (PBL)** in Dallas who initiated the conversations with **Texas Oncology**, **Baylor Health Care System**, and **US Oncology** that directly led to the formation of the nation's most interesting new laboratory business. (See pages 3-6.)

It marks one of the few times in the past decade that a new pathology business has launched with tens of millions of business capital and with pathologists serving on the Board of Directors and in executive positions. A key figure in this effort has been Peter Dysert, II, M.D., a Managing Partner of Pathologists Biomedical. Dysert has kept a low profile in the news stories published about the newest laboratory competitor in Dallas.

The four-partner laboratory consortium is called MedFusion. It has a simple proposition. It wants to establish a clinical

laboratory testing facility designed to provide the range of reference and esoteric tests that are commonly referred out by hospital laboratories, along with a sophisticated and highly-integrated informatics capability.

What gives MedFusion immediate market presence is that it will have access to the send out testing from the 2,500 beds in the hospitals that are part of the Baylor Health Care System.

## ➤ **New Territory For Lab Testing**

On one level, this laboratory business model resembles a regional version of **ARUP Laboratories** and **Mayo Medical Laboratories**. What takes the MedFusion business model into new territory are several things.

First, two of the four partners are sizeable, profitable enterprises. Baylor Health Care System has \$3.1 billion in revenue. US Oncology has \$3.3 billion in revenue and ranks 646 on the *Fortune 1,000*. These two partners bring substantial financial resources to the new laboratory company. This financial strength is likely to be a source of competitive market advantage going forward.

Second, MedFusion intends to do more than just be a reference and esoteric laboratory for hospitals, health systems, and other types of clients. MedFusion CEO Keith Laughman stated that the new company plans to offer such services as site management, organization support, and a CRO (contract research organization).

### ► How The CRO Opens Doors

The CRO is an interesting twist. THE DARK REPORT believes this element is connected to MedFusion's relationship with Baylor Health, US Oncology, and Texas Oncology (a business division of US Oncology). Given the growing importance of access to patients to enroll them in clinical studies and drug trials, MedFusion is shrewd to create a CRO.

After all, Baylor handles 102,000 inpatient admissions annually and has 88 primary care centers and other health centers. Texas Oncology serves 68,000 cancer patients each year and its parent, US Oncology, serves 720,000 patients annually. Thus, MedFusion's CRO would have the necessary access to patients to screen and qualify them for clinical trials.

Next, MedFusion will have the ability to provide all the laboratory testing needed by the CRO for diagnostic and patient monitoring purposes—along with access to a patient's inpatient lab test data if it is held by Baylor Health. For clinical studies, it is an advantage to have one laboratory provide all the lab test data over the entire multi-year course of the study.

### ► Electronic Interfaces

Another strategic element in MedFusion's favor is its plans to develop a tightly-integrated information technology (IT) platform. This is important. It would make it possible for MedFusion to electronically interface with Baylor, Texas Oncology, and US Oncology's (EHR) electronic health record systems.

But that is not all. MedFusion's clinical and anatomic pathologists would likely

also have electronic access to the full patient records held by each of these organizations. That would give pathologists the information they need to participate as full consultants with the referring physicians, possibly even in real time.

All of these attributes of MedFusion will be designed to serve the vision of personalized medicine, which includes a greater role for companion diagnostics. In all these respects, the organizers of MedFusion are designing a laboratory organization to serve the healthcare needs of tomorrow, while competing for business today.

But MedFusion is just one part of a more comprehensive business strategy that brings together Baylor Health, US Oncology, Texas Oncology, and Pathologists Bio-Medical Laboratories. This strategy centers on cancer.

### ► Oncology Laboratory

It should be noted that, within the 172,000 square foot facility in Lewisville, Texas, leased by MedFusion for its laboratory, there will be a second laboratory, owned solely by US Oncology. As described by MedFusion principals, this laboratory will process tissue specimens and perform genetic and molecular testing in support of cancer patients under the care of Texas Oncology and US Oncology.

Because US Oncology serves 720,000 patients per year in the United States, this cancer laboratory is likely to quickly grow into one of the largest cancer testing laboratories in the United States. It also means that US Oncology will be generating substantial revenue from the technical component (TC) claims submitted for these cancer tests.

It can be expected that Pathologists Bio-Medical Laboratories—as one of the four partners in MedFusion—will provide the professional component (PC) services to US Oncology and Texas Oncology. PBL already has a wide range of subspecialty expertise in place and has considerable experience with the latest molecular and genetic test technologies.



Also, Baylor Health Care is opening a new cancer center. This gives the pathologists at PBL a unique opportunity to serve both Baylor and US Oncology. It positions these pathologists to possibly grow into one of the nation's largest pathology group in coming years.

### ➤ Unique Lab Testing Model

By any measure, the pathologists at Pathologists Bio-Medical Laboratories have participated in creating a unique new model for laboratory testing. One underlying theme among the four partners and the two separate laboratory organizations is the goal of using laboratory testing and pathology professional expertise to support integration of clinical care.

Timing may be in favor of this nascent laboratory venture. A host of developing technologies in genetics and molecular diagnostics will provide MedFusion with new opportunities to add value while supporting greater integration of patient care, even as the demographics of an aging population mean more cases of cancer and other diseases associated with aging.

THE DARK REPORT observes that the consolidation of healthcare in the United States continues. The partnership developing MedFusion shows how consolidated provider organizations, because of their size and scale, are capable of creating ancillary businesses that have immediate access to the volume of patients needed to ensure financial viability.

### ➤ Pathology's Future

The pathology profession should also consider this new laboratory partnership as a reminder that the heyday of the smaller, generalist pathology group practice is approaching its end. For that reason, most community hospital-based private pathology groups should be prepared to reassess current strategy. Large pathology supergroups will be the future, and Pathologists Bio-Medical Laboratories in Dallas is showing one way to prosper as healthcare transitions to personalized medicine. **TDR**

## Baylor's Pathologists Have Key Role at MedFusion

**F**OR MORE THAN THREE DECADES, pathologists at 998-bed **Baylor University Hospital**, have been an active force in laboratory testing in the Dallas, Texas, healthcare marketplace.

These pathologists own Pathologists Bio-Medical Laboratories (PBL), an independent laboratory that has been affiliated with Baylor University Hospital since 1950. The pathologists in that group are on the faculty of the **Baylor School of Medicine**. They also own and operate an independent laboratory that serves the Baylor Health Care System and other hospitals in the Dallas area.

During the late 1980s, Baylor's pathologists were involved in an attempt to create a new regional hospital reference and esoteric testing laboratory that included **Nichols Institute** as a partner. That project did not succeed.

During the 1990s, the Baylor pathologists were actively involved in long-running discussions among pathologists in the region to create what would have been one of the nation's largest pathology IPAs (independent physician associations). This was a response to the contracting practices of HMOs and managed care companies. However, it proved difficult to gain the agreement of all the interested pathologists and the proposed IPA never came to fruition.

In recent years, it was the pathologists at PBL who initiated the discussions that eventually brought four partners together to invest \$40 million and create MedFusion. The Baylor pathologists have thus positioned themselves to have a role in the development of personalized medicine, including the development and expanded use of companion diagnostics.


**Pathology Update**

# Pathology Errors in Canada Make National News Once Again

*Mastectomy on a patient who didn't have cancer triggers suspension of one pathologist, review of cases*

**Y**ET ONE MORE TIME, pathology errors are making national headlines in Canada. News of errors by a surgeon and a pathologist in a Windsor, Ontario, hospital caught provincial health officials off balance.

The simple story is that an experienced surgeon at 305-bed **Hotel-Dieu Grace Hospital** performed a mastectomy on a patient that did not have breast cancer. The surgery happened because the surgeon, Dr. Barbara Hartwell, misread the pathology report.

## ► A Complex Story

The details of the story are more complex. First, the pathology report was described as “confusing,” one reason why Hartwell says she “misread” the pathologist’s findings. Second, it was reported that Hartwell had a second report prior to surgery that said the patient was negative for breast cancer, thus raising more questions about why she didn’t catch this error prior to surgery.

Third, the pathologist, Dr. Olive Williams from **Windsor Essex Pathology Associates**, had been issued a written caution by the **College of Physicians and Surgeons (CPSO)** in November 2009—the same month as the unnecessary mastectomy was performed—after having admitted that, in 2007, she missed reviewing a slide that showed an obvious tumor of the appendix. That patient was later properly diagnosed.

Fourth, the mastectomy was performed on November 5, 2009 and the error was communicated to the patient within days. Yet hospital executives remained unaware of this case until contacted by a local television news reporter about the error on February 5, 2010.

Fifth, however, within days of the mastectomy, the chief pathologist at Hotel-Dieu Grace Hospital learned of the adverse event and a review of Williams’ pathology cases was conducted. Press reports say that seven cases of “serious concern” were identified and Williams lost her privileges at Hotel-Dieu Grace Hospital on January 4, 2009.

Sixth, another patient who suffered an unnecessary mastectomy went public with her story. After Laurie Johnston of Leamington, Ontario, who was the patient in the November case, identified herself to the media, another patient came forward. Janice Laporte publicly stated that Dr. Hartwell had performed a mastectomy on her in September 2001, then told her a week later that she had been cancer-free prior to the surgery.

## ► Daily Headlines

This steady series of disclosures has fueled almost daily headlines about problems with pathology testing. Hotel-Dieu Grace Hospital quickly decided to review 15,000 pathology reports handled by Williams since she began service there in 2003.

At the provincial level, the Ministry of Health has appointed three physicians to conduct a review that will include 3,000 pathology cases that go back two years. Leading the team is Dr. Barry McLellan, currently CEO of **Sunnybrook Health Sciences Centre** in Toronto and formerly the Chief Coroner of Ontario.

Meanwhile, some credible critics say that the review of pathology problems doesn't go far enough. Tom Closson, President of the **Ontario Hospital Association**, wants a full, province-wide review of pathology cases, arguing that there is a lack of consistent standards in how pathology is performed across the province and a shortage of pathologists.

"We'd like to see a broader pathology review in Ontario," Closson told reporters. "We've seen a number of examples over the last few years of false positives or negatives." Calling pathology an "inexact science" which could contribute to misinterpretations of some specimens, Closson asked "Are we sure that we have a consistent approach to doing peer review—one pathologist looking at another pathologist's work? I think the answer to that question is 'no!'"

### ► Response To Clossen

In responding to Clossen's remarks, Dr. Laurette Geldenhuis, President of the **Canadian Association of Pathologists** (CAP) talked to a reporter from the *Vancouver Sun*, who wrote that Geldenhuis "disagreed with Clossen's comments but conceded pathology is 'an art as much it is a science.'"

"The practice of pathology in Canada is very good and Canadian pathologists are very well-trained," noted Geldenhuis. "Of the hundreds of thousands of reports that go out, virtually all of them are of exceptional quality."

In recent years, the Canadian Association of Pathologists has repeatedly urged provincial health plans and the federal government to institute stricter laboratory accreditation requirements and quality

## Is Pathologist Overwork And Understaffing an Issue?

**D**OES ONTARIO HAVE AN ADEQUATE NUMBER OF PATHOLOGISTS to deliver a high quality and consistent service? This question has been asked by the press following the disclosure of pathology errors in at least one hospital in Windsor, Ontario.

Approximately 463 pathologists practice in the province. Currently 10 pathologists work in Windsor (not including Williams, who is suspended). Its two hospitals serve a population of 325,00 in the Windsor metropolitan area.

Ontario Health Minister Deb Matthews told a reporter that government funding for pathology training positions has increased. In 2003, just seven pathologists were in training. The increased funding now supports 28 pathologist training positions. However, across Canada, a number of pathology residence positions go unfilled each year.

standards. On their own initiative, pathologists have established several voluntary quality programs. (See *TDR*, May 18, 2009.)

The discovery of an unacceptable number of errors by a pathologist in Windsor is one more example that supports the argument that sustained underfunding of pathology services by health systems in Canada has begun to compromise quality, analytical integrity, and patient safety.

### ► When Lab Budget Cuts Hurt

THE DARK REPORT has observed how ongoing, multi-year budget cuts for laboratory testing services eventually must reach the point where quality cannot be maintained, given the shortage of pathologists and the inadequate resources available to them to process and diagnose specimens with a high degree of proficiency. The increasing number of examples of unacceptable pathology errors in Canada may be the sign that its health system has finally reached this point. **TDR**

# Preparing for New Lab Role In Personalized Medicine

► **Multiple disruptive forces are actively reshaping clinical laboratory testing and anatomic pathology**

►► **CEO SUMMARY: Laboratory medicine is about to find itself between the two jaws of a powerful vise. One jaw is pending major legislative overhaul of the entire healthcare system, along with dwindling reimbursement as Medicare and Medicaid runs out of money. The other jaw is personalized medicine, companion diagnostics, and expensive molecular testing. As these jaws squeeze tighter, clinical laboratories and anatomic pathology groups will need effective response strategies.**

**P**ERSONALIZED MEDICINE may represent the single most disruptive force facing both healthcare and laboratory medicine today. But that's just one of several highly disruptive developments that need to be tracked by pathologists and laboratory managers.

The short list of pending disruptors might include the major healthcare reform legislation that continues to show signs of life in Congress; the predicted tidal wave of physician adoption of electronic medical record (EMR) systems in response to federal incentive payments; and the need for labs to offer genetic and molecular test technologies which are more complex and expensive.

## ► **Increased Pace Of Change**

Collectively, these disruptors portend an increased pace of change, along with the need for clinical laboratories and anatomic pathology groups to be nimble in their responses. To inform and educate pathologists and laboratory executives about the threats and opportunities associated with these powerful and disruptive forces, special sessions and presentations will take place at the upcoming 15th

Annual *Executive War College on Laboratory and Pathology Management*. The event takes place on April 27-28, 2010 in New Orleans at the Sheraton Hotel.

Personalized medicine as a disruptor will be addressed by several experts. At **UCLA Medical Center**, the pathology group and the radiology group created a joint venture and earlier this year opened what might be the nation's first purpose-built integrated imaging/pathology service center for patients.

During a single visit, a patient can get all needed imaging studies, along with location-guided biopsies. Within 48 hours or less, the UCLA pathologists and radiologists deliver the single, integrated diagnostic report to the patient's physician.

Scott Binder, M.D., Senior Vice Chair, Pathology and Laboratory Medicine, will be at the *Executive War College* to discuss this innovative effort to deliver an integrated, personalized medicine service that combines *in vivo* and *in vitro* diagnostics. Of equal interest is the fact that the business plan for UCLA's pathology and radiology joint venture projects millions of dollars in new case referrals as physicians

take advantage of a “one-stop” integrated diagnostic service for the specific types of cancers involved in the joint venture.

### ► Reshaping Lab Medicine

For a strategic look at how personalized medicine, companion diagnostics, informatics integration, and evidence-based medicine (EBM) will reshape healthcare and laboratory testing, two speakers will offer informed perspectives.

David King, CEO of **Laboratory Corporation of America**, will take attendees “behind the scenes” with insights as to how employers, payers, and the pharmaceutical industry are using laboratory test data in innovative ways. He’ll offer the likely evolution of laboratory testing as companion diagnostics incorporates rapid, multi-analyte molecular testing into care pathways.

Equally powerful insights on the transformation of anatomic pathology will be the theme of Thomas Grogan, M.D., Founder and Chair Emeritus at **Ventana Medical Systems, Inc.**, of Tucson, Arizona. Clients and regular readers of THE DARK REPORT will recall that Ventana, with annual revenues of \$290 million, was acquired by **Roche Holdings** in early 2008 for a purchase price of \$3.4 billion. (See TDR, July 16, 2007.)

### ► Anatomic Pathology’s Future

The premium price Roche paid for Ventana was an early example of how pharma companies will pay substantial amounts of money to buy and control biomarkers that would be useful as companion diagnostic tests for their therapeutic drugs. Grogan will address this subject, and provide detailed perspectives about how a variety of technologies are likely to reshape anatomic pathology—ranging from multi-analyte molecular assays and rapid sequencing to automation of tissue processing and analysis and digital pathology.

Turning to digital pathology and its potential to disrupt the nation’s existing net-

## Clin Lab, Pathology M&A At Executive War College

**M**ERGER AND ACQUISITION (M&A) ACTIVITY picked up at the end of 2009. Experts believe that important transactions will take place this year that have the potential to reshape the competitive marketplace.

Once again, for the third consecutive year, the *Executive War College* is assembling the leading experts in lab and pathology M&A to assess the current market. This special session will take place on Tuesday, April 27, on the first day of the *Executive War College*.

Leading off the session will be a review of laboratory and pathology sales closed during 2009 and 2010 year to date, conducted by Chris Jahnle, Principal at **Haverford Health Advisors** in Paoli, Pennsylvania. Jahnle will also identify trends affecting the value and sales prices of labs and pathology groups.

There will be sessions for sellers on tax planning and pre-sale issues, along with the latest information on seller due diligence concerning billing and reimbursement issues. A sellers panel and a buyers panel will provide insights about why deals are happening and how recent laboratory sales prices reflect current market conditions.

work of private pathology practices, Ajit Singh, Ph.D., CEO of **BioImagene, Inc.**, of Sunnyvale, California, will discuss this topic. Before coming to BioImagene, Singh was CEO of the Image and Knowledge Management Group of **Siemens Healthcare**, based in Erlangen, Germany.

Thus, Singh is able to provide pathologists and laboratory executives with unique insights about how digital pathology is likely to transform surgical pathology and shift case referral patterns. He will also discuss the expected points of interaction and integration between radiology and pathology, based upon wider adoption of digital pathology images.

Shifting from strategic to operational, one threat immediately confronting clinical labs and pathology groups is increased adoption of EMRs by office-based physicians. If the laboratory cannot respond with the right solutions, these physicians will move their lab test referrals to a laboratory that is ready to rapidly install a functional LIS-to-EMR interface.

### ► Meaningful Use

But, the new complication is the need for laboratories to support the “meaningful use” requirements which a physician must meet before qualifying for the federal EMR adoption incentives. To speak on this topic at the *Executive War College* is Pat Wolfram, Vice President, Marketing & Customer Services at Portland, Oregon-based **Ignis Systems Corporation**.

Wolfram is in the thick of connecting labs to physicians’ EMRs. He is blunt about the need for action. “To remain competitive, every clinical laboratory and hospital lab outreach program needs to gear up and provide a functional LIS-to-EMR interface that allows the physician—from within his EMR, and as a natural part of his work flow—to order lab tests and have the laboratory test results automatically populate the patient record,” he said. “If any medical laboratory is unable to do this, it will lose physician clients as they turn to a laboratory competitor who can provide this service.”

### ► LIS-To-EMR Interfaces

Recognizing the importance of this new trend, two other speakers will address LIS-to-EMR interfaces and meaningful use. With a focus on the HITECH legislation and health information exchanges (HIEs), Rob Atlas, CEO of **Atlas Medical Software**, in Calabasas, California, will advise labs on how to leverage these developments in their favor.

The need to integrate laboratory test data across the health system and into out-

reach physicians’ offices will be addressed by Ravi Sharma, CEO at **4Medica** in Culver City, California. His company is working with several first-mover laboratories and health systems so that lab test results and information in the patient EHR are able to move seamlessly throughout the system.

All laboratories have an immediate need to improve quality, reduce cost, and increase productivity. Each of these goals is to be addressed by speakers at the *Executive War College*.

### ► Blood Product Costs

Take the skyrocketing costs of blood products for example. At the **University of Alabama in Birmingham** (UAB), the lab’s transfusion service initiated a successful program to improve utilization. Marisa Marques, M.D., Coagulation Service Director at UAB, will share how red blood cell usage was reduced by 25% over the first stage of this multi-year effort.

Offering a different perspective on improved utilization of transfusion and blood bank services is Priscilla Figueroa, M.D., who is Section Head of Transfusion Medicine at the **Cleveland Clinic** in Cleveland, Ohio. At the Cleveland Clinic, Figueroa’s lab team is using Lean, work flow redesign, and similar methods to improve utilization of blood products while improving quality. These approaches can be used by other labs seeking similar improvements.

Because most laboratories have used automation for several years now, a focused series of presentations has been organized. Five different speakers will share how their organizations are achieving “best practices” from their laboratory automation systems.

**TDR**

### Executive War College Details

- April 27-28, 2010 at Sheraton Hotel
- New Orleans, Louisiana
- Special optional programs on April 29
- Visit [www.executivewarcollege.com](http://www.executivewarcollege.com)



# Assessing the Year-End Financials For Nation's Biggest Lab Companies

*Quest Diagnostics, LabCorp, Sonic Health, and Bio-Reference Labs report performance*

IN RECENT WEEKS, the last of the nation's largest public laboratory companies released year-end 2009 financial reports. Each lab firm's financial report provides useful insights about active trends in the lab testing marketplace, particularly in lab testing referred by office-based physicians.

**Quest Diagnostics Incorporated** and **Laboratory Corporation of America** are the two dominant national companies competing for doctors' office lab testing. The two other largest publicly-traded lab companies active in this segment of the lab testing market are **Bio-Reference Laboratories, Inc.**, of Elmwood Park, New Jersey, and **Sonic Healthcare Ltd.**, of Sydney, Australia.

It is not easy to directly compare these four public laboratory companies. Quest Diagnostics and LabCorp probably share the most characteristics among the four laboratories. However, all four major lab companies differ significantly from each other.

## ► Regional Versus National

For example, Bio-Reference Labs primarily serves office-based physicians in the greater New York City region and has developed a number of regional and national specialty testing activities. It also reports its financial performance using a fiscal year that ends on October 31.

In the case of Sonic Healthcare, although it has annual revenue from laboratory testing in the United States that

exceeds \$500 million, the larger proportion of its annual sales come from countries outside the United States. Its stock is traded in Australia and its fiscal year ends June 30.

Keeping these differences in mind, the financial performance of these laboratory companies during 2009 reveals common perspectives on the current state of laboratory testing in the United States. Moreover, because 2009 was the second year of the deepest economic recession in the United States since 1980-81, it was a tough environment in which to increase specimen volume and revenue.

## ► 2009 Full Year Revenue

That fact was reflected in the performance of the two Blood Brothers. At Quest Diagnostics, full year revenue totaled \$7.5 billion, up from \$7.25 billion in 2008. This was a growth rate of 2.8%. LabCorp's 2009 and 2008 full year revenue was \$4.7 billion and \$4.5 billion, respectively, representing a 3.8% growth rate.

During Q4-2009, revenue per requisition at Quest and LabCorp grew by 2.6% and 4.3%, respectively. Bad debt for the full year was 4.9% at Quest and 5.3% at LabCorp.

On a smaller revenue base, during its fiscal year ending October 31, 2009, Bio-Reference Labs reported full-year revenue of \$362 million, which was a growth rate of 20%. The number of patients served (as measured by requisitions) grew 14%, to 4.7 million.

In its most recent quarter ending January 31, 2010, Bio-Reference said revenue had increased by 31% over Q1-09, to \$99.3 million. Similarly, the number of patients served grew to 1.2 million, an increase of 29% for the quarter. Revenue per requisition increased 2%, to \$79.21.

### ► Sonic Healthcare's Revenue

Sonic Healthcare, reporting on its fiscal year ending June 30, 2009, announced revenue from all businesses of US \$2.7 billion, which was 26.7% growth from US\$2.2 billion in FY2008.

For the first six months of FY2010, Sonic disclosed revenue of US \$1.4 billion from all businesses compared with revenue of US \$1.3 billion during the first six months of FY2009, a 3.5% growth rate.

Sonic says about 23% of its revenue comes from laboratory testing in the United States. That business division generated US \$636 million during FY2009 and about US \$306 million during the first six months of FY2010.

If there is one clear difference that stands out among these four laboratories, it is the growth rate posted by Bio-Reference Laboratories. Each year over the past decade, it has regularly reported double-digit growth in both specimen volume and revenue. It has accomplished this based on two primary strategies.

First, it maintains one of the nation's best-performing sales programs that targets office-based physicians. Its sales reps are consistently effective at winning—and keeping—new client accounts from competitors in the greater New York City metro. Bio-Reference Labs' "sales cost to acquire a new account" is much more effective than its larger peer lab companies.

### ► Selling Esoteric Tests

Second, Bio-Reference's second strategy is to build subspecialty expertise in reference and esoteric testing, then sell those services both in the local New York market and nationally. It has a high average revenue

per requisition when compared to other laboratories that serve office-based physicians. (*See TDR, July 16, 2007.*)

In the case of Sonic Healthcare, it is regularly using acquisitions as a way to build its business in the United States. It was 2005 when Sonic made its first lab acquisition in this country. In just four years, its U.S. lab testing business has grown to almost two-thirds of a billion dollars. Sonic continues to be an opportunistic acquirer of laboratories in the United States.

On the other hand, it has been more challenging for Quest Diagnostics and LabCorp to consistently outbid rivals for the larger laboratory businesses that have come to market during the past 24 months. Along with Sonic Healthcare, a growing number of private equity companies are willing to bid aggressively to acquire any attractive laboratory company that comes to market.

### ► New Buyers Bid For Labs

For example, last November, Quest Diagnostics filed public documents as a preliminary step to raising \$750 million in senior notes. The prospectus indicated the proceeds would be used to repay existing debt, for general corporate purposes, and "to fund a potential cash acquisition in its entirety." At that time, *MassDevice.com* speculated that Quest Diagnostics was preparing to close a deal "potentially worth \$225 million."

The following month, on December 11, it was announced that **Spectrum Laboratory Network** of Greensboro, North Carolina, had been acquired by **Welsh, Carson, Anderson, & Stowe**. Financial analysts indicated that Quest Diagnostics had taken steps to line up the money needed to acquire Spectrum, but found itself outbid in the final rounds of negotiations.

Moreover, just a few weeks later, **Carilion Labs**, of Roanoke, Virginia, announced its merger with Spectrum Laboratory Network. Again, another party



## Nation's Four Largest Public Labs Report Financial Performance for Full Year 2009

IT CAN BE CHALLENGING TO COMPARE THE MARKET PERFORMANCE of the four largest public laboratory companies that compete in the United States for laboratory test referrals from office-based physicians. Each laboratory company has significant attributes that distinguish it from competing laboratory firms.

As the nation's two largest public lab companies, Quest Diagnostics Incorporated and Laboratory Corporation of America have unique visibility. In the case of Bio-Reference Laboratories, Inc., of Elmwood Park, New Jersey, the fact that it primarily serves the doctor's office market in New York City and surrounding states means that it doesn't have immediate name recognition in other regions across the country. The newest member in this group is Sonic Healthcare, Ltd., a long-established laboratory company in Australia, but which only launched business operations in the United States in 2005.

Another challenge in comparing the performance of these four public laboratory companies is the different fiscal years used by Bio-Reference Labs and Sonic Healthcare. The table below provides information for the latest full year financial report released by each of these four public laboratory companies.



### Quest Diagnostics Incorporated

- 2009 Revenue: \$7.5 billion
- 2008 Revenue: \$7.25 billion
- **Growth rate: 2.8%**
- 2009 Net Income: \$729 million
- 2008 Net Income: \$581 million
- **Profit Increase: 25%**



### Laboratory Corp. of America

- 2009 Revenue: \$4.7 billion
- 2008 Revenue: \$4.5 billion
- **Growth rate: 3.8%**
- 2009 Net Earnings: \$555 million
- 2008 Net Earnings: \$478 million
- **Profit Increase: 16.2%**



### Bio-Reference Laboratories, Inc. (Fiscal year ends October 31)

- FY2009 Revenue: \$363 million
- FY2008 Revenue: \$301 million
- **Growth rate: 20.6%**
- FY2009 Net Income: \$21.9 million
- FY2008 Net Income: \$15.6 million
- **Profit Increase: 40.4%**



### Sonic Healthcare, Ltd. (Fiscal year ends June 30)

- FY2009 Revenue: US\$2.7 billion
- FY2008 Revenue: US\$2.2 billion
- **Growth rate: 26.7%**
- FY2009 Net Profit: US\$286 million
- FY2008 Net Profit: US\$223 million
- **Profit Increase: 28.6%**

outbid Quest Diagnostics and LabCorp to acquire a large laboratory organization.

Laboratory acquisitions were a topic during the most recent quarterly conference calls. One executive at Quest Diagnostics answered an analyst's question, stating that "We'll continue looking for opportunities which leverage our core competency and diagnostic testing, whether that is domestic acquisitions or regional esoteric or hospital laboratories."

During LabCorp's conference call, its executives addressed the acquisition question by noting that LabCorp would be interested in opportunities to expand the company's esoteric portfolio. Specifically mentioned were genetic testing, specialized endocrinology, specialized coagulation, oncology, and infectious disease testing.

### ► Esoteric Testing Emphasis

Both Quest Diagnostics and LabCorp are working to expand the proportion of esoteric testing because of its higher reimbursement and better profit margins.

At Quest, "gene-based, esoteric and anatomic pathology testing now account for approximately 36% of all revenues." Similarly, LabCorp disclosed that, for Q4-09, 37% of its revenues came from "genomics, esoteric, and anatomic pathology categories." It stated a goal of increasing that to 40% of revenue within five years.

By point of comparison, Bio-Reference Laboratories stated in its Q1-10 conference call that esoteric testing was now 54% of net revenues. That was up from 51% in Q1-09.

Hot growth areas at Quest Diagnostics were "Vitamin D testing using tandem mass spec [which] grew more than 50%, allergy testing using ImmunoCap grew more than 10%, and our Leumeta family of leukemia and lymphoma tests grew more than 40%."

At LabCorp, it was acknowledged that Vitamin D testing was a fast growth assay. LabCorp executives stated that they

include Vitamin D tests in their esoteric test mix.

Information technology (IT) is a strategy both laboratories are emphasizing as a way to differentiate themselves with referring physicians. At LabCorp, activities are underway to "enhance our IT platforms with a focus on online services, client connectivity and analytic tools. We will also continue to improve the patient experience through such initiatives as online appointment scheduling and automating the work flow in our patient service centers."

### ► Offering IT Solutions

Quest Diagnostics has several important IT initiatives. It recently launched its Care360 electronic health record (EHR) system for physicians. Last year it introduced a specimen tracking system. Quest executives stated the number of physicians using its e-prescribing solution doubled during 2009.

Emphasizing the importance placed on IT as a point of competitive differentiation, during the conference call, one Quest executive observed "We've always thought about EHR and e-prescribing as something that helps us imbed ourselves into the work flow in the office and make the relationship with those physicians and hospitals even stickier."

### ► Current State Of Lab Market

As a window on the current state of the laboratory testing marketplace, the financial reports released by these four laboratories show the mature nature of the competitive market for the testing referred by office-based physicians.

The nation's two largest laboratory companies continue to grow at single digit rates. Meanwhile, Both Bio-Reference Laboratories and Sonic Healthcare are using different strategies to sustain higher rates of growth. As these higher rates of growth compound over time, it should help them achieve attractive economies of scale. In turn, that could make them even tougher competitors.

# INTELLIGENCE

**LATE & LATENT**  
 Items too late to print,  
 too early to report



On March 1, **Omnyx, LLC**, of Pittsburgh, Pennsylvania, licensed certain virtual microscopy and digital pathology patents from **Olympus America, Inc.** Omnyx is a joint venture between **GE Healthcare** and the **University of Pittsburgh Medical Center (UPMC)** that was created to develop and market digital pathology systems. The agreement grants Omnyx a non-exclusive worldwide license and access to Olympus' portfolio of patents relating to creating, storing, and delivering virtual microscopy images.

## LENETIX LAB SELLS TO BIO-REFERENCE

Last week, **Bio-Reference Laboratories, Inc.**, (BRLI) of Elmwood Park, New Jersey, announced an agreement to acquire **Lenetix Medical Screening Laboratory** of Mineola, New York. Purchase price is \$5.5 million. BRLI intends to add Lenetix' pre-natal fetal and genetic tests to its existing menu of pre-natal obstetric tests.

## DLS IN HONOLULU BUILDS NEW LAB

**Diagnostic Laboratory Services (DLS)** of Honolulu, Hawaii, is building a new 84,000 square foot laboratory in leased warehouse space in Halawa, just north of Honolulu. The \$20 million laboratory is expected to become operational in December. **Sonic Healthcare, Ltd.**, acquired DLS in June, 2008.

## TRANSITIONS

- Earlier this month, Jack Redding joined **MedLink International** of Ronkonkoma, New York, as Executive Vice President. The company develops and sells electronic health record (EHR) and practice management solutions. Redding was formerly President of **Lifepoint Informatics**.

- Barbara Goldsmith, Ph.D., is the new Vice President, Marketing and Development, for the **Clinical Laboratory**

**Standards Institute (CLSI)** of Wayne, Pennsylvania. Goldsmith is a past President of the **American Association of Clinical Chemistry (AACC)** and was most recently Vice President of Laboratory Services at **Caritas Christi Health Care** in Boston, Massachusetts.



## DARK DAILY UPDATE

*Have you caught the latest e-briefings from DARK Daily? If so, then you'd know that...*

...the first national survey of compensation and benefits for laboratory CEOs, COOs, CFOs and other executive positions is now being conducted by **Slone Partners** of Miami, Florida. The Lab Executive Compensation Survey findings will be announced at the *Executive War College* on April 27-28, 2010.

*You can get the free DARK Daily e-briefings by signing up at [www.darkdaily.com](http://www.darkdaily.com).*

*That's all the insider intelligence for this report.  
 Look for the next briefing on Monday, March 29, 2010.*

**Make plans  
Now!**

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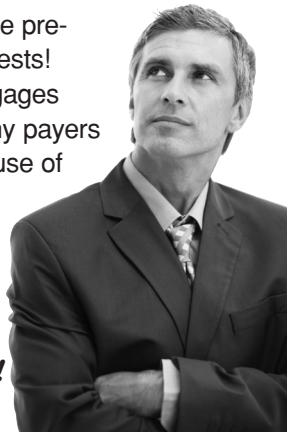
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