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Competitive Market Analysis For Laboratory Management Decision Makers

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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

CAP URGES CHANGES TO FDA DRAFT GUIDANCE ON LDTs

While the Food and Drug Administration's (FDA) draft guidance on regulation of laboratory-developed tests (LDTs) is similar in some ways to a 2009 proposal from the College of American Pathologists (CAP), further refinements need to be made in how LDTs are defined and how risk classification is determined, the College maintains.

In its comments submitted to the FDA, the CAP noted that it supports oversight that focuses on analytical and clinical validity, a three-tiered risk-based approach to LDT categorization, enforcement discretion for LDTs identified as having low risk to patients, and FDA focus on tests that pose a higher risk to patients. However, the CAP says it cannot support the proposed guidance in its current form.
Continued on page 6.

VETTING THERANOS

Over the past year, Theranos and its photogenic CEO Elizabeth Holmes have been admiringly featured in dozens of newspapers and magazines, including *Fortune Magazine, USA Today, The New Yorker* and *The Wall Street Journal*. Theranos claims to have invented a revolutionary lab testing system that uses a fingerstick to collect a micro-quantity specimen from which it can perform hundreds of tests. It's impossible to judge these assertions because the company has provided no peer-reviewed validation data for its assays—all of which Theranos is marketing as laboratory-developed tests (LDTs).

However, even if you believe the company has developed groundbreaking lab testing technology, that's only a small part of what's necessary to successfully compete against Quest Diagnostics, LabCorp and the 100,000+ other CLIA-certified labs doing business in the United States.

Regardless of the lab technology used to test specimens inside a laboratory, 1) a doctor still needs to prescribe the test; 2) a phlebotomist must obtain a specimen; and 3) the specimen must be transported to the laboratory. So *Laboratory Economics* wonders how much will it cost and how quickly Theranos can build a national network of couriers, labs and phlebotomist-staffed patient service centers (PSCs)?
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VETTING THERANOS (*cont'd from page 1*)

Currently, Theranos operates a standalone CLIA-certified lab in Palo Alto and is preparing to open a second CLIA-certified lab in Scottsdale, Arizona. It has one PSC at a Walgreens in Palo Alto plus another 40 PSCs at Walgreens locations in the Phoenix area.

We contacted Theranos by both phone and e-mail and requested an interview or at least answers to a written list of questions. But the company did not respond. Below *Laboratory Economics* has summarized some of the concerns we have with the company's business model.

Theranos founder and CEO Elizabeth Holmes: "The company's culture is such that confidentiality is the essence of its existence."

Low Prices Do Not Equal Low Costs

To its credit, Theranos publishes its lab test prices for all to see. And its prices are about 50% of Medicare Part B lab test rates. But can a lab company with 700 employees that performs less than 1 million tests per year make a profit by charging 50% of Medicare?

Let's generously assume that Theranos is collecting $20 per test and meets its stated goal of performing 1 million tests this year. That would equate to $20 million of revenue. Now let's assume that the average Theranos employee is paid $50,000 per year (salary and benefits)—a low estimate given that the company is headquartered in expensive Palo Alto, California. That would equate to $35 million in employee costs per year (700 employees x $50,000 per year = $35 million). So even if you exclude all other costs (instrumentation, transportation, information technology, rent, supplies, etc.), *Laboratory Economics* cannot figure out how a lab company of this size can earn a profit by charging 50% of Medicare rates.

Lab Test Price Comparison

CPT	Description	Medicare	AZ Medicaid	CA Medicaid	Theranos
80048	Basic Metabolite Panel	$11.51	$9.98	$9.30	$5.82
80055	Obstetric Panel	NA	22.57	37.99	30.07
80061	Lipid Panel	NA	15.80	13.88	9.21
82306	Vitamin D	40.29	27.33	24.79	20.35
83970	Parathyroid Hormone	56.17	48.71	45.39	28.36
84443	TSH	22.87	19.83	18.48	11.55
85025	CBC	10.58	7.57	8.55	5.35
85610	Prothrombin Time	5.35	4.65	4.32	2.70
87536	HIV-1 RNA Quantitative	115.80	100.42	93.57	58.48
86141	High-Sensitivity CRP	17.62	15.28	14.24	8.90

Source: *Laboratory Economics* from Arizona and California Medicaid programs and Theranos

It's not unusual for startup companies to fund operations with capital from outside investors. But over time, if a company is not able to generate significant revenue and profits, outside investors can grow impatient and their willingness to keep supplying cash can evaporate.

Since being formed in 2003, Theranos has reportedly raised more than $400 million from outside investors including Oracle Corp. CEO Larry Ellison and Menlo Park venture capital firm Draper Fisher Jurvetson.

Theranos has stated plans to establish collection centers in a "substantial percentage" of Walgreens' 8,200 drugstores in all 50 states. "It is the first step in Holmes's audacious plan to place a Theranos

center within five miles of almost every American and within one mile of every city dweller," according to an article in *Fortune Magazine* (June 12, 2014).

But how quickly can Theranos build a national network of couriers, labs and PSCs? Will it take 3 years, 5 years, 10 years? And *Laboratory Economics* wonders if the company will be able to continue to attract the hundreds of millions of dollars from outside investors that will be needed to build such a national infrastructure.

The Drug Store Model: Quest Diagnostics Has "Been There, Done That" and It Didn't Work

The idea of offering lab tests directly to consumers at drug store chains is nothing new. More than 10 years ago, Quest Diagnostics entered the direct-to-consumer testing market in a big way. It announced a partnership with the drug store chain CVS Stores. Quest branded its service as "QuesTest" and began marketing lab tests at CVS Stores in Florida and Ohio. Quest also partnered with U.S. Wellness Inc. and opened PSCs in Giant Food Supermarkets in Maryland and Virginia. In addition, Quest opened more than 20 standalone retail lab testing stores in Colorado, Kansas, Montana, Missouri and Utah that allowed consumers to walk in and order and pay for lab tests on their own without a doctor's prescription. And finally, Quest partnered with the Stop & Shop Supermarket Company to open QuesTest centers in more than 60 Stop & Shop Pharmacies throughout Connecticut in 2003.

"The QuesTest service taps directly into an important megatrend that's impacting the health care world—more empowered consumers choosing to take control over their health," said Hughes R. Bakewell, Jr., former Vice President at the former Consumer Health Division at Quest Diagnostics [from a press release in August 2002].

The biggest challenge that the QuesTest program faced was that nobody cared. Most of the direct-to-consumer retail locations were only able to attract a few patients per day and some literally attracted zero patients per day. Your publisher can attest to this because I personally visited several QuesTest locations and ordered tests for myself back in mid-2002. At one location in Connecticut, your publisher was actually the first and only customer that a particular site had served six months after its launch, according to the Quest phlebotomist who quickly and painlessly drew my blood.

By 2005 Quest Diagnostics determined that the direct-to-consumer testing market was a dead end and QuesTest was quietly shut down.

Similarly, in 2006, LabCorp partnered with Duane Reade, a big drug store chain in New York City, and opened 20 PSCs at retail locations throughout the city. On May 11 2007, I visited one of these PSCs at a busy Duane Read store in Manhattan. I got my blood drawn quickly and painlessly by a LabCorp phlebotomist who told me she was averaging about 10 patients per day. That's better than zero, but is it enough to pay for a $15-per-hour phlebotomist, plus NYC rent, supplies, courier, etc.?

It appears that Theranos might be facing the same challenge. "There are no 'coworkers.' You work alone inside a room and you're lucky to see 5 patients a day. The hardest part of the job is sitting in a room for nine hours six days a week literally doing nothing productive," according to an anonymous phlebotomist who formerly worked for Theranos at a Walgreens' drugstore in Arizona.

Both Quest and LabCorp figured out a long time ago that the best location to staff a phlebotomist is directly at the source of referrals—a physician office—and they each employ thousands of phlebotomists at physician offices and doctors' parks throughout the country.

Where Are the Peer-Reviewed Studies?

Where are the published articles describing the accuracy of Theranos' medical technology in respected medical journals like *JAMA* or *The New England Journal of Medicine*? When questioned on this topic in a recent feature article in *The New Yorker*, Holmes could only point to a study published in an online-only Italian journal named *Hematology Reports*. This study used Theranos' testing system to analyze one biomarker (C-reactive protein) in a total of only six patients using blood samples collected from a central venous catheter, NOT a finger stick.

The study concluded that:

> *Future prospective studies with a larger cohort of patients using the micro sample test system for real-time measurements of these and additional biomarkers are needed to validate our results and determine the sensitivity and specificity of this approach.*

For the sake of comparison, *Laboratory Economics* notes that Quest Diagnostics and its medical and scientific staff of more than 725 MDs and PhDs authored approximately 100 articles in peer-reviewed journals in 2013 alone.

Fingerstick or Traditional Needle Draw?

Theranos claims that its lab testing technology can analyze samples as small as 1/1,000 the size of the typical blood draw. "Instead of a big, intimidating needle, our certified phlebotomists can use a tiny finger stick or a micro-sample from a venous draw. Occasionally, a venipuncture may be required based on the lab order, but this is uncommon, and our aim is to eliminate that scenario entirely," according to the Theranos' website.

In addition, Walgreens' web page promoting the service uses the marketing slogan "Goodbye big bad needle," but a footnote reads "Blood may be drawn by a finger stick or venous draw performed by a Theranos-trained technician for Theranos testing performed in their CLIA-certified laboratory."

At the Theranos website, the company's marketing pitch to potential physician clients states, "You can draw samples in your office using your standard venipuncture draw method."

So *Laboratory Economics* has to wonder: Is Theranos actually testing the majority of the patient specimens it collects by fingerstick or is it using the same 'big, intimidating' needles used by Quest, LabCorp and every other traditional lab?

At the very least, *Laboratory Economics* thinks that Theranos is probably using traditional needle draws to collect samples from patients when blood does not flow freely by fingerstick. When a finger has to be squeezed to get enough blood, the chances of hemolysis, or ruptured red blood cells, is increased and this can distort test results.

The FDA

Laboratory Economics wonders if Theranos will ever receive an "it has come to our attention" letter from the FDA inviting the company to explain why its testing system should not be subject to FDA review.

Theranos claims that its tests are properly classified as laboratory-developed tests, or LDTs, which are not currently subject to FDA review.

However, in its recent draft guidance for regulatory oversight of LDTs, the FDA provided specific examples of devices that it does not consider to meet the definition of an LDT. These include:

- An entity that owns several clinical laboratories develops a device in one of its clinical laboratories and then transfers the device to several clinical laboratories within its network.
- A laboratory contracts with a third-party manufacturer to produce a key component (e.g., coated microtiter plate, specialized specimen collection kit) used in its device.

So the questions for Theranos are: 1) Does it plan to use its testing system anywhere besides its current sole CLIA-certified lab in Palo Alto? and 2) Is any key component of its testing system manufactured by a third party?

Finally, keep in mind that there are numerous FDA-cleared point-of-care testing systems already on the market. These include Abbott's i-Stat handheld analyzer, Roche's cobas Liat PCR System, Alere's Cholestech LDX System and the Abaxis Piccolo Xpress. These systems use small blood samples and provide results in minutes. Thousands of these systems are already in place at physician offices, hospitals, urgent care centers and pharmacies throughout the United States.

An Odd Board of Directors for a Lab Company

Why is the Board of Directors at Theranos dominated by old military men and politicians? It includes:

- *Henry Kissinger*, age 91, Former National Security Advisor and Secretary of State
- *William Perry*, age 87, Former Secretary of Defense
- *Bill Frist*, age 63, Former U.S. Senate Majority Leader
- *Samuel Nunn*, age 76, Former U.S. Senator and Chairman of the Senate Armed Services Committee
- *James "Mad Dog" Mattis*, age 64, Former Wells Fargo & Co. Chairman and CEO and retired four-star Marine General

Seems like an odd group of fellows for a cutting-edge lab company.

Valuation Comparison: Quest Diagnostics vs. LabCorp vs. Theranos

According to *Fortune Magazine*, Theranos has raised more than $400 million from investors and is effectively valued at $9 billion. That's about the same valuation as Quest Diagnostics and LabCorp. However, based on annual test volume, Theranos is less than 1% the size of Quest or LabCorp.

In fact, Quest and LabCorp's operations in the Phoenix area alone dwarf those at Theranos. For example, Quest has a partnership with Banner Health that operates Sonora Quest Laboratories. This joint venture company was formed in 1997 and has more than 2,800 employees statewide that manage a major independent lab facility in Tempe (just outside Phoenix) as well as the labs at 13 Banner Health hospitals in Arizona. *Laboratory Economics* estimates that revenue at Sonora Quest Labs easily exceeds $100 million per year.

Meanwhile, in 2013, LabCorp opened a state-of-the art, 147,000-square-foot lab facility in Phoenix to consolidate several of its facilities located in the Western United States. This single facility processes more than 10 million lab tests per year.

Valuation Comparison

	Quest Diagnostics	LabCorp	Theranos
Market Value ($ millions)[1]	$10,100	$9,730	$9,000
Annual Revenue ($ millions)	$7,435	$5,940	NA
Est'd Annual Test Volume (millions)	468	395	1
Number of Employees	45,000	34,500	700
Number of PSCs[2]	5,400	3,000+	41

[1]As of February 9, 2015. [2]Includes PSCs plus employed phlebotomists working at physician offices. Source: *Laboratory Economics* from companies

CAP URGES CHANGES TO FDA DRAFT GUIDANCE ON LDTs (*cont'd from p. 1*)
"The CAP recommends that the FDA should make significant changes to its draft guidance to ensure that patients have access to laboratory tests that are the standards of care," CAP President Gene N. Herbek, M.D., FCAP, tells *Laboratory Economics*. "Without these changes, the CAP believes the guidance would stifle medical innovation and cause significant hardship for laboratories and patients. The College's comments to the FDA seek to address the oversight of these tests in an inclusive, systematic way that is best for our patients."

"The CAP believes that any LDT oversight framework should be a risk-based model employing a public-private partnership to address oversight of LDTs in a rational, inclusive, and systematic way," says the College in its comments. "In addition, we believe any approach should rely on third-party accreditors and inspectors to oversee and monitor standards for low- and moderate-risk LDTs through the existing CLIA regulatory processes. We believe high-risk LDTs, as defined by the CAP, would be reviewed directly by the FDA."

The CAP estimates that at least 1,000 LDTs would be classified as equivalent to existing companion diagnostics under the FDA's draft guidance and therefore classified as high-risk LDTs. The CAP has urged the FDA to modify its risk classification category to narrow the focus of its regulatory oversight to those truly high-risk LDTs that rely on proprietary algorithms.

CAP is among dozens of industry groups and stakeholders who have submitted comments to the FDA on the proposed guidance. The 120-day public comment period on the LDT framework guidance ended Feb. 2, and resulted in 231 comments to the public docket, according to Eric J. Pahon, press officer for the FDA. He says the agency will carefully review and consider all comments to the docket as it works to finalize the guidance.

The FDA has no set timetable for issuing a final guidance. However, one year after final guidance is issued, the agency will require premarket review for the highest-risk LDTs, including companion diagnostics. Premarket review will then be slowly phased in for all other LDTs.

While some are calling for changes to the guidance, others reject any effort by the FDA to regulate LDTs. The American Clinical Laboratory Association, for example, is actively opposing the FDA's proposal and has engaged two highly respected experts in constitutional law and administrative procedures, Laurence Tribe from Harvard Law School and Paul Clement, the former Solicitor General of the United States.

Officials with Mayo Medical Laboratories also have been outspoken in their opposition to the FDA's proposal. Mayo offers 1,600

FDA Timeline

The FDA has proposed the following timeline once the final guidance is issued:

- 6 months – Registration and listing and adverse event reporting for high-risk LDTs (Class III) and moderate risk LDTs (Class II).
- 1 year – Premarket review begins for highest-risk LDTs, including companion diagnostics. Phased in over 4 years for remaining high-risk tests.
- Within 2 years – FDA publishes priority list for remaining high-risk LDTs.
- 3 years – Premarket review begins for first group of high-risk LDTs.
- 3-5 years – Premarket review for remaining high-risk LDTs.
- Within 4 years – FDA publishes list for moderate-risk (Class II) LDTs.
- 5 years – Premarket review requirements begin for moderate-risk LDTs (Class II). Phased in over 4 years.
- 9 years – Phased-in enforcement of all LDTs completed.

Source: *Laboratory Economics* from FDA

LDTs, and over the past six years has performed 2.5 million tests for its on-site patients and more than 18 million tests for outside clients. According to Curtis Hanson, M.D., Professor of Laboratory Medicine and Pathology at Mayo, the proposal as it stands now would have a negative impact on reference laboratories' ability to provide tests. "Obviously, the implications are huge," Hanson said during the FDA's January public workshop on LDTs.

PALMETTO FINALIZES SPECIAL STAINS LCD; POLICY EFFECTIVE MARCH 16

Palmetto GBA, the Medicare contractor for J11, has finalized its local coverage determination (LCD) limiting coverage for special histochemical and immunohistochemistry (IHC) stains. The new policy takes effect March 16 in North Carolina, South Carolina, Virginia, and West Virginia.

The LCD (35693) was finalized despite significant concerns raised by the College of American Pathologists (CAP), which argued that the supporting evidence behind the LCD lacked credibility and was unsubstantiated, and that the LCD encroached on the pathologist's medical judgment. The College had called on Palmetto to withdraw the draft LCD, released in October 2014 (*LE*, January 2015, p. 5).

The final special stains LCD is substantially the same as the draft. The LCD limits Medicare coverage for reflex templates or pre-orders for special stains prior to review of the routine hematoxylin and eosin (H&E) stain by the pathologist, as well as special stains and/or IHC stains without clinical evidence that the stain is actionable.

Noridian Healthcare Solutions, the Medicare contractor for Jurisdictions E and F, also is proposing the same LCD for providers in its jurisdiction, which covers 13 western states (AZ, CA, NV, OR, WA, et al.). The draft LCD was issued Feb. 5, and the comment period ends March 30. While Palmetto is the lead Medicare administrative contractor (MAC) on molecular diagnostic testing policies under the MolDx program, labs are not required to follow Palmetto's policies. However, many do look to Palmetto when making determinations that affect labs.

"The special stains/IHC policy is technically not a MolDx policy, so it is up to Noridian to decide, just as any other contractor can decide, to take this policy or not," says Elaine Jeter, M.D., the MolDx medical director for Palmetto GBA.

"Only CMS can make and publish national policy," adds Mike Barlow, vice president of Palmetto. "MolDx specific policies, or any individual MAC policy, such as our IHC policy, is not automatic to any other jurisdiction. Each AB MAC is responsible for the policies that are put into effect in their jurisdiction and their policies, whether previously published in some form by another MAC, must go through the local draft, comment, CAC review and notice period."

Palmetto has been watching billing patterns for special and IHC stains, and in August 2014 mailed comparative billing reports (CBR) to about 5,000 pathologists comparing their billing patterns for these stains with a national average of their peers. The providers were chosen because their billing patterns differed in some way from national patterns.

Mick Raich, president of Vachette Pathology (Blissfield, MI), believes that the new policy should not have a significant effect on revenues for most pathologists, although it may slow turnaround time. The greatest impact will be felt by pathologists who have been ordering excessive stains. "There has been some abuse," he tells *Laboratory Economics*. "If we don't regulate ourselves, someone else will."

Palmetto Targeting Other Areas

Special and IHC stains are not the only areas where Palmetto believes there has been overutilization. The MAC recently issued a draft non-coverage policy (LCD 35912) related to genetic testing for hypercoagulability/thrombophilia (Factor V Leiden, Factor II Prothombin, and MTHFR).

According to the draft LCD, there is insufficient evidence in the published peer-reviewed scientific literature to determine how testing for mutations in the Factor V Leiden gene, the Prothombin gene, or the MTHFR genes guide decisions in the clinical setting related to disease treatment, management, or prevention.

"Furthermore, it is not known whether health outcomes are improved as a result of clinical decision-making based on these gene tests," said the draft LCD. "Additionally, according to existing evidence and recent guidelines, the presence of inherited thrombophilia is not an important factor in determining the optimum length of anticoagulation in patients with VTE. Consequently, genetic testing for inherited thrombophilia, specifically for Factor V Leiden, Prothrombin and MTHFR mutations, is considered investigational and is not a Medicare benefit."

FDA PONDERING BEST APPROACH TO REGULATE NGS TESTING

The Food and Drug Administration (FDA) is considering a standards-based approach to regulation of next-generation sequencing (NGS) testing using centralized databases and is seeking stakeholder input on how such an approach should be structured.

The agency held a public meeting Feb. 20 to accept comments on possible approaches to regulation of NGS tests. In a discussion paper issued Dec. 29, 2014, the FDA described opportunities and regulatory challenges presented by NGS testing, also known as high throughput sequencing. While most in-vitro diagnostic devices (IVDs) detect only a single or defined number of substances to diagnose one or several specified conditions, NGS tests can identify an unlimited number of variants based on the more than 3 million base pairs that comprise the human genome, notes the FDA in the paper.

Typically, when evaluating IVDs, the FDA reviews the clinical performance of the tests, but the agency admits that this is not practical for NGS tests in part because the tests detect rare variants and because the rare mutations co-exist with other possible causative variants. Thus, the FDA is exploring the use of genetic databases that would provide information on genetic variants and their association with disease.

The FDA is also considering new approaches to determining analytic performance of NGS testing. In assessing the analytic performance of the only NGS instrument and two tests that it has approved for marketing (see box), the FDA relied on a subset of variants in various sequence contexts. Demonstrating adequate analytical performance for this subset provided reasonable assurance that the tests would be able to successfully identify relevant variants in the genome without requiring the company to submit data for every possible variant the test could identify, says the agency.

FDA Approved NGS Instruments and Assays

- Illumina MiSeqDx™
- Illumina Universal Kit Reagents
- Illumina MiSeqDx™ Cystic Fibrosis 139 Variant Assay
- Illumina MiSeqDx™ Clinical Sequencing Assay

The FDA plans to continue to use this subset-based approach when evaluating the analytical performance of NGS platforms but is considering other approaches for establishing analytical performance for specific NGS tests. The FDA is seeking

feedback with regard to: 1) the value of a standards-based approach to regulatory review of NGS tests, 2) the contents of standards to be developed that will assure that conformity to the standard will assure test accuracy and reliability, 3) who should develop such standards, and 4) appropriate mechanisms to ensure compliance.

Michael Pellini, president and chief executive officer of Foundation Medicine, tells *Laboratory Economics* that he is cautiously optimistic about the FDA's approach to oversight of NGS testing. Foundation, based in Cambridge, Mass., has developed two NGS tests–FoundationOne for solid tumors and FoundationOne Heme for hematological malignancies and sarcomas.

"A standards-based approach shows flexibility," says Pellini. "We would hope that the FDA will include standards already put in place under CLIA, CAP, and by New York State. Rigorous standards are important for ensuring patient safety, and appropriate FDA oversight could be an important step for Foundation Medicine."

Comments on FDA regulation of NGS testing are due by March 20.

QUEST DIAGNOSTICS REPORTS FULL-YEAR 2014 RESULTS

Quest Diagnostics (Madison, NJ) reported net income of $556 million for full-year 2014, down from $849 million in 2013. Quest's reported revenue increased by 4.0% to $7.435 billion in 2014. *Laboratory Economics* estimates that Quest's organic revenue was down approximately 3% after adjusting for the acquisitions of Solstas Lab, Steward Health Lab and Summit Health. On January 29, the company held a conference call with analysts and investors to discuss its year-end results. Here's a summary of some key topics:

Growth Areas

Quest cited several specific fast-growing tests, including its BRCAdvantage breast cancer test, noninvasive prenatal testing, and hepatitis C. In addition, Quest said it continues to see notable growth from prescription drug monitoring. Among its weakest areas was anatomic pathology, where revenue fell by 8.8% to $633 million in 2014.

Falling Profit Margins

Adjusted operating income from continuing operations for 2014 was $1.1 billion, or 15.0% of revenue, compared with $1.2 billion, or 16.2% of revenue, for 2013.

Quest Diagnostics Financial Summary ($ millions)

	2014	2013	% Change
Revenue by product			
Gene-based and esoteric	$1,864	$1,811	2.9%
Anatomic pathology	633	694	-8.8%
Routine	4,145	3,868	7.2%
Drugs of abuse	231	213	8.5%
Other*	562	559	0.5%
Total revenue	7,435	7,146	4.0%
Operating cash flow	938	652	43.9%
Capital expenditures	308	231	33.3%
Free cash flow	630	421	49.6%
Pretax income	849	1,348	-37.0%
Net income	556	849	-34.5%
Diluted EPS	3.81	5.54	-31.2%
Total debt	3,762	3,332	12.9%
Cash & securities	192	187	2.7%
Shareholders' equity	4,330	3,973	9.0%
Bad debt %	4.0%	3.8%	5.3%
Days sales outstanding	48	47	2.1%
# Employees	45,000	41,000	9.8%
Est'd number of reqs	156.4	147.1	6.3%
Est'd revenue per req	$43.97	$44.78	-1.8%

*Other revenue includes clinical trials testing, information technology services and testing services for life insurance companies
Source: Quest Diagnostics and requisition estimates from *Laboratory Economics*

Factors hurting margins included 1) continued pricing pressure; 2) wage inflation (note: Quest's number of employees increased almost 10% to 45,000); and 3) lower margins at acquired businesses.

Repricing of CLFS

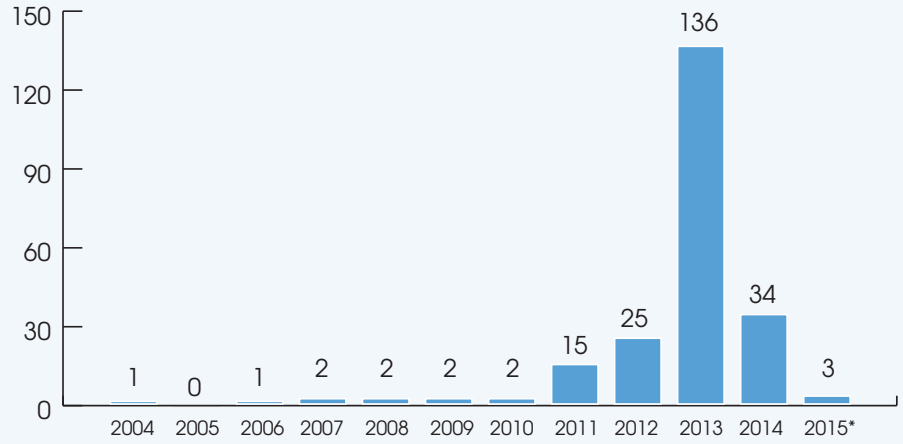
Quest CEO Steve Rusckowski said the American Clinical Lab Association (ACLA), continues to work closely with CMS on the rulemaking process for repricing lab tests on Medicare's Clinical Lab Fee Schedule (CLFS). "We are hopeful the rulemaking process will be defined in 2015 and will establish an approach to building a representative view of the market. The market view that will be used to update the fee schedule should include participants from the entire market, including large and small independent commercial labs, boutique labs, as well as hospitals," said Rusckowski. CMS is expected to issue a Proposed Rule on how private payer data will be collected from labs by June 30. The current timetable calls for pricing data to be collected from labs in 2016 with initial revisions to the CLFS taking effect in 2017.

PRESIDENT'S BUDGET SEEKS TO BAN IN-OFFICE PATHOLOGY LABS

For the second year in a row, President Obama's budget proposal includes provisions to close the in-office ancillary services (IOAS) exception to the Stark law. The budget for fiscal year 2016 stipulates that, starting in 2017, advanced imaging, radiation therapy, anatomic pathology and physical therapy services would be removed from the IOAS exception except for certain limited cases. The budget plan projects that closure of the IOAS exception would produce more than $6 billion in Medicare savings over 10 years.

The President's budget proposal for 2016 states:
"While there are many appropriate uses for this exception, certain services, such as advanced imaging and outpatient therapy, are rarely furnished on the same day as the related physician office visit. Additionally, there is evidence that suggests that this exception may have resulted in overutilization and rapid growth of certain services. Effective calendar year 2017, this proposal would seek to encourage more appropriate use of ancillary services by amending the in-office ancillary services exception to prohibit referrals for radiation therapy, therapy services, advanced imaging, and anatomic pathology services, except in cases where a practice is clinically integrated and required to demonstrate cost containment."

Number of Specialty Groups Receiving CAP-Accreditation for Their Pathology Lab



*Year to date through February 15, 2015. Source: *Laboratory Economics* from CAP

However, even though the President supports

closing the self-referral loophole, Congress still must pass legislation for the provision included in the budget to become law.

Separately, *Laboratory Economics* notes that the formation of in-office pathology labs seems to have slowed after a peak in activity two to three years ago. This is a function of two factors: 1) most large urology and gastroenterology groups have already built in-office pathology labs; and 2) lower Medicare reimbursement for pathology services is discouraging new groups from building labs.

The number of specialty groups receiving CAP accreditation for their in-office pathology labs peaked at 136 groups in 2013, driven largely by Aetna's requirement for accreditation. So far this year, three specialty groups have received CAP accreditation for their pathology labs: Women's Health Connecticut (Rocky Hill, CT) with 215 Ob/Gyns, Fore River Urology (South Portland, ME) with three urologists, and Greater Boston Gastroenterology (Framingham, MA) with six gastroenterologists.

LABCORP COMPLETES $6.1 BILLION ACQUISITION OF COVANCE

LabCorp's purchase of Covance Inc. (Princeton, NJ) makes it a major player in the clinical trials testing business (see *LE*, November 2014). Under the transaction, which closed on February 19, each share of Covance was exchanged for $75.76 in cash and 0.2686 LabCorp shares. In total, LabCorp paid $6.1 billion for Covance and financed the deal largely through added debt.

The purchase price works out to be 2.4 times Covance's 2014 revenue of $2.542 billion, approximately 25 times its pretax income of $246 million and 4.1 times its book value of $1.5 billion.

LabCorp management believes the combined company will "provide a one-stop shop for pharmaceutical outsourcing needs which will support the continuum from drug and diagnostic development to clinical utilization." LabCorp expects the combined company to achieve annual cost-cut savings in excess of $100 million to be fully realized within three years.

Covance Financials in Brief ($ millions)

	2013	2014E	2015E
Revenue	$2,402	$2,542	$2,726
Pretax income	228	246	342
Net income	195		258

Source: Covance Inc. Proxy Statement, 1/16/15

Covance's Chairman and CEO Joseph L. Herring, 59, has become CEO of LabCorp's new Covance Division and will report directly to LabCorp's Chairman and CEO Dave King. In his new position, Herring will earn an annual salary of $1 million plus the potential for a bonus equal to 120% of his pro-rated salary. He will also receive $2.3 million in LabCorp stock. Herring is expected to remain with LabCorp through 2015 to help with the transition.

In addition, the sale to LabCorp triggered several "golden parachute" change-in-control payments to Herring that will total up to $25 million. These include $14.4 million in vested Covance restricted stock and options, plus $6.7 million in cash and $4.1 million in incremental pension payments.

LAB STOCKS UP 15% YTD

Fourteen lab stocks have increased by an unweighted average of 15% year to date through February 16. In comparison, the S&P 500 Index is down 3%. The top-performing lab stock so far this year is Foundation Medicine, which has jumped 120% on news that Roche is buying a majority stake in the company. Meanwhile, Quest Diagnostics is up by 7% and LabCorp is up 8%.

Company (ticker)	Stock Price 2/16/15	Stock Price 12/31/14	2015 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	$34.63	$32.13	8%	$961	20.1	1.2	3.0
Cancer Genetics Inc. (CGIX)	7.07	6.68	6%	69	NA	8.1	1.8
CombiMatrix (CBMX)	1.83	1.29	42%	20	NA	1.4	2.3
Enzo Biochem (ENZ)	3.12	4.44	-30%	140	NA	1.4	3.9
Foundation Medicine (FMI)	48.88	22.22	120%	1,384	NA	26.1	14.2
Genomic Health (GHDX)	31.12	31.97	-3%	987	NA	3.5	6.8
LabCorp (LH)	116.90	107.90	8%	9,878	18.9	1.7	3.6
Myriad Genetics (MYGN)	34.03	34.06	0%	2,484	22.3	3.4	3.5
NeoGenomics (NEO)	4.10	4.17	-2%	246	NA	2.6	4.2
Psychemedics (PMD)	15.26	15.15	1%	82	25.4	2.8	6.4
Quest Diagnostics (DGX)	71.68	67.06	7%	10,360	16.4	1.4	2.4
Response Genetics (RGDX)	0.52	0.32	66%	20	NA	1.1	10.1
Sonic Healthcare (SHL.AX)	18.94	18.50	2%	7,603	19.7	2.0	2.5
Veracyte (VCYT)	8.77	9.66	-9%	197	NA	5.1	4.1
Unweighted Averages			15%		20.5	4.4	4.9

Source: Bloomberg

Jondavid Klipp, Editor and Publisher Jennifer Kaufman, Associate Editor

SPECIAL TELECONFERENCE

LABORATORY ECONOMICS

Save the DATE! Tuesday, March 24

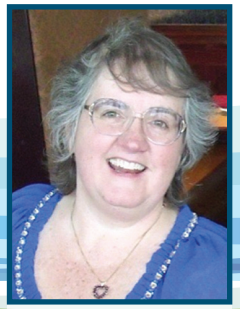
Keeping Ahead of the Curve: CLIA Update 2015

Please join ***Laboratory Economics*** for a 75-minute conference call on Tuesday, March 24, 2015, at 1:00 p.m. Eastern with **Karen Dyer, acting director of the Division of Laboratory Services, Centers for Medicare and Medicaid Services.** Ms. Dyer will provide an update on critical CLIA programs and initiatives for 2015.

This independent, non-sponsored teleconference is an absolute essential for all clinical and anatomic pathology laboratories.

- Get the latest info on lab compliance with the patient access rule that went into effect April 7, 2014 (labs were required to comply by Oct. 6, 2014)
- Learn more about regulations implementing the TEST (Taking Essential Steps for Testing) Act and how they will affect laboratories
- Find out about the CMS policy memorandum on waived testing
- Get an update on the Individualized Quality Control Plan (IQCP) and when IQCP enforcement is slated to begin
- Hear about CMS' work with the Centers for Disease Control and Prevention (CDC) on updating the CLIA proficiency testing regulations
- Learn about a proposed rule on fecal occult blood testing and when a final rule is expected

Special Guest:



Karen Dyer is the acting director of the Division of Laboratory Services at the Centers for Medicare and Medicaid Services. Ms. Dyer is a registered medical technologist with certification in laboratory management. Ms. Dyer received a BA degree from the University of Maryland Baltimore County in Health Science and Policy. Prior to joining the CLIA program at CMS, Ms. Dyer was employed by the Johns Hopkins Hospital Medical Laboratories, as an Affiliate Laboratory Supervisor and Point of Care Testing Coordinator.

Moderator:

Kimberly Scott is a seasoned healthcare analyst with extensive experience covering medical diagnostics. From 2001 to 2014, Ms. Scott worked for G2 Intelligence (formerly Washington G-2 Reports) in various capacities, most recently as managing editor overseeing four monthly publications. Prior to that, Ms. Scott worked as a reporter and editor for various health care publishing companies, including U.S. Medicine, Harling Communications, and the Daytona Beach News-Journal.

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