Jondavid Klipp, Editor, labreporter@aol.com

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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

PATHGROUP NOT UP FOR SALE

Contrary to a recent article in the *Wall Street Journal*, Ben Davis, MD, Chairman and CEO at PathGroup (Nashville, TN), tells *Laboratory Economics* that his company is not up for sale. "PathGroup is not seeking a sale. We are exploring a debt and equity recapitalization to properly fund the company as we continue to execute on our growth plans," according to Davis. He indicated that under any potential transaction, pathologists will continue to hold a significant ownership stake in PathGroup.

Continued on page 10.

PRESSURE CONTINUES TO BUILD FOR DELAY OF PAMA LAB TEST REPRICING

Pressure continues to build on CMS to delay implementation of a new payment system for clinical lab testing based on private-payer rates. The most recent action came in the form of a letter from more than two dozen congressmen and women, including the chairman of the House Ways and Means Health Subcommittee.

Continued on page 5.

WHAT WENT WRONG AT ATHEROTECH?

Atherotech Inc. (Birmingham, AL) filed for Chapter 7 bankruptcy on March 3 after failing to secure new loans from its lenders or find a willing buyer to rescue it. In Chapter 7 proceedings, a company liquidates its assets and ceases operations. Atherotech's main asset—its VAP lipid panel test—is licensed out of the University of Alabama at Birmingham and can't be sold.

Atherotech had been owned by the New York City investment firm Behrman Capital. At its high point in mid-2014, Atherotech employed more than 300 people and had over $100 million in annual revenue.

However, beginning in the middle of 2014, cardiovascular disease (CVD) testing labs like Atherotech began to experience a series of regulatory changes and increased scrutiny from private payers leading to a severe drop in volumes in 2015.

Continued on page 2.

Contents

SIX REASONS WHY ATHEROTECH WENT BANKRUPT (*cont'd from page 1*)

Atherotech is the third CVD testing lab company to file for bankruptcy in less than three years. Aviir Inc., which marketed its proprietary "MiRisk" CVD test, filed for Chapter 7 bankruptcy in January 2014. And Health Diagnostic Laboratory, which had been by far the biggest CVD testing lab company, filed for Chapter 11 bankruptcy in June 2015.

Atherotech's VAP lipid panel includes tests for total cholesterol, LDL, HDL, VLDL, and lipoprotein subclasses at a list price to patients of $38. However, dozens of add-on tests often raised the price much higher. For example, its average allowed payment received from Medicare was $245 per patient in 2013, according to data from CMS.

Below *Laboratory Economics* outlines six reasons that led to the downfall of Atherotech.

1. OIG Issues Special Fraud Alert

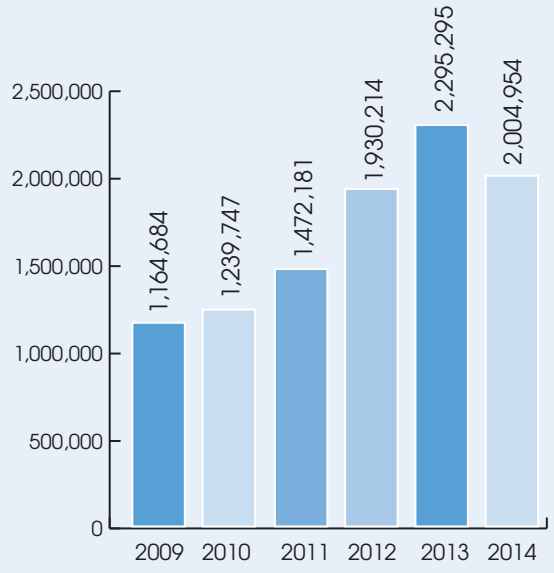
The first shoe dropped on June 25, 2014, when the Office of the Inspector General (OIG) issued a Special Fraud Alert indicating that the $10-$20 specimen process and handling (P&H) fees that cardiovascular disease testing labs had been paying to ordering doctors raised a "substantial risk of fraud and abuse under the anti-kickback statute."

Following the Fraud Alert, Atherotech and other CVD testing labs stopped paying P&H fees to their physician clients. As would be expected, many of these doctors stopped ordering the more-expensive advanced CVD tests.

2. Ongoing OIG and DOJ Investigation

Shortly after the OIG's Special Fraud Alert, the *Wall Street Journal* reported that the OIG and Department of Justice were investigating the P&H payments made by five CVD testing labs: Atherotech, Boston Heart Diagnostics, Health Diagnostic Laboratory (HDL), Singulex Inc. and Quest's Berkeley HeartLab.

Advanced Lipid Testing: Volume of Medicare Allowed Services*



*Total allowed services by Medicare for CPT 82172 (Assay of apolipoprotein), 83695 (Assay of lipoprotein(a)), 83698 (Assay lipoprotein pla2), 83701 (Lipoprotein bld hr fraction), 83704 (Lipoprotein bld by nmr)
Source: *Laboratory Economics* from CMS

In early 2015, two of the lab companies under investigation agreed to pay a combined $48.5 million to settle allegations that they had billed Medicare for medically unnecessary testing. HDL agreed to pay $47 million and Singulex agreed to pay $1.5 million.

However, no settlements have been announced and investigations are believed to be ongoing for Boston Heart Diagnostics, Quest's Berkeley HeartLab and Atherotech (at least up until its bankruptcy).

Undoubtedly, the ongoing investigation and threat of a potential multi-million dollar settlement hindered Atherotech's ability to raise new capital to stay in business.

3. Difficulty Collecting Money from Patients

In late 2014, Cigna filed an $84 million lawsuit against HDL alleging that it waived patient copays and deductibles then billed Cigna

inflated prices thereby violating the Employee Retirement Income Security Act and other federal and state laws. Aetna filed a similar lawsuit against HDL in April 2015.

Both lawsuits referenced an OIG Special Fraud Alert (Dec. 19, 1994) that stated: "Routine waiver of deductibles and copayments by charge-based providers, practitioners or suppliers is unlawful because it results in … false claims … [and] excessive utilization of items and services paid for by Medicare."

So it was no coincidence that in early 2015, Atherotech changed its billing practices and stopped waiving patient copays and deductibles. Predictably, this led to a drop in test orders. Also predictably, the company had extreme difficulty collecting direct payment from those patients that did get tested.

4. Medicare Carrier Non-Coverage Decisions

Effective 10/5/15, the influential Medicare carrier Palmetto GBA, which processes Part B claims in North Carolina, South Carolina, Virginia and West Virginia, issued a local coverage determination (LCD) for Biomarkers in Cardiovascular Risk Assessment (L36129). The policy denies coverage of CVD risk-assessment panels, except the basic lipid panel, for all patients.

The policy, which still allows a physician to order individual CVD lipid tests on symptomatic patients, is intended to stop physicians from ordering mega-panels for CVD. For example, HDL had performed an average of 32 tests per Part B beneficiary in 2013, while Boston Heart Diagnostics performed an average of 24 tests, and Atherotech averaged 13 tests, according to CMS data (see graph).

Cigna Goverment Services, which processes Part B claims in Kentucky and Ohio, issued a similar LCD (L36139) also effective 10/5/15.

In addition, Noridian has a pending policy (L36358) for California and Nevada that becomes effective 6/1/16.

5. Rising Costs

In late 2014, just as its test volumes were beginning to decline, Atherotech doubled its leased space by moving its corporate headquarters into a newly-renovated 48,000-square-foot office (1853 Data Drive, Birmingham), while maintaining its existing 48,000-square-foot laboratory at nearby 201 London Parkway.

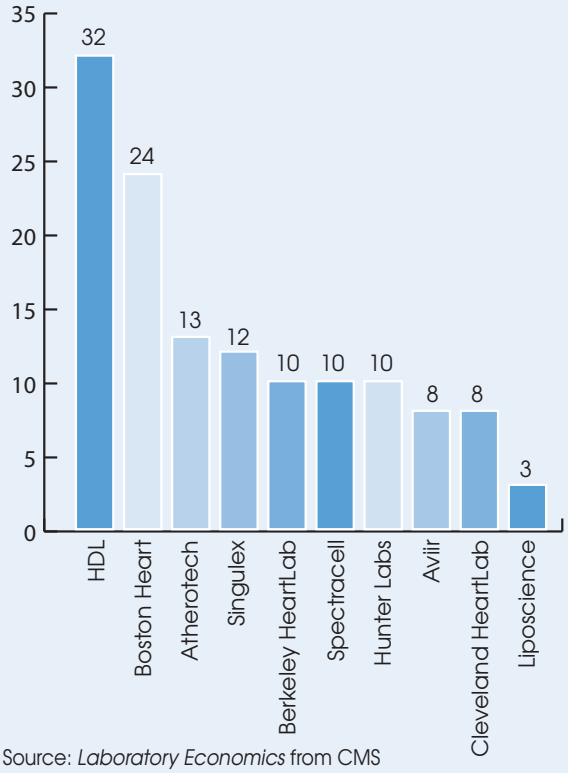
The company's billing and collection costs also increased when it started billing patients directly.

In addition, the ongoing government investigation added significant legal costs.

6. No Buyers

With test volume declining and costs rising, Atherotech's owner Behrman Capital brought

Average Number of Tests per Medicare Patient, 2013



Source: *Laboratory Economics* from CMS

in a new CEO, Jim McClintic, in early 2015. McClintic had successfully run another Behrman-owned lab company, Esoterix, which was eventually sold to LabCorp for $150 million in 2005.

Behrman was probably hoping that McClintic could engineer a turnaround and an eventual sale of Atherotech.

McClintic initiated several rounds of layoffs totaling some 100 employees. He also tried to diversify Atherotech's revenue by expanding its test menu and reducing its reliance on CVD testing.

In mid-2015, Behrman reportedly infused $7 million of capital into Atherotech and negotiated an additional $3 million line of credit from its primary lender Madison Capital Funding (Chicago).

Atherotech also hired the investment bank Lincoln International to seek a sale. About 50 potential suitors were contacted but no acceptable bids were offered.

By late 2015, Behrman determined that it was unable to continue providing funding to Atherotech without a significant restructuring of the company's bank loans. However, despite months of negotiations, Atherotech was ultimately unable to reach a long-term deal with the second of its two key lenders, Regions Bank (Birmingham). Madison Capital had reportedly accepted a deal to restructure Atherotech's debt, but Regions Bank refused.

Atherotech's bankruptcy filing lists more than 1,800 creditors. Its two largest secured creditors are Madison Capital (owed $25.8 million) and Regions Bank (owed $17.4 million).

Status of 10 Lab Companies Specializing in CVD Testing

Laboratory Name	*Location*	*Medicare Revenue 2013**	*Current Status*
Health Diagnostic Laboratory	Richmond, VA	$151,896,269	Acquired by True Health Diagnostics out of bankruptcy in September 2015.
Atherotech	Birmingham, AL	$26,237,321	Filed for Chap. 7 bankruptcy in March 2016.
Boston Heart Diagnostics	Framingham, MA	$19,537,391	Acquired by Eurofins Scientific in January 2015.
Singulex	Alameda, CA	$13,051,547	Owned by Fisk Ventures, OrbiMed Advisors, JAFCO and ProLog Ventures.
Berkeley HeartLab	Alameda, CA	$5,310,057	Berkeley HeartLab was acquired by Celera Corp. in 2007; Celera was acquired by Quest Diagnostics in 2011.
Cleveland HeartLab	Cleveland, OH	$4,544,231	Spun-off from Cleveland Clinic in 2009; now operates independently.
Hunter Laboratories	Campbell, CA	$3,351,093	Acquired by Bio-Reference in August 2013; Bio-Reference was acquired by Opko Health in August 2015.
Spectracell Laboratories	Houston, TX	$1,988,791	Still operating independently.
LipoScience	Raleigh, NC	$1,332,481	Acquired by LabCorp in November 2014.
Aviir	Irvine, CA	$534,929	Filed for Chap. 7 bankruptcy in January 2014; Cleveland HeartLab purchased the intellectual property and copyrights to Avviir's MiRisk test

*Medicare revenue is for each company's total allowed services paid by Part B in 2013.
Source: *Laboratory Economics*

Pressure Continues to Build for Delay (*cont'd from page 1*)

The March 29 letter, signed by Rep. Pat Tiberi (R-OH), Bill Pascrell (D-NJ), Pat Meehan (R-PA) and 24 other committee members, urges CMS to delay implementation of Section 216 of the Protecting Access to Medicare Act (PAMA).

The lawmakers say they are concerned that the implementation process for the new market-based payment methodology for the Clinical Laboratory Fee Schedule (CLFS) will be rushed since CMS has yet to issue a final rule. Section 216 of PAMA called for a January 1, 2017 effective date for the new prices, but the legislation also included two other key deadlines that CMS has missed: publication of a final rule by June 30, 2015, and reporting of private-payer rates beginning on January 1, 2016.

"We believe the critical alterations to the CLFS must be accomplished in a deliberate and measured manner so that laboratories have sufficient time, once the final rule and subregulatory guidance are issued, to comply. Given the delays in the rulemaking process, the January 1, 2017 effective date for the new CLFS payment methodology is not feasible and should be delayed," according to the letter sent to acting CMS Administrator Andy Slavitt.

The March 29 missive follows several earlier letters sent by lawmakers seeking a delay in the new payment system, including two in December signed by more than 60 lawmakers and one in January sent by Senate Finance Committee Chairman Orrin Hatch (R-UT) and ranking member Ron Wyden (D-OR). Industry groups, including the American Clinical Laboratory Association (ACLA), the National Independent Laboratory Association (NILA) and the College of American Pathologists (CAP) have also called on CMS to put off implementation of the market-based system.

While a CMS official responsible for overseeing publication of the final rule has indicated the new system will not be in effect as of January 1, 2017 (see *LE*, March 2016), there has been no official word from CMS about a delay or when implementation of the new system might occur.

Alan Mertz, ACLA president, tells *Laboratory Economics* that he is confident that CMS officials have heard all the stakeholder concerns and believes the agency will delay implementation. ACLA has called for a one-year delay if the final rule and subregulatory guidance is issued by June 30, 2016. If the final rule comes out after that date, Mertz notes that the association would support a two-year delay as sought by NILA.

NILA Administrator Mark Birenbaum, PhD, notes that NILA is extremely concerned about the impact this law and corresponding regulations will have on regional and community laboratories and the Medicare beneficiaries they serve. "For our labs, this is very challenging," he tells *Laboratory Economics*. "The resources required will be significant. We want to be sure this is all carefully thought out."

Birenbaum adds that NILA has never supported the approach of Section 216. "The law itself is fundamentally flawed, as it requires CMS to determine a weighted median of all the test rates/volumes reported in order to set new payment rates. Clearly, the largest players in the laboratory market – the two national publicly-traded laboratories – will drive the test volumes, and their rates will dominate CMS's evaluation. The law does nothing to consider variances in the market and the impact that adjustments will ultimately have on community and regional laboratories, particularly those that offer significantly smaller test menus in comparison to their national competitors."

CMS FOUND 45 DEFICIENCIES AT THERANOS LAB

A 100+ page inspection report from the Centers for Medicare and Medicaid Services (CMS) on Theranos that was made public in late March paints a damning picture of failures at the company's laboratory in Newark, California. The report details 45 deficiencies, including five CLIA Condition-level requirements, found during an on-site inspection that occurred in November 2015.

The report indicates that Theranos employed unqualified lab personnel at its lab in northern California who had difficulty adhering to basic CLIA requirements while operating standard lab instruments, including Siemens' lab systems for immunoassays (Centaur), chemistry (Advia XPT) and hematology (Advia 2120i), Bio-Rad's Evolis immunoassay system and Diasorin's Liason for immunoassays.

Many of the cited deficiencies were related to the failure of Theranos' lab director to establish and maintain quality control programs. During 2015, Theranos' lab director in northern California was Sunil Dhawan, MD, a dermatologist with no background in laboratory science. Evidently, Dr. Dhawan spent most of his time practicing dermatology at his group, The Center for Dermatology Cosmetic and Laser Surgery (Freemont, CA), rather than supervising the Theranos laboratory.

The CMS report also noted that two Theranos technical supervisors failed to have the required four years of training or experience in a specialty required to qualify as technical supervisors. In another example, the report noted that one lab employee failed to meet the educational requirements for working in a high-complexity lab. This individual had a bachelor's degree in liberal studies rather than the required degree in clinical laboratory science or medical technology.

Theranos submitted a plan of correction to CMS in early February explaining how it is addressing every issue identified by CMS, including hiring a new full-time lab director, Kingshuk Das, MD, who is a board-certified pathologist. Theranos has also appointed a new Director of Quality.

However, CMS has found the company's plan to fix deficiencies at its northern California lab "not credible" and has proposed sanctions that include revocation of its CLIA certificate and barring Theranos' two owners, Elizabeth Holmes and Ramesh Balwani, from operating a lab for two years. A final decision from CMS is expected by the end of April.

Mt. Sinai Study Says Theranos Results Often Abnormal

Separately, a peer-reviewed study released March 28 by scientists at the Icahn School of Medicine at Mt. Sinai in New York found that Theranos reported "tests outside of the normal range" more often than LabCorp and Quest.

Researchers analyzed data collected in July 2015 from LabCorp, Quest and Theranos. Multiple samples were collected and controlled for variables such as age, sex, and time of collection. The study found that more than half of test results showed significant differences between test providers. Triglyceride levels and red blood cell counts were among the most consistent results, while white blood cell counts and overall cholesterol levels were among the most variable. The study concluded that Theranos' results for total cholesterol were lower by an average of 9.3% than those produced by Quest and LabCorp, a big enough gap to have an effect on whether or not statin therapy would be initiated.

Overall, test results from Theranos were flagged as abnormal 1.6 times more often than those from LabCorp or Quest. The study was published in the *Journal of Clinical Investigation*.

Theranos officials dispute the study results, calling them "flawed and inaccurate." For example, they said, "the collection of large amounts of venous samples before collecting capillary samples is

contrary to the Theranos CLIA lab collection procedures and could negatively impact the quality of subsequent capillary blood collection."

Meanwhile, a spokeswoman from the Cleveland Clinic tells *Laboratory Economics* that a planned validation study of Theranos' fingerstick testing technology hasn't begun yet. Theranos announced a partnership with Cleveland Clinic to perform a study more than one year ago. "There is no update to give. Nothing has started," according to the Cleveland Clinic's spokeswoman.

Negative Publicity Taking a Toll

The concerns over the quality of testing at Theranos may be beginning to take a toll on the company. Patrick Staar, owner of an Any Lab Test Now lab franchise in Phoenix, tells *Laboratory Economics* that he is starting to see some of the direct-pay clients previously lost to Theranos now returning to his laboratory.

"We have seen a small increase in clients from the latest Theranos news," he says. "The concern is less the price and more the quality of test results. Losing trust in lab results due to inaccurate readings can be detrimental. The clients that we have want accurate test results to monitor over time. They feel with the latest news [about Theranos], their results may not be correct and could lead to a false diagnosis."

Staar also observes that Theranos advertising in the Phoenix area appears to have slowed recently. "I haven't heard as many radio ads as I did before, and the TV ads have become less," he says. "I felt like before I would hear some sort of Theranos ad on multiple stations during the morning and evening commute, but I haven't heard a Theranos ad in a month."

KEY TAKEAWAYS FROM FINAL RULE ON RETURNING OVERPAYMENTS

Four years after the issuance of the Proposed Rule, CMS has released its long-awaited Final Rule detailing providers' responsibilities to report and return Medicare and Medicaid overpayments. The rule (aka "the 60-day rule") governs when an "identified" overpayment must be repaid to the government before it becomes subject to federal False Claims Act (FCA) liability.

The Final Rule included two key revisions, according to Matt Fornataro, attorney at Arnold & Porter (Washington, DC).

In a meaningful departure from the Proposed Rule, the final regulation revises the definition of the term "identified" to include quantification of the overpayment. Thus the 60-day clock for returning an overpayment to the government begins after a provider has both identified an overpayment and quantified the amount. Fornataro notes that CMS set six months as the benchmark for timely investigation of an overpayment, but he also cautioned that the duration of a reasonable investigation likely would scale, in the government's view, depending on the circumstances. Thus, he says, providers should work diligently following notice of a possible overpayment to quantify such overpayment (if it is confirmed), and report and return that overpayment.

CMS retreated from its position in the proposed rulemaking to impose a 10-year look back, and instead reduced the period to six years. However, Fornataro says a six-year requirement still imposes an enormous burden on providers, especially for smaller providers with less sophisticated recordkeeping.

Finally, Fornataro warns that publication of the Final Rule will undoubtedly serve to trigger new whistleblower False Claims Act cases. "The worst thing a laboratory can do is ignore an employee's concerns about a billing issue. Labs need to have protocols in place to take appropriate action when receiving credible evidence of an overpayment," Fornataro advised.

PUBLICLY-TRADED LABS GREW 2.8% IN 2015

On a combined basis, 20 publicly-traded labs grew their revenue by 2.8% to $19.7 billion in 2015 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*.

Excluding Quest Diagnostics and LabCorp, 18 publicly-traded labs grew by 3.7% last year (after adjusting for acquisitions).

Revenue growth was fastest at three small genetic-testing lab companies—Exact Sciences (up 2093%), Rosetta Genomics (up 523%) and Invitae Corp. (up 422%).

Acquisition-adjusted revenue for LabCorp was up 4.6% last year, while Quest Diagnostics' revenue was up 1%. The third largest U.S. lab company, Opko/Bio-Reference Labs, had estimated revenue growth of 9.3% (after adjustments for acquisitions).

Revenue Growth at 20 Publicly-Traded Lab Companies ($000)

Company	Revenue 2015	Revenue 2014	Reported Change	Pro Forma Change*
LabCorp	$8,505,700	$6,011,600	41.5%	4.6%
Quest Diagnostics	7,493,000	7,435,000	0.8%	1.0%
Opko/Bio-Reference1	910,000	832,282	9.3%	9.3%
Myriad Genetics2	723,100	778,216	-7.1%	-7.1%
Sonic Healthcare USA3	715,500	701,500	2.0%	2.0%
Genomic Health	286,825	275,706	4.0%	4.0%
Aurora Diagnostics	263,744	242,561	8.7%	2.2%
Miraca Life Sciences USA4	257,500	219,300	17.4%	0.0%
Sequenom Laboratories	119,556	151,569	-21.1%	-21.1%
NeoGenomics	99,802	87,069	14.6%	10.0%
Foundation Medicine	93,203	61,079	52.6%	52.6%
Enzo Clinical Labs5	63,414	58,689	8.1%	8.1%
Veracyte	49,503	38,190	29.6%	29.6%
Exact Sciences	39,437	1,798	2093.4%	2093.4%
CareDx	28,144	27,306	3.1%	3.1%
Psychemedics	26,975	29,205	-7.6%	-7.6%
Cancer Genetics Inc.	18,040	10,199	76.9%	23.0%
Combimatrix	10,088	8,042	25.4%	25.4%
Invitae Corp.	8,378	1,604	422.3%	422.3%
Rosetta Genomics	8,268	1,327	523.1%	523.1%
Total, 20 companies	$19,720,177	$16,972,242	16.2%	2.8%
Total, 18 companies (excluding Quest and LabCorp)	$3,721,477	$3,525,642	5.6%	3.7%

*Pro forma change is estimated by *Laboratory Economics* after adjustments for acquisitions.

[1]Bio-Reference's revenue is estimated for fiscal year ended October 31, 2015; [2]Myriad Genetics' revenue is for fiscal year ended June 30, 2015; [3]Sonic Healthcare USA's revenue is for fiscal year ended June 30, 2015 (using constant exchange rate of 1 AUD = 0.77 USD; [4]Miraca's revenue is for U.S. lab business for fiscal year ended March 31, 2015 (using a constant exchange rate of 1 Yen = 0.009 USD); [5]Enzo's revenue is for lab services only for fiscal year ended July 30, 2015.

Source: *Laboratory Economics* from company reports

AURORA DIAGNOSTICS REPORTS $83M LOSS FOR 2015

Aurora Diagnostics (Palm Beach Gardens, FL) reported a net loss of $83.4 million for 2015 versus a net loss of $55.5 million in 2014; revenue increased 8.7% to $263.7 million. Excluding the benefit of acquisitions, Aurora's revenue increased 2.2% in 2015. The company processed 2.1 million accessions in 2015 (up 5.5%), while average revenue per accession was $125 (up 1.4%).

As of Dec. 31, 2015, Aurora reported cash holdings of $19.1 million and total long-term debt of $389.3 million. As of mid-April, Aurora's $200 million of unsecured senior notes (CUSIP: 051620AB8, 10.75%, maturity 1/15/2018) was selling at approximately 75 cents on the dollar with a yield to maturity of 30%. Aurora says it is exploring financing options to either refinance or extend the maturity of this debt.

Aurora also has $189 million of debt outstanding under its senior secured credit facility from the private investment firm Cerberus Business Finance, LLC. This debt, which is secured by essentially all of Aurora's assets, must be repaid in October 2017 if the company's $200 million of senior notes are not refinanced or their maturity is not extended prior to October 14, 2017.

Aurora Buys Two Hospital-Based Pathology Groups

On April 1, Aurora announced the acquisition of Pacific Pathology Associates, a hospital-based practice providing professional and technical pathology services to five hospitals and more than 225 physicians' offices in the Willamette Valley area located between Portland and Eugene, Oregon. Pacific Pathology Associates operates one technical processing lab near Salem Hospital. The practice provides extensive pathology services, including surgical pathology, cytopathology and hematopathology. Clark McDonald, MD, the Board-certified pathologist who led the ownership group of Pacific Pathology Associates, will continue to lead the local lab after the transaction. The group has a total of 25 employees, including eight pathologists.

In addition, on April 8, Aurora announced the acquisition of Pathology Associates of Sebring, a hospital-based practice that provides pathology services to Highlands Regional Medical Center (HRMC). George Leidel, MD, a pathologist and former owner of Pathology Associates of Sebring, will now work for Aurora and continue to serve HRMC, which has 126 beds and is located in central Florida.

With these two acquisitions, Aurora Diagnostics now operates 25 labs and employs more than 150 pathologists that serve 86 hospitals throughout the U.S.

Aurora Diagnostics Financial Summary ($000)

	2015	2014	% Chg
Total revenue	$263,744	$242,561	8.7%
Operating cash flow	2,330	7,834	-70.3%
Capital expeditures	2,279	2,746	-17.0%
Free cash flow	51	5,088	-99.0%
Interest expense	40,980	35,997	13.8%
Net loss	-83,435	-55,548	NA
Total debt*	389,262	375,595	3.6%
Shareholders' Equity	-190,783	-107,574	NA
Total number of requisitions	2,076,000	1,967,000	5.5%
Avg. revenue per requisition	$125	$123	1.4%

*Excludes contingent consideration owed to acquired pathology practices
Source: Aurora Diagnostics

PATHGROUP NOT UP FOR SALE (*cont'd from page 1*)

The private-equity firm Primus Capital (Cleveland, OH) took a minority equity investment in PathGroup six years ago that included a co-investment by Brentwood Capital Partners (Franklin, TN). The equity investment and new debt facilities brought PathGroup more than $100 million in new capital.

PathGroup used the money to make a few small acquisitions and to expand its lab operations, especially in molecular diagnostics. Since raising the capital in 2010, PathGroup has doubled its annual revenue to more than $200 million. PathGroup currently has more than 1,000 employees, including 80 pathologists, and operates a major central lab in Nashville.

Under any potential new financial transaction, Primus Capital and Brentwood Capital would likely cash in all or part of their investment in PathGroup. And PathGroup would raise fresh capital from new investors, notes *Laboratory Economics*. (Note: See the January 2016 issue of *Laboratory Economics* for a more in-depth summary of PathGroup.)

LABCORP BUYS CALIFORNIA OUTREACH LAB

Henry Mayo Newhall Hospital (Valencia, CA), a 238-bed community hospital, has reached an agreement to sell its outreach laboratory business to LabCorp.

Henry Mayo operates six outpatient laboratories in Santa Clarita (just north of Los Angeles). The labs are currently managed for Henry Mayo by United WestLabs Inc. (Santa Ana, CA).

"The market has changed considerably since 2006 when Henry Mayo and United West Labs began providing outreach laboratory services for Santa Clarita Valley physicians," said Bob Hudson, senior vice president and chief financial officer for Henry Mayo. "Our primary mission is to serve inpatients. Selling our outreach laboratory business will help ensure we can carry out our primary mission."

LabCorp Closes on Purchase of Pathology Inc.

Separately, LabCorp announced completion of its acquisition of the operating assets of Pathology Inc. (Torrance, CA). Pathology Inc. is a full-service histology and Pap testing lab.

Pathology Inc.'s test volumes are expected to be transferred to nearby LabCorp facilities.

ACCUMEN BUYS CHI SOLUTIONS INC.

Accumen Inc. (San Diego, CA) has acquired Chi Solutions Inc. (Ann Arbor, MI) for an undisclosed amount. Chi has 25 employees and specializes in lab management and consulting services for hospital lab outreach businesses. Accumen provides lab consulting services to health systems, including outreach lab management and patient blood management programs. The combined company will have 125 employees.

Accumen CEO Jeff Osborne wouldn't provide financial details for the transaction. However, he confirmed that the Chi acquisition was about 20% the size of Accumen (based on revenue) and was an internally funded, primarily cash purchase.

Chi's long-time CEO Kathleen Murphy, PhD, will be Senior Growth Advisor for the combined company.

UHC WARNS LABS NOT TO WAIVE COPAYS OR DEDUCTIBLES

In its March bulletin to network providers, UnitedHealthcare (UHC) directed providers to refer UHC members to in-network clinical and anatomic pathology labs.

"Some nonparticipating labs attempt to attract customers by waiving or capping copayments, coinsurance or deductibles. Such arrangements undermine the benefit plan by eliminating incentives created to encourage members to choose to receive care within the network and to discourage overutilization of services," according to UHC's bulletin. "Routine waiver of coinsurance, copayments or deductibles may be a violation of the Federal False Claims Act, subject to investigation by the Office of the Inspector General and/or any applicable state insurance department's fraud division," warned UHC.

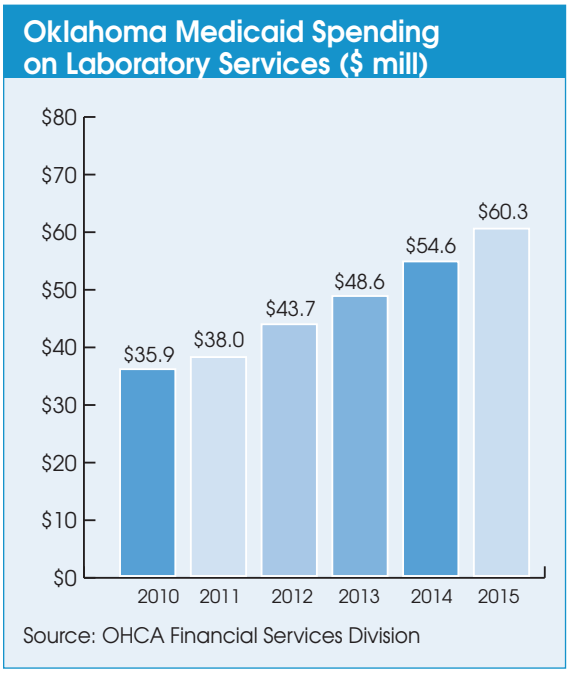
UHC has contracts with 1,500 clinical labs, including a national contract with LabCorp and all its subsidiary labs (since January 1, 2007, through the end of 2018).

For years, UHC and other private insurers have struggled to stop leakage to out-of-network labs. They have tried: 1) educating physicians on the cost differences between in-network and out-of-network labs; 2) threatened to fine or revoke the in-network status of physicians who order from out-of-network labs; and 3) disregarded the assignment of payment by patients to out-of-network labs and then paid patients directly. The UHC bulletin's mention of the "Federal False Claims Act" represents the latest escalation in its efforts to reduce leakage to out-of-network labs, notes *Laboratory Economics*.

OKLAHOMA MEDICAID PROPOSES 25% RATE CUT

The Oklahoma Health Care Authority, which oversees Medicaid in Oklahoma, has proposed an across-the-board 25% rate cut for all Medicaid providers effective July 1. The decision comes amid the state's budget crisis and estimated $1.3 billion deficit next year. Nearly 800,000 of Oklahoma's 3.9 million citizens are enrolled in Medicaid.

The proposed cut, which must first go through a series of public hearings over the next 60 days, would affect all provider types, including hospitals, physicians, laboratories and nursing homes.



Oklahoma's Medicaid program, known as SoonerCare, currently reimburses labs and pathologists at about 80% of Medicare fees. The proposed 25% cut would lower the state's Medicaid rates to approximately 60% of Medicare rates.

The physician office lab market in Oklahoma is dominated by Diagnostic Laboratory of Oklahoma (DLO), a joint venture owned by Integris Health and Quest Diagnostics.

Oklahoma Medicaid spent $60.3 million on lab services in the fiscal year ended June 30, 2015, up 10.4% from $54.6 million in the previous year. Over the past five years, the state's Medicaid spending on lab services has risen by an average of 10.9% per year, while its enrollment has declined from 881,220 recipients in 2010 to a current 796,000 recipients.

LAB STOCKS DOWN 6% YTD

Sixteen lab stocks have fallen by an unweighted average of 6% year to date through April 13. In comparison, the S&P 500 Index is up 1.4% and Nasdaq is up 5.5%. The top-performing lab stock so far this year is the drug-testing company Psychemedics, up 39%. Meanwhile, Quest Diagnostics is up by 3% and LabCorp is down 4%.

Company (ticker)	Stock Price 4/13/16	Stock Price 12/31/15	2016 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$2.62	$3.30	-21%	$36	NA	1.6	1.1
CombiMatrix (CBMX)	3.35	10.95	-69%	3	NA	0.3	0.5
Enzo Biochem (ENZ)	4.94	4.50	10%	228	38.3	2.3	4.8
Exact Sciences (EXAS)	7.46	9.23	-19%	727	NA	17.6	2.1
Foundation Medicine (FMI)	18.00	21.06	-15%	621	NA	6.5	2.4
Genomic Health (GHDX)	26.68	35.20	-24%	880	NA	3.0	6.2
Invitae (NVTA)	10.50	8.21	28%	336	NA	41.3	2.5
LabCorp (LH)	118.25	123.64	-4%	12,070	27.3	1.4	2.4
Myriad Genetics (MYGN)	39.50	43.16	-8%	2,810	29.7	3.8	3.7
NeoGenomics (NEO)	6.95	7.87	-12%	527	NA	4.2	6.6
Opko Health (OPK)	10.96	10.05	9%	5,980	NA	13.0	3.2
Psychemedics (PMD)	14.10	10.14	39%	76	50.4	2.8	6.5
Quest Diagnostics (DGX)	73.22	71.14	3%	10,390	15.0	1.4	2.2
Rosetta Genomics (ROSG)	1.24	1.23	1%	26	NA	3.4	1.0
Sonic Healthcare (SHL.AX)	18.92	17.87	6%	7,850	21.3	1.7	2.2
Veracyte (VCYT)	5.50	7.20	-24%	153	NA	3.2	2.6
Unweighted Averages			-6%		30.3	6.7	3.1

Source: Capital IQ

Jondavid Klipp, Editor and Publisher Jennifer Kaufman, Associate Editor Kimberly Scott, Associate Editor