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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

OPKO TO BUY BIO-REFERENCE LABS

Opko Health Inc. (Miami, FL) has agreed to purchase Bio-Reference Laboratories Inc. (BRLI-Elmwood Park, NJ) in an all-stock transaction that initially valued BRLI at $1.47 billion. After the deal closes, BRLI shareholders will own 14% of the combined company.

Opko said it will merge its existing prostate biopsy lab operations into BRLI's laboratories. Opko plans to use the payer relationships and sales and marketing resources of Bio-Reference to push sales of its 4Kscore Test, a laboratory-developed test panel for determining aggressive prostate cancer risk.

However, investors have questioned the strategic rationale for the deal. Opko shares have fallen 20% to $15.31 since the deal was announced on June 4 through the market's close on June 15. As a result, the deal currently values BRLI at $1.18 billion. *Continued on page 3.*

MOST NEW MDX CPT CODES NOT PRICED UNDER PRELIMINARY DETERMINATIONS

First the good news: The Centers for Medicare and Medicaid Services (CMS) on May 26 released preliminary pricing from local contractors for new CPT codes for molecular diagnostic testing.

Now the bad news: The Medicare administrative contractors (MACs) priced only 10 of the 29 new codes and by and large did not even attempt to price large cancer panels assessing 51 or more genes.

The failure of MACs to price two-thirds of the new codes is problematic given that CMS is supposed to use the median price for each test to set payment beginning in 2016. CMS says final pricing will be posted around September 2015. CMS will accept comment on the proposed prices until July 20, 2015. *Continued on page 2.*

ANOTHER MAC FOLLOWS PALMETTO'S POLICY

CGS Administrators, the Medicare Administrative Contractor (MAC) for Part B claims in Kentucky and Ohio, has issued a draft local coverage determination (LCD) policy for immunohistochemistry and special stains that follows the coverage decision finalized by Palmetto GBA in January 2015. *Continued on page 10.*

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MOST NEW MDX CPT CODES NOT PRICED (*cont'd from page 1*)
The fact that MACs have not priced the majority of codes indicates they probably will not be priced at all, believes Kyle Fetter, vice president of advanced diagnostics with XIFIN Inc., a revenue cycle consulting company based in San Diego. While many of the codes are considered non-covered by contractors, the lack of pricing will create problems if and when the tests are used on Medicaid patients.

"Our biggest issue with MACs or CMS not pricing costs is, first and foremost, just because they're not covered by a local Medicare contractor doesn't mean they're not covered by Medicaid, and Medicaid needs pricing," he says. "Also, even when a code is considered noncovered for Medicare patients, that means it's not covered for the majority of Medicare patients, not all of them. Lack of pricing just forces labs to have to go through a lengthy appeals process."

Of the codes that were priced by MACs, many were well below what labs are currently billing CMS. For example, cancer panels assessing between five and 50 genes typically are billed at about $2,564 when using code stacking. Cahaba, the Medicare Part B contractor for Alabama, Georgia, and Tennessee, priced codes for cancer panels assessing between five and 50 genes at $90.

Median MAC Pricing for New MDx Test Codes

CPT Code	Description	Median MAC Price
81161	DMD Dystrophin	$140.00
81246	Tyrosine Kinase Domain	82.96
81287	MGMT Methylation	83.01
81288	MLH1 Gene	95.10
81313	PCA3/KLK3 Gene	200.00
81435	Panel: Hereditary Colon	795.95
81436	Add on: Dup Del	795.95
81445	Panel: Tumors, 5-50 genes	90.00
81450	Panel, hematolymphoid, 5-50 genes	90.00
81519	21 gene breast cancer (Onctotype DX)	3,416.00

Source: Median pricing calculated by Bruce Quinn, Foley Hoag

Bruce Quinn, a Medicare policy specialist with the law firm Foley Hoag, notes in a blog posting on the firm's website that not a single code was priced by all MACs. Quinn conducted an analysis of the proposed prices, calculating both the average and the median of pricing by state for the 10 codes that were priced. CMS would calculate the median by MAC, not by state, so these numbers don't necessarily reflect the exact medians that would be used, but they are a good approximation.

According to CMS, if there is no price for a given code by a specific MAC, this may be due to one of several reasons:

- There is no benefit category for the test;
- There is no high-quality evidence published in the peer-reviewed literature demonstrating clinical utility for the Medicare population;
- There is a lack of medical necessity; knowing the exact genetic sequencing will not change the treatment or prognosis of a beneficiary; or
- The MAC has not received a technical assessment that qualifies the test for coverage.

The list of preliminary gapfill payment determinations is available at *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Gapfill-Pricing-Inquiries.html*

OPKO TO BUY BIO-REFERENCE LABS (*cont'd from page 1*)
Longer term, Opko says that BRLI's genetic testing lab and genomics data should benefit Opko in its drug discovery and clinical trials programs. Opko recently submitted an application to the FDA for its first drug product Rayaldee. The company is seeking marketing approval for Rayaldee for the prevention and treatment of secondary hyperparathyroidism in patients with chronic kidney disease and vitamin D insufficiency. Opko has several other drugs under development as well.

The Boards of Directors for both companies have already approved the transaction. BRLI shareholders will vote on the deal sometime within the next few months. BRLI's largest shareholder is its chairman and CEO Marc Grodman, MD, age 62, who founded the company in 1981. Grodman owns 2.741 million shares, or 9.9% of BRLI, currently valued at approximately $110 million.

Opko & Bio-Reference at a Glance ($000)

FY 2014	*Opko*	*BRLI*
Revenue	$91,125	$832,282
Operating income	-145,815	83,425
Net income	-171,666	46,758
Long-term debt	348,812	15,397
# Employees	674	3,877

Source: Company annual reports for 2014

BRLI will be the second lab acquisition for Opko, which acquired the uropathology-focused OURLab (aka Prost-Data) in 2012 for $42 million. At the time, Opko said that the acquisition of OULab would help with the commercialization of its 4KScore Test. Opko has been marketing the test to urologists in the United States since March 2014.

Opko's 4Kscore Test is not currently covered by private insurance, Medicare or Medicaid. The 4Kscore Test costs $395 and requires an out-of-pocket payment by the patient. The test measures four existing prostate-specific tests (total PSA, free PSA, intact PSA human kallikrein 2 [hK2]), which are then combined with patient age, digital rectal exam results and prior biopsy (yes/no) to determine the probability of finding an aggressive prostate (Gleason score 7 or higher) cancer prior to biopsy. Opko says the test has the potential to reduce the number of unnecessary prostate biopsies by 50% or more.

Over the past seven years, BRLI has been successful at creating a women's health division that markets panels of tests for cervical cancer (e.g., liquid Pap test, HPV, chlamydia/gonorrhea, et al.) under the brand name GenPap. On a June 11 conference call with investors, Grodman said 4Kscore has the potential to become the linchpin at BRLI's new men's health division.

BRLI Short Sellers Slammed/Opko Short Sellers Rejoice

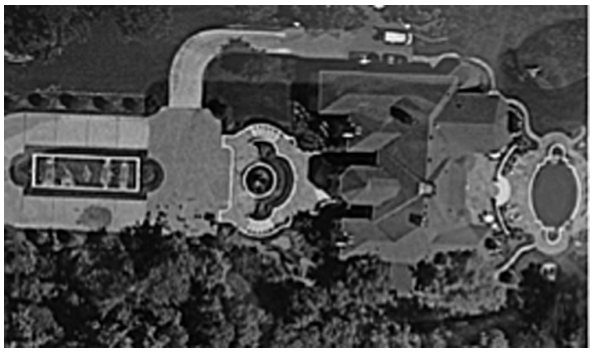
Short sellers, who bet on stock price declines, have had significant positions in both BRLI and Opko over the past few years. For example, as of May 29, investors held a short position of approximately 4.5 million shares of BRLI common stock which represented approximately 18% of the public float. BRLI's stock price has risen 21% to $40 since announcement of the deal with Opko. Completion of the sale to Opko will mean financial wipeout for those who bet against BRLI.

On the other hand, short sellers in Opko are profiting. As mentioned earlier, Opko shares have fallen 20% to $15.31 since its acquisition of BRLI was announced. As of May 29, investors held a short position of approximately 44 million shares of Opko common stock which represented approximately 18% of the public float. These short sellers have benefited from Opko's decline.

FAMILY DERMATOLOGY STAYS IN BUSINESS DESPITE $3.2M SETTLEMENT

Earlier this year, Family Dermatology P.C., which owns and operates a dermatopathology laboratory in the Atlanta area, agreed to pay the United States $3.2 million, which will be paid out in installments over five years, to settle allegations that it violated the False Claims Act over a ten-year period beginning in 2003.

Under the alleged scheme, Family Dermatology and its husband-and-wife owners, Yinka Adesokan and Paula Nelson, MD, would: (1) purchase small dermatology practices from dermatologists across the United States; (2) hire those dermatologists to stay on to provide professional services as independent contractors; and (3) mandate that these dermatologists send all their pathology work to Nelson Dermatopathology and Pathology Laboratory (which was owned by Dr. Nelson). Nelson allegedly performed a significant portion of her pathology services at a lab located in the basement of her home—an $8.5 million Buckhead mansion purchased from country singer Kenny Rogers in 2006.



The Buckhead mansion is up for foreclosure auction.

The government charged that Family Dermatology and its laboratory did not meet the in-office ancillary services exception to the Stark Law because: 1) independent contractor physicians cannot qualify as members of a group practice because they are not owners or employees; and 2) Nelson Dermatopathology and Pathology Laboratory was not located in the "same building" as a bona-fide physician practice.

In addition to the $3.2 million, the settlement agreement requires Adesokan and Nelson to fork over 50% of the net proceeds of the sale of their mansion, which has been scheduled for a public foreclosure auction. The home is 15,409 square feet with 6 bedrooms and 9 bathrooms on 5 acres in the exclusive Buckhead suburb of Atlanta, according to the website Realtor.com.

"Health care companies that make sweetheart deals with physicians to boost profits undercut both the financial integrity of Medicare and the public's trust in the medical profession," said Special Agent in Charge Derrick L. Jackson of the Department of Health and Human Services' Office of Inspector General (HHS-OIG) in an April 23 press release. "Our agency will continue to hold those who engage in such improper financial schemes accountable."

However, the settlement did not require Family Dermatology or its owners to admit wrongdoing and the company and Dr. Nelson remain in business with Medicare billing privileges intact.

Dr. Nelson billed the Medicare Part B program for 8,268 units of CPT 88305 from which she received $440,749 in Part B payments in 2013. Overall, Nelson received $496,066 in Part B payments for pathology services (88305, 88342, 88312, et al.) in 2013 (see table on page 5). But that may just be the tip of the iceberg because Family Dermatology billed Medicare for many pathology services using the provider IDs of its referring dermatologists. In fact, the government's inves-

tigation identified $10.5 million of false claims billed over a 10-year period. At its height, Family Dermatology owned 53 dermatology practices, mostly in Georgia and Pennsylvania, which were referring thousands of skin specimens to the company's lab each week, according to the lawsuit.

Terms of the settlement require Family Dermatology to now submit Medicare claims using only one provider number.

The government's case arose from three separate lawsuits filed by three whistleblowers, Scott M. Ross MD, Mark F. Baucom and Harold Milstein, MD, under the qui tam provisions of the False Claims Act. The whistleblowers will collectively receive more than $584,000 from the recovery as it is paid out over the next five years.

TOP 20 DERMATOLOGY GROUPS WITH IN-OFFICE PATHOLOGY SERVICES*

GROUP NAME	PROVIDER(S) LAST NAME	CITY	STATE	2013 CPT 88305 VOLUME	AVG. MEDICARE PAYMENT	TOTAL PART B PAYMENT
SKIN AND CANCER ASSOCIATES	BRETTSCHNEIDER/ WILENTZ	AVENTURA	FL	48,034	$46.35	$2,226,582
ADVANCED DERMATOLOGY	REICHEL	FRESH MEADOWS	NY	20,517	$62.11	$1,274,216
ADVANCED DERMATOLOGY & COSMETIC SURGERY	GLANZ/COHEN	DELRAY BEACH	FL	40,656	$27.52	$1,118,705
ANDERSON SKIN & CANCER CLINIC	QUARTERMAN	ANDERSON	SC	20,251	$49.92	$1,011,011
WEST DERMATOLOGY	ABRISHAMI	REDLANDS	CA	16,554	$59.86	$990,981
ANNE ARUNDEL DERMATOLOGY	PFAU	GLEN BURNIE	MD	17,689	$49.11	$868,748
WATERS EDGE DERMATOLOGY	SCHIFF	PALM BEACH GARDENS	FL	14,178	$54.04	$766,216
DERMATOLOGY INC.	BRASHEAR	INDIANAPOLIS	IN	17,129	$42.89	$734,583
COASTAL DERMATOLOGY & PLASTIC SURGERY	LUXENBERG	LOS ALAMITOS	CA	11,616	$63.16	$733,708
DERMATOLOGY ASSOCIATES OF WISCONSIN	KATZ/XIA/HANSON	MANITOWOC	WI	25,662	$27.21	$698,286
MIAMI BEACH SKIN CENTER	RIVLIN	MIAMI BEACH	FL	12,173	$55.57	$676,431
THE DERMATOLOGY GROUP	HENNER	MOUNT DORA	FL	12,281	$52.23	$641,457
GEORGIA DERMATOLOGY	PALKO	HINESVILLE	GA	22,944	$25.33	$581,107
DERMONE	LAPIS	TOMS RIVER	NJ	9,600	$58.95	$565,927
ADVANCED DERMATOLOGY AND SKIN CENTER	NA	BOARDMAN	OH	10,204	$51.58	$526,317
TREASURE COAST DERMATOLOGY	GOLOMB	PORT ST LUCIE	FL	9,626	$52.87	$508,899
CHEYENNE SKIN CLINIC	SURBRUGG	CHEYENNE	WY	9,991	$49.18	$491,400
VILLAGE DERMATOLOGY	TRAN	THE VILLAGES	FL	19,076	$25.16	$479,927
CATALINA SKIN INSTITUTE, LLC	NA	TUCSON	AZ	8,817	$50.88	$448,644
FAMILY DERMATOLOGY	NELSON	LILBURN	GA	8,268	$53.31	$440,749

*Ranked by Medicare Part B payments for CPT 88305 in 2013

Source: *Laboratory Economics* from 2013 Medicare Part B Utilization and Payment Data

NAVIGATING COMPLIANCE RISKS IN CLIENT BILLING ARRANGEMENTS

A recent advisory opinion issued by the Health and Human Services' Office of Inspector General (OIG) regarding exclusive arrangements between laboratories and referring physicians has raised a number of questions about client billing arrangements and what is and is not permissible.


Jane Pine Wood

Two attorneys with extensive experience advising clinical and anatomic pathology laboratories addressed these concerns during a May 21 teleconference sponsored by *Laboratory Economics*. Karen Lovitch, an attorney with Mintz Levin (Washington, D.C.) and Jane Pine Wood, an attorney with McDonald Hopkins (Boston), advised laboratories to be careful when structuring agreements with clients but noted that because there are so many variables involved, it is impossible to give blanket advice that will cover all client billing arrangements.

Federal Laws

On the federal level, the anti-kickback statute (AKS) is perhaps the most important law to be aware of when structuring billing arrangements. The AKS prohibits knowingly and willfully paying, receiving, offering, or soliciting remuneration (i.e., something of value) in exchange for the referral of services covered by a federal health care program (FHCP). Safe harbors immunize certain categories of arrangements if all requirements are met. Client billing arrangements can implicate the AKS if deep discounts are offered to clients in exchange for business (including FHCP business) to be billed to payers.


Karen Lovitch

The "substantially in excess" (SIE) provision, which is part of the OIG's permissive exclusion authority, could also be implicated in client billing arrangements. This provision prohibits charging Medicare and Medicaid "substantially in excess" of "usual charges" for the same items or services provided to private payers. While the OIG has tried and failed many times to define key terms used in this provision, the OIG has nevertheless stated on more than one occasion that client billing arrangements could implicate the SIE provision. However, the OIG has also said that a provider need not worry about the SIE provision unless it is discounting close to half of its non-Medicare or non-Medicaid business. The OIG has never actually enforced this provision, probably because of the difficulty in defining key terms, noted Lovitch.

State Laws

There are also a number of state laws and regulations that must be taken into account when structuring client billing arrangements. Most state medical practice acts prohibit fee splitting, which involves the division of professional fees in exchange for a referral. However, state medical boards have declined to take disciplinary action against physicians who engage in fee splitting through discounted account billing arrangements, noted Wood.

A handful of states prohibit any markup of services by a physician. What's more, many states require the lab performing testing to bill payers directly. Most of the client billing prohibitions apply exclusively to AP services, although the scope varies from state to state. For example, some prohibitions apply only to the professional component (PC) while some states allow labs to bill physician practices for the technical component if the physician practice performs the PC.

Many states also have disclosure requirements, under which clients must disclose certain information (including the party that performed the services and the price paid) when billing third parties. Both Wood and Lovitch advised labs to consult with their local counsel on state regulations when structuring billing agreements with clients.

The OIG's Take

The OIG has weighed in periodically on arrangements between labs and clients. Advisory Opinion 99-13 is probably one of the most significant advisory opinions for labs related to billing arrangements. In this opinion, requested by Wood on behalf of an anatomic pathology laboratory client in 1999, the OIG explained that lab and pathology providers and the physicians who purchase such services risk violating the AKS if they have deeply discounted pricing arrangements.

The OIG wrote that suspect discounts include, but are not limited to, discounted prices that are below the pathology and laboratory provider's cost. In determining whether a discount is below cost, the OIG explained that it will consider the total of all costs (including labor, overhead, equipment, etc.) divided by the total number of tests.

While the OIG frowns on deeply discounted arrangements, it does appear open to modest discounts. In Advisory Opinion 98-8, the OIG explained that some discounted pricing could be justified by the cost savings achieved by the seller as a result of a "cash and carry" purchase arrangement. In conversations with Wood in 1999, the OIG's attorneys stated that a selling pathology and laboratory provider could recognize costs savings from a client billing arrangement (lower billing and collection costs, reduced bad debt) and these savings could justify a modest discount.

"The OIG would be more upset about an arrangement if the laboratory's profit margin on Medicare work was substantially higher than its profit margin on client bill work," said Wood.

The OIG's most recent opinion related to arrangements between labs and physicians came this April (No. 15-04). The opinion concerned an exclusive services arrangement between a laboratory and its physician office clients under which the lab would not bill out-of-network commercial payers or patients covered by those payers. The OIG concluded that this arrangement resulted in prohibited remunerations based on consistent reference ranges and savings from the need for only one interface that doesn't involve maintenance fees. The OIG also said the arrangement could lead to steering of FHCP business and could implicate the substantially-in-excess provision.

Waiver of Payment

Waiver of amounts owed by out-of-network (OON) patients is a particularly tricky area, noted Wood and Lovitch. Most of the enforcement in this area has come not from the federal government, but from private payers who have become more aggressive in their efforts to stop labs from waiving patient balances.

In two recent high-profile cases, both CIGNA and Aetna filed lawsuits against Health Diagnostic Laboratories (HDL), claiming that the lab failed to charge members for OON services and that the lab allegedly submitted "grossly inflated, phantom charges" that didn't reflect its actual charges and openly advertised that patients would have no payment responsibility.

While federal enforcement agencies have not focused on client billing arrangements, Wood and Lovitch cautioned labs not to become too complacent, especially considering that private payers are becoming more aggressive in enforcing contracts and that the federal government is paying attention to what is happening.

"Even though the most recent advisory opinion is non-binding, fact-specific and seemingly inconsistent with previous OIG guidance, laboratories should nevertheless consider it when structuring client billing arrangements," advised Lovitch.

"We're living in a new world of enforcement," said Wood. "The bar for intent under the anti-kickback statute has fallen, and the bar for enforcement has also fallen. Arrangements that might not have attracted scrutiny in the past might attract attention now."

HEALTH DIAGNOSTIC FILES FOR CHAPTER 11 BANKRUPTCY

Health Diagnostics Laboratory (HDL-Richmond, VA) filed for Chapter 11 Bankruptcy after its bank, BB&T, refused to allow HDL access to the funds in any of the company's accounts with BB&T. HDL has about $10 million in outstanding loans from BB&T which the bank has declared to be in default.

HDL owes a grand total of more than $100 million to over 200 different creditors, according to the company's bankruptcy filing made in the U.S. Bankruptcy Court for the Eastern District of Virginia (case: 15-32919-KRH) on June 7.

HDL's largest unsecured creditor is the U.S. Department of Justice, which is owed $49.5 million for a settlement that ended an investigation into HDL's practice of paying a "processing and handling" fee of $20 to ordering physicians. Other major creditors include Randox Laboratories (owed $4.5 million), Metabolon (owed $3.1 million) as well as former CEO LaTonya Mallory (owed $2.4 million).

The bad publicity surrounding the DOJ investigation and settlement led to a severe decline in HDL's business. HDL processed an average of 3,600 patient specimens per day and recorded revenue of $375 million in 2013. HDL currently processes about 2,000 patient specimens per day and *Laboratory Economics* estimates that its revenue has fallen to approximately $200 million per year.

"Coupled with the agreement we reached earlier this year with the U.S. Department of Justice—one that resolved all allegations against our Company while making it clear that there was no finding of wrongdoing—the protections of Chapter 11 should allow the Company to put a difficult period behind it and build on the future of the vitally important work we do to help improve the health of millions of Americans," HDL CEO Joseph McConnell said in a statement.

Top 12 Unsecured Claims of HDL

Name of Creditor	Claim	Amount
U.S. Dept. of Justice	Settlement Contract	$49,512,344
Randox Laboratories	Contract/Trade Debt	$4,517,068
Metabolon	Contract	$3,067,775
LaTonya S. Mallory (former CEO)	Contract	$2,421,754
Roche Diagnostics	Trade Debt	$1,708,119
Kansas Bioscience Authority	Contract	$1,589,875
diaDexus	Trade Debt	$1,504,662
Ropes & Gray LLP	Legal Fees	$1,483,365
Oncimmune Limited	Contract	$737,675
Numares Group	Contract/Trade Debt	$734,798
FedEx	Trade Debt	$606,422
Cleveland HeartLab	Trade Debt	$600,028
Total Top 12 Creditors		$68,483,885

Source: Bankruptcy Court, Richmond Division (case: 15-32919-KRH)

NATERA SEEKS $100 MILLION FROM IPO

Natera Inc. (San Carlos, CA) has filed with the Securities & Exchange Commission to raise up to $100 million from an initial public offering (IPO). The investment banks Morgan Stanley, Cowen and Company and Piper Jaffray are managing the IPO.

Natera operates a CLIA-certified lab in northern California that markets prenatal genetic tests. Its primary product is a laboratory-developed blood test, branded "Panorama," that screens for Down syndrome and other chromosomal abnormalities at a list price of $1,495. The test uses a simple blood draw from the mother and can be performed within the first trimester of pregnancy, as early as nine weeks, without any risk to the fetus.

The company is also developing a liquid biopsy test to analyze circulating tumor DNA of common cancers, including breast, ovarian and lung cancer.

Natera at a Glance

Founded	2003
Revenue 2014	$159.3 M
Net loss 2014	-$5.2 M
Test volume 2014	215,000
# Employees	647

Source: Natera IPO filing

Natera reported a net loss of $5.2 million in 2014 versus a net loss of $37.1 million in 2013; revenue increased from $55.2 million to $159.3 million. The company processed 215,000 tests in 2014 versus 85,000 tests in 2013. Since being formed in 2003, Natera has accumulated losses totaling $190 million.

Natera competes with a number of other labs offering non-invasive prenatal genetic screening tests, including Quest Diagnostics (Qnatal Advanced), LabCorp (informaSeq), Illumina (verifi Prenatal Test), Sequenom (MaterniT21 PLUS) and Roche's Ariosa Diagnostics (Harmony Prenatal test).

The largest owners of Natera include Sequoia Capital, 20% stake; Claremont Creek Ventures, 19%; and Lightspeed Venture Partners, 10%. Natera's founder and CEO Matthew Rabinowitz, PhD, age 42, owns 14% of the company.

SUMMIT PATHOLOGY BUYING ANAPATH DIAGNOSTICS

Summit Pathology (Loveland, CO) has agreed to acquire AnaPath Diagnostics Inc. (Cheyenne, WY) a pathology laboratory with three pathologists serving Wyoming and western Nebraska. AnaPath's owners Drs. Phil Haberman and Jakub Stefka will become partners of Summit Pathology. Financial terms of the deal, which is expected to close Aug. 1, were not disclosed.

Summit Pathology will add three pathologists from AnaPath, including Haberman and Stefka, to its staff of 15 pathologists. AnaPath's lab in Cheyenne will remain open.

Summit Pathology has lab director contracts with 10 hospitals in northern Colorado and will also take over AnaPath's contract with the Cheyenne Regional Medical Center.

AURORA DIAGNOSTICS REPORTS $55M LOSS FOR 2014

Aurora Diagnostics (Palm Beach Gardens, FL) reported a net loss of $55.5 million for 2014 versus a net loss of $73 million in 2013; revenue was down 2.3% to $242.6 million. The company processed 2.113 million accessions in 2014 (down 1%), while average revenue per accession was $115 (also down 1%). Aurora's reporting of its 2014 financial results were delayed by a change in its accounting firm (see *LE*, April 2015, page 6).

As of Dec. 31, 2014, Aurora reported cash holdings of $26.4 million and total long-term debt of $370.8 million. The company's shareholders equity (aka book value) was -$107.6 million as of Dec. 31, 2014.

As of June 10, Aurora's senior debt (CUSIP: 051620AB8, 10.75%, maturity 1/15/2018) was selling at approximately 88 cents on the dollar with a yield to maturity of 16%.

VERITAS OFFERS DEEP DISCOUNT PRICING FOR BRCA TESTING

The genetic testing lab startup company, Veritas Genetics (Boston, MA), has launched a new saliva-based BRCA1 and BRCA2 breast cancer mutation test at a list price of $199. Veritas says it can earn a profit from the test at this price point, even though it is a fraction of the $3,340 list price that market leader Myriad Genetics charges for its competing test (BRACAnalysis). In addition, Veritas says it will match every purchased test with a donated test to advocacy organizations for distribution to women in financial need.

Testing for the laboratory-developed test, which is being sold under the brand name "myBRCA," will be performed at Veritas' CLIA certified laboratory in Danvers, Massachusetts.

Veritas was founded in 2014 by leaders in genomics from Harvard Medical School, including Dr. George Church, Mass General Hospital and others. The company recently raised $10 million from Lilly Asia Ventures, a venture capital firm affiliated with Eli Lilly.

ANOTHER MAC FOLLOWS PALMETTO'S POLICY (*cont'd from page 1*)

CGS is the second MAC to follow Palmetto's policy on IHC and special stain ordering by pathologists. Earlier this year, Noridian Healthcare Solutions, the MAC for thirteen western states including California, instituted the same coverage decision (see *LE*, February 2015, pp. 7-8). The policy is now in effect for a total of 19 states (AK, AZ, CA, HI, ID, KY, MT, NC, ND, NV, OH, OR, SC, SD, UT, VA, WA, WV and WY), assuming that CGS finalizes the LCD.

The policy 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. The College of American Pathologists (CAP) has opposed the policy arguing that the supporting evidence behind Palmetto's LCD lacked credibility and was unsubstantiated and that the LCD encroached on the pathologist's medical judgment.

Separately, *Laboratory Economics* notes that Palmetto recently issued a draft non-coverage policy (LCD 35912) related to genetic testing for hypercoagulabilty/thrombophilia (Factor V Leiden, Factor II Prothrombin and MTHFR).

WHO IS THE NATION'S LARGEST PATHOLOGY LAB?

Miraca Life Sciences' main laboratory in Irving, Texas is the nation's largest pathology lab, as measured by volume of CPT 88305 services billed to Medicare in 2013, according to an exclusive analysis of Medicare Part B utilization data by *Laboratory Economics*. Miraca's Texas lab billed Medicare for 237,170 units of CPT 88305 in 2013, down 0.5% from 238,429 units in 2012.

Top 25 Pathology Labs by Medicare Part B Volume of CPT 88305

LABORATORY NAME	CITY	ST	2013 VOLUME	2012 VOLUME	% CHG
MIRACA LIFE SCIENCES	IRVING	TX	237,170	238,429	-0.5%
AMERIPATH NEW YORK LLC	PORT CHESTER	NY	128,225	128,775	-0.4%
COHEN DERMATOPATHOLOGY	NEWTON	MA	126,016	119,110	5.8%
BOSTWICK LABORATORIES	UNIONDALE	NY	116,779	106,175	10.0%
AMERIPATH FLORIDA LLC	POMPANO BEACH	FL	104,840	95,282	10.0%
AMERIPATH CINCINNATI	CINCINNATI	OH	99,897	97,883	2.1%
DIANON SYSTEMS	SHELTON	CT	98,057	100,966	-2.9%
AMERIPATH FLORIDA LLC	TAMPA	FL	94,573	92,065	2.7%
SONIC/CBLPATH	RYE BROOK	NY	89,904	102,666	-12.4%
INSTITUTE FOR DERMATOPATHOLOGY	NEWTOWN SQUARE	PA	84,363	72,733	16.0%
MIRACA/PLUS DIAGNOSTICS	UNION	NJ	78,887	20,716	280.8%
BAKOTIC PATHOLOGY ASSOCIATES, LLC	ALPHARETTA	GA	76,794	69,005	11.3%
DERMATOPATH LAB OF CENTRAL STATES	DAYTON	OH	74,049	64,968	14.0%
AMERIPATH FLORIDA LLC	ALTAMONTE SPRINGS	FL	73,970	77,213	-4.2%
PROPATH SERVICES, LLP	DALLAS	TX	65,420	67,089	-2.5%
PATHOLOGY SOLUTIONS LLC	EATONTOWN	NJ	63,372	54,676	15.9%
LABCORP	LOUISVILLE	KY	51,821	59,117	-12.3%
AMERIPATH FLORIDA LLC	FORT MYERS	FL	48,508	48,629	-0.2%
UCSF DERMATOPATHOLOGY SERVICE	SAN FRANCISCO	CA	48,331	35,379	36.6%
PATHOLOGISTS MEDICAL LABORATORY	ASHEVILLE	NC	43,719	42,079	3.9%
LABORATORY MEDICINE CONSULTANTS	LAS VEGAS	NV	43,462	7,413	486.3%
AMERIPATH NEW YORK LLC	NEW YORK	NY	43,387	44,924	-3.4%
DIANON SYSTEMS	OKLAHOMA CITY	OK	42,007	49,109	-14.5%
GULF COAST DERMATOPATHOLOGY LAB	TAMPA	FL	38,895	41,451	-6.2%
AMERIPATH 501A CORP.	DALLAS	TX	38,735	91,020	-57.4%
TOTAL, TOP 25 LABS			2,011,181	1,926,872	4.4%
TOTAL, ALL LABS			21,061,686	20,755,448	1.5%

Source: *Laboratory Economics* from CMS Medicare Part B Carrier Utilization Data for 2013 & 2012

LAB STOCKS UP 14% YTD

Fourteen lab stocks have increased by an unweighted average of 14% year to date through June 16. In comparison, the S&P 500 Index is up 3.2% and Nasdaq is up 4%. The top-performing lab stocks so far this year are Cancer Genetics Inc., up 78%; Foundation Medicine, up 43%; and NeoGenomics, up 37%. Meanwhile, Quest Diagnostics is up by 8% and LabCorp is up 12%.

Company (ticker)	Stock Price 6/16/15	Stock Price 12/31/14	2015 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	$40.20	$32.13	25%	$1,120	22.1	1.3	3.3
Cancer Genetics Inc. (CGIX)	11.87	6.68	78%	117	NA	8.9	3.8
CombiMatrix (CBMX)	1.43	1.29	11%	18	NA	2.3	1.9
Enzo Biochem (ENZ)	3.00	4.44	-32%	138	NA	1.4	4.1
Foundation Medicine (FMI)	31.67	22.22	43%	1,090	NA	16.0	12.5
Genomic Health (GHDX)	25.93	31.97	-19%	837	NA	3.0	5.3
LabCorp (LH)	120.48	107.90	12%	12,100	26.7	1.9	2.7
Myriad Genetics (MYGN)	32.41	34.06	-5%	2,370	25.9	3.0	3.3
NeoGenomics (NEO)	5.70	4.17	37%	344	NA	3.8	5.8
Psychemedics (PMD)	14.76	15.15	-3%	79	29.1	2.7	6.3
Quest Diagnostics (DGX)	72.57	67.06	8%	10,420	20.1	1.4	2.5
Response Genetics (RGDX)	0.33	0.32	4%	13	NA	0.8	NA
Sonic Healthcare (SHL.AX)	21.37	18.50	16%	8,590	22.6	2.1	2.6
Veracyte (VCYT)	11.25	9.66	16%	309	NA	7.4	7.2
Unweighted Averages			14%		24.4	4.0	4.7

Source: Bloomberg

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