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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

PRESIDENT'S 2017 BUDGET SEEKS TO CLOSE SELF-REFERRAL LOOPHOLE

President Obama's budget for fiscal year 2017 supports excluding anatomic pathology (AP) services from the In-Office Ancillary Services (IOAS) exception to the Stark Law. This is the third year in a row that the president's budget has proposed removing AP from the IOAS exception. Closing the self-referral loophole would strike a deathblow to in-office histology labs at urology, gastroenterology and dermatology practices. But despite support from the Obama administration, closing the loophole is still far from a sure thing. For a full update on the current state of insource lab and pathology services at specialty groups, *see page 5*.

UPTICK IN LAB ENFORCEMENT; CUSTOM PANELS UNDER INCREASED SCRUTINY

The recent uptick in enforcement actions against clinical laboratories could be an indication that there are more settlements to come in 2016, says an attorney speaking at the annual meeting of the American Clinical Laboratory Association on March 3.

The increase in cases in 2015 is reminiscent of the Project LabScam settlements of the late 1990s, which involved a number of multi-million-dollar civil and criminal settlements and criminal convictions, said Karen Lovitch, an attorney with Mintz Levin (Washington, DC).

"Some of the issues we're seeing now—such as medical necessity—are the same that we saw almost 20 years ago," said Lovitch. "For example, we are seeing a laser-like focus on custom panels right now." *Cont'd on page 8*.

FDA CONFIRMS INTENT TO RELEASE FINAL LDT GUIDANCE THIS YEAR

A Food and Drug Administration (FDA) official earlier this month confirmed that it is the agency's intention to release final guidance on oversight of lab-developed tests (LDTs) before the end of the year. Speaking at the annual meeting of the American Clinical Laboratory Association (ACLA) March 3, Jeff Shuren, MD, Director of the FDA Center for Devices and Radiological Health, said that the actual date of release is out of his control but that policymakers are well aware of "certain timeframes related to the Congressional clock and the administration that we have to be aware of." *Cont'd on page 2*.

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FDA CONFIRMS INTENT TO RELEASE FINAL LDT GUIDANCE (*cont'd from p. 1*)
Congress is scheduled to adjourn at the end of September until mid-November. Following the elections, Congress is expected to be in session just a few weeks because of holidays. Target adjournment for the year is December 16. The FDA is required to give Congress 60 days' notice before issuing the final guidance.

Once the FDA completes the final guidance, it will have to go through additional review with the Department of Health and Human Services and the Office of Management and Budget (OMB).

Sources say there is great pressure from the Obama Administration to release all healthcare regulations and guidance prior to the end of Obama's term. *Laboratory Economics* predicts that final guidance will be issued prior to the start of the October adjournment period, perhaps even as soon as late summer.

Shuren also noted that release of a final guidance would not necessarily preclude Congress from enacting an alternative proposal. There are several alternatives currently being discussed on the Hill, including legislation drafted by the House Energy and Commerce Committee on which the FDA has provided technical guidance. This draft is based on an alternate framework proposed by the Diagnostic Test Working Group, a coalition of IVD companies and laboratories, which would create a new FDA center for in vitro clinical tests.

Asked about his thought on using third-party reviewers for LDTs, which has been proposed by several industry groups, Shuren said the agency is accustomed to using such outside reviewers and is very comfortable with the concept. "I think it could work," he noted.

CMS OFFICIAL SAYS DELAY IS LIKELY FOR NEW LAB PAYMENT SYSTEM

The head of the group overseeing development of the final rule implementing a revised Medicare payment system for clinical laboratories declined on March 3 to say when the rule would be published, but he did confirm that the new system would not be in place by Jan. 1, 2017, as required by the Protecting Access to Medicare Act (PAMA).

"Given that the final rule isn't out yet, it's pretty clear that [implementation] won't be Jan. 1, 2017," said Marc Hartstein, Director of the Hospital and Ambulatory Policy Group at the Centers for Medicare and Medicaid Services (CMS). Hartstein spoke during the annual meeting of the American Clinical Laboratory Association (ACLA). The proposed rule was published on Sept. 25, 2015.

ACLA has called for a one-year delay in implementation while the National Independent Laboratory Association (NILA) has called for a two-year delay, with implementation on Jan. 1, 2019. In comments submitted to CMS, ACLA proposed a data collection period from Jan. 1 to June 30, 2016, with the data reporting period from Jan. 1 to March 31, 2017. NILA recommends that data collection run from Jan. 1 to June 30, 2017, with reporting from Jan. 1 to March 31, 2018.

Hartstein would not say whether he favors a one- or two-year delay. He also would not indicate when he expects the final rule to be published other than to joke, "If it's not out by Election Day, we're in trouble." Asked if CMS would consider releasing an interim final rule to allow for additional comments before the rule is finalized, Hartstein left open the possibility.

Addressing concerns raised by some about civil money penalties (CMPs) that could be imposed for failure to report data or for reporting inaccurate data, Hartstein said he believes the lab industry is more concerned than it needs to be. The statute calls for CMPs of $10,000 per day for each failure to report or each such representation or omission of reporting of private payer data.

"My experience would suggest that if we see a pattern of submitting fraudulent data, then a lab should be concerned," he told conference attendees. "An errant keystroke is not cause for concern."

LABCORP REPORTS FULL-YEAR 2015 RESULTS

LabCorp (Burlington, NC) reported net income of $436.9 million for the full-year 2015, down from $511.2 million in 2014. LabCorp's overall revenue increased by 41.5% to $8.506 billion in 2015, driven by the acquisition of Covance Inc. on February 19, 2015.

LabCorp's traditional lab testing business increased its revenue by 6.2% to $6.199 billion in full-year 2015. This increase was driven by organic requisition volume growth of 3.2%. BeaconLBS contributed 0.9%, and average revenue per requisition was up 0.4%. In addition, lab acquisitions (including Physicians Reference Laboratory) added 2.5% to growth, while currency fluctuations decreased revenue by 0.8%.

On February 18, LabCorp held a conference call with analysts and investors. Here are some comments on key topics from CEO David King.

Growth Areas
"The biggest areas of growth in esoteric testing are probably women's health, NIPT (noninvasive prenatal testing), and we are continuing to see good momentum with BRCA and infectious disease."

BeaconLBS
"For BeaconLBS, the expansion opportunities in 2016 are new markets with the existing customer, which is United, new customers, which are other organizations that may be interested in subscribing to the tool, and new channels, which is the addition of more capabilities such as molecular diagnostics to the menu."

"And all those things are underway, and we feel very good about where we are with BeaconLBS. This is a service that the BeaconLBS team within LabCorp has really invented, created, designed, and implemented, and I am really proud of them, and they should be really proud of themselves about what they've accomplished, because it's terrific. And it's generating a fairly significant amount of revenue now, and we see the opportunity for great growth there."

Bad Debt
"Bad debt improved throughout the year (from 4.6% in 2014 to 4.3% in 2015). The team did a terrific job in terms of both reducing the bad-debt rate and recapturing additional revenue that previously was going to bad debt. The issue on self-pay is we're seeing, as you see more patients come through exchanges, exchanges do tend to have higher deductibles, higher self pays, and now we are experiencing something, although in a limited way that you've heard other providers talk about, which is people who are on and off the exchange. So they are on the exchange and then they're off the exchange and then they sign back up again. There are 29 different reasons right now why people can get on an exchange even outside the enrollment period. And so we're seeing some of that, and it does mean that more bills go to the patient. So for now we feel like we have the situation well in hand, but it is something that we're keeping a close eye on."

Update on PAMA Lab Test Repricing
"We have not heard anything further. Obviously there were some very positive developments from our perspective in terms of strong letters going from the House, from the Senate and from the Chair and Ranking Member of the Finance Committee encouraging both the inclusion of at least a selection of key hospital labs as well as a delay in the implementation of PAMA. We continue to believe that the inclusion of key hospital labs is absolutely vital to accomplish the Congressional purpose, which was a market-based price for Medicare. Now we're at the end of February and the rule has not been finalized. It's hard for me to imagine how this could be implemented in January of 2017 in a way that would be fair to our industry."

LabCorp Financial Summary ($ millions)

	2015	2014	% Change
Total revenue	$8,505.7	$6,011.6	41.5%
LabCorp Diagnostics	6,199.3	5,838.0	6.2%
Covance Drug Development	2,306.4	173.6	1228.6%
Operating cash flow	982.4	739.0	32.9%
Capital expeditures	255.8	203.5	25.7%
Free cash flow	726.6	535.5	35.7%
Pretax income	732.1	826.7	-11.4%
Net income	436.9	511.2	-14.5%
Diluted EPS	4.34	5.91	-26.6%
Total debt	6417	3029.8	111.8%
Cash & securities	716.4	580.0	23.5%
Shareholders' equity	5010.3	2820.5	77.6%
Bad debt %	4.3%	4.6%	-6.5%
Days sales outstanding	49	49	0.0%
Est'd number of requisitions	138.6	131.1	5.7%
Est'd revenue per requisition	44.72	44.54	0.4%

Source: LabCorp and requisition estimates from *Laboratory Economics*

QUEST COMPLETES PURCHASE OF CONNECTICUT OUTREACH LAB

Quest Diagnostics has completed its previously announced acquisition of the outreach laboratory business Clinical Laboratory Partners (CLP) from Hartford HealthCare (HHC). HHC operates five hospitals in Connecticut. Financial terms were not disclosed.

Under the agreement, CLP will transition its clinical lab testing now provided by its lab in Newington (just south of Hartford) to Quest's rapid-response labs in Stratford, Torrington and Wallingford, Connecticut, and to Quest's new 200,000-square-foot mega-laboratory in Marlborough, Massachusetts.

HHC's hospital-based laboratories and the inpatient and outpatient services they provide are not included in the transaction and will remain part of the HHC system. Professional pathology services performed by Hartford Pathology Associates are also not part of the acquisition.

This is the sixth acquisition of a hospital lab outreach business by Quest since 2012.

Hospital Outreach Labs Acquired by Quest Diagnostics, 2012-2016

Feb. 2016	Clinical Laboratory Partners (Hartford, CT)	NA
Aug. 2015	Memorial Healthtech Laboratories (Los Angeles, CA)	$35M
Apr. 2014	Steward Health outreach lab	$34M
Apr. 2013	Dignity Health outreach lab (CA & NV)	~$30M
Jan. 2013	UMass Memorial outreach lab	$90.4M
Jan. 2012	SED Medical Laboratories (Albuquerque, NM)	$50.5M

Source: *Laboratory Economics* from Quest Diagnostics, UMass and Dignity Health annual reports

PRESIDENT'S 2017 BUDGET SEEKS TO CLOSE LOOPHOLE (*cont'd from p. 1*)

For his 2017 budget, the President has again included striking AP in addition to advanced imaging, radiation therapy, and physical therapy services from the IOAS exception. Removing these services would reduce overutilization and result in an estimated $4.98 billion in Medicare savings over 10 years (2017-2026), according to the budget proposal.

However, even though the President supports closing the loophole, the budget only serves as a blueprint for Congress. Therefore, Congress would still need to pass legislation for the provision included in the budget to become law.

To this end, Rep. Jackie Speier (D-CA) and Rep. Tom Price, MD (R-GA) are working to reintroduce legislation that would remove AP from the IOAS exception.

Rep. Speier had first introduced such a bill, the Promoting Integrity in Medicare Act of 2013 (H.R. 2914), on August 1, 2013. The bill was cosponsored by Reps. Dina Titus (D-NV) and Jim McDermott (D-WA) but was only able to attract support from 11 other members of Congress and never made it out of the House Energy and Commerce Subcommittee on Health.

Meanwhile, Congress and CMS have instead chosen to address alleged overutilization indirectly by reducing Medicare reimbursement rates for pathology services, and this has hurt pathologists as much as or more than self-referring physicians with in-office labs, notes *Laboratory Economics*.

WHAT'S NEW WITH IN-OFFICE PATHOLOGY LABS?

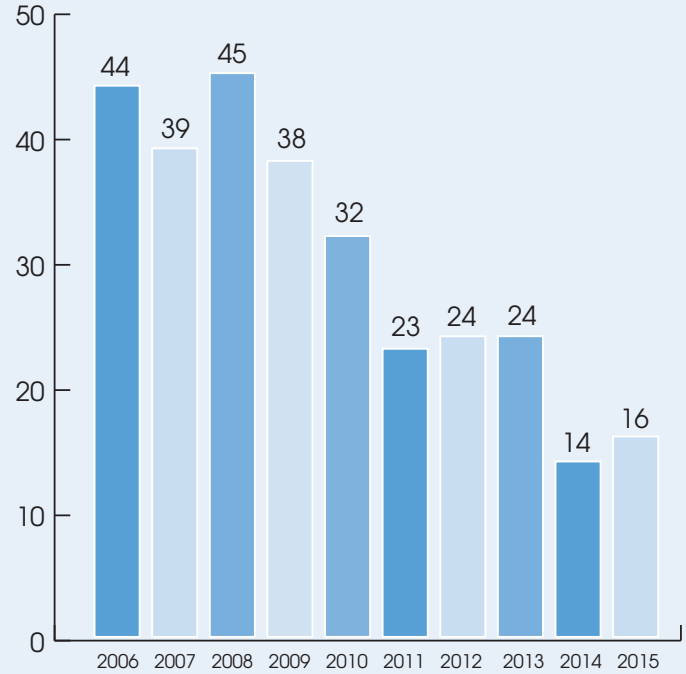
For perspective on the current state of in-office pathology labs at specialty groups, *Laboratory Economics* spoke with Joe Plandowski, Principal at In-Office Pathology LLC (Lake Forest, IL), which has helped install histology labs at 67 specialty groups over the past 10 years.

Urology

Plandowski says Medicare rate cuts have virtually halted all new construction of in-office labs at urology practices for the past year or two. Prior to 2013, a 12-core prostate biopsy was being reimbursed at about $1,260 globally (12 x $105). Today, that same procedure is being reimbursed with a single code (G0416) at a flat rate of $534 regardless of the method or number of core specimens tested. "Urology is a dead market," declares Plandowski.

In fact, some in-office urology labs are quietly shutting down or selling out, notes *Laboratory Economics*.

Number of New CLIA Certificates Issued to Urology Groups for Moderate- or High-Complexity Labs*



*Includes all labs certified for moderate- or high-complexity testing, including both in-office histology labs and clinical labs
Source: *Laboratory Economics* from CMS

For example, Urology of Greater Atlanta (Stockbridge, GA) sold its histology lab to nearby Northside Hospital (Atlanta) last year.

Meanwhile, an analysis of CMS data shows that only 16 urology groups nationwide were issued CLIA certificates to conduct moderate- or high-complexity laboratory testing last year. This compares with an average of 40-50 new labs per year at the peak of the in-office laboratory boom in the mid-2000s.

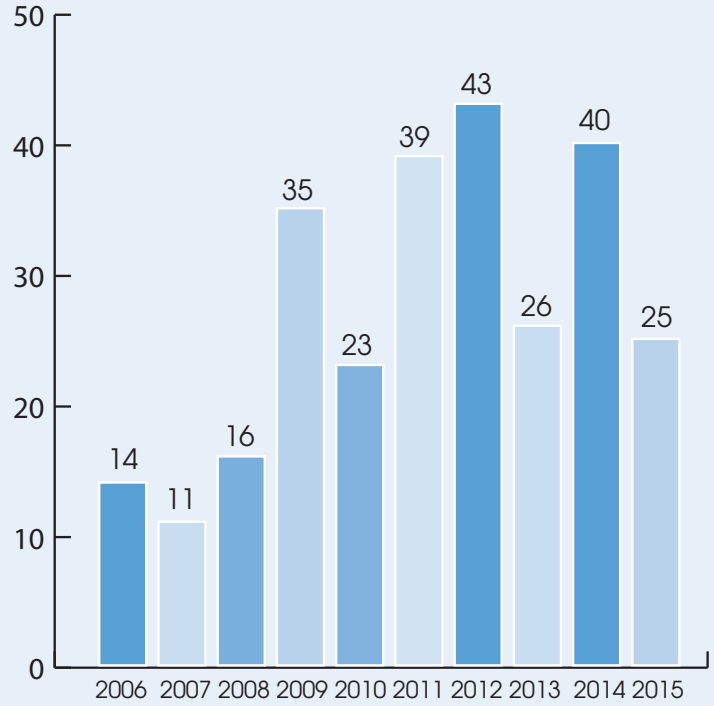
Gastroenterology

Plandowski says gastroenterologists have been most active in setting up new in-office pathology labs. Last year, Plandowski's company helped install five new in-office labs and all five were at gastroenterology groups.

He says the average gastroenterologist generates approximately 1,000 CPT 88305's per year with an average staining rate of about 40%. A gastroenterology group with as little as four doctors can profitably operate their own histology lab and contract with a local pathologist to provide professional interpretations.

CMS data shows that 25 gastroenterology groups nationwide were issued CLIA certificates to conduct moderate- or high-complexity laboratory testing last year. The all-time high was in 2012 when 43 groups opened new labs.

Number of New CLIA Certificates Issued to Gastroenterology Groups for Moderate- or High-Complexity Labs*



*Includes all labs certified for moderate- or high-complexity testing, including both in-office histology labs and clinical labs
Source: *Laboratory Economics* from CMS

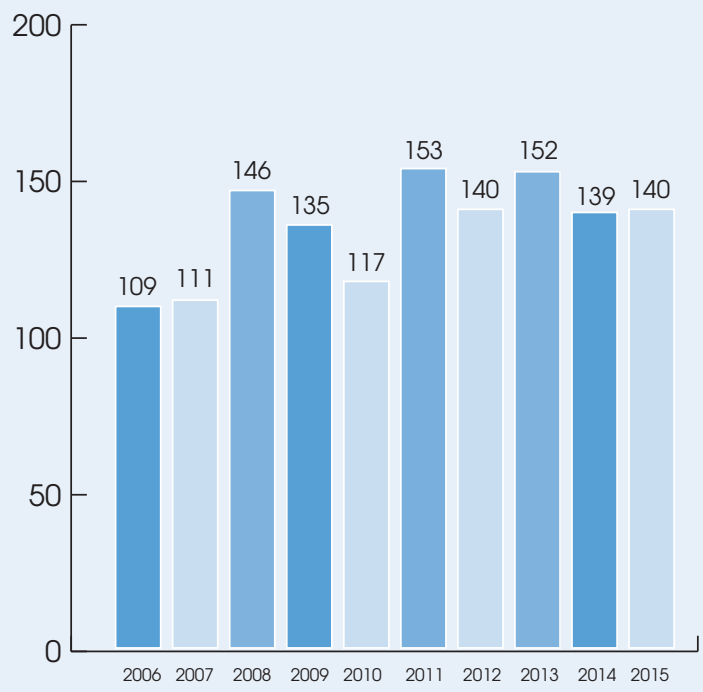
Dermatology

Cuts to 88305-TC in 2013 has slowed down the number of derm groups trying to open their own full-service histology labs, but not stopped the trend completely, according to Plandowski. "It's not rip roaring like it was a few years ago, but the derm market for in-office labs is still alive," he says. Most dermatologists have no problem reading routine tissue cases themselves, but anything questionable they want read by a dermatopathologist," he adds.

CMS data shows that 140 dermatology groups nationwide were issued CLIA certificates to conduct moderate- or high-complexity laboratory testing last year. The all-time high was in 2011 when 153 groups opened new labs.

A large portion of in-office dermatology labs are Mohs labs used for samples collected by microscopically-controlled surgery for skin cancer in areas where tissue preservation is paramount (face,

Number of New CLIA Certificates Issued to Dermatology Groups for Moderate- or High-Complexity Labs*



*Includes all labs certified for moderate- or high-complexity testing, including both in-office histology labs and clinical labs
Source: *Laboratory Economics* from CMS

hands, feet, genitals). Mohs surgery is typically done on an outpatient basis with the dermatologist performing both the surgical excision of the skin cancer and microscopic examination. The surgical pathology codes 88300–88309, 88331–88332, and 88342 are part of the Mohs surgery and are bundled into the derm codes 17311–17315.

A Mohs lab only does specimens derived from Mohs surgery procedures. In addition to a microtome and microscope, the equipment in a Mohs lab consists primarily of a cryostat and a manual linear stainer. It is basically a frozen section lab similar to those found in hospitals, notes Plandowski.

He says an in-office Mohs typically requires about 150 sq. feet of space vs. 300 sq. feet for a full-service histology lab.

Plandowski says the most common reasons why dermatologists object to transforming their Mohs lab into a full-service histology lab are 1) the cost; and 2) the ability to obtain the services of a local dermatopathologist.

Ob/Gyn

A few major Ob/Gyn practices around the country insourced cervical cancer screening tests over the past three years. These include Women's Health Connecticut (200+ physicians) and Women's Care Florida (135 physicians). However, there has been no widespread trend toward insourcing at Ob/Gyn groups, according to Plandowski.

Plandowski says he has tried marketing the concept to Ob/Gyn groups but they have shied away because of the declining volume trend in Pap testing due to extended intervals. Current U.S. Preventative Services Task Force (USPSTF) and American College of Obstetricians and Gynecologists (ACOG) recommendations say women ages 30-65 years should be screened with Pap and HPV testing ("co-testing") once every 3-5 years. Extra revenue from add-on tests for sexually transmitted diseases (e.g., chlamydia/gc, gardnerella, trichomonas, yeast and vaginosis profile) isn't enough to make up for the extended screening interval, he notes.

In addition, Plandowski points out that most big Ob/Gyn groups are composed of a network of small offices (1-3 physicians) spread out over a big geographic region. And this raises courier and information technology expenses for centralized labs at Ob/Gyn groups.

UPTICK IN LAB ENFORCEMENT; CUSTOM PANELS SCRUTINIZED (*cont'd from p. 1*)

Recent federal enforcement actions highlight this focus. In the last year, the feds have gone after both Millennium Health and Health Diagnostic Laboratories (HDL) for violations of the False Claims Act (FCA). Both agreed to large multi-million dollar settlements. There were other lower-profile settlements in 2015 as well involving Family Dermatology, Pharmasan Labs and Piedmont Pathology Associates.

Karen Lovitch

Lovitch advises that laboratories offering custom panels should consider requiring each physician who orders one or more custom panels to sign a custom panel authorization form. She says the form should include an acknowledgement that the physician will order the custom panel only when all tests are medically necessary for the patient and a warning that failure to do so could result in liability for the physician and the laboratory.

"Laboratories should educate physicians on Medicare's medical necessity requirements (and similar requirements imposed by commercial insurers) and the clinical utility of each test offering, and offer physicians the opportunity to consult with the laboratory's clinical personnel," Lovitch tells *Laboratory Economics*. "Laboratories should provide this type of education regardless of whether custom panels are offered."

In addition, the laboratory compliance department should participate in the process by establishing a policy governing custom panels and reviewing and approving custom panel authorization forms, if appropriate, she says. Labs should also consider whether it is appropriate to set a limit on the number of tests that can be included in a custom panel, and recertification should be required at least annually and prior to implementation in any changes to a custom panel.

Individuals at Risk

The federal government is also increasing its focus on the pursuit of individuals in corporate cases as the result of a memo released in September 2015 by Deputy Attorney General Sally Quillian Yates, according to Bill Jordan, a partner with Alston & Bird.

Bill Jordan

The memo mandates a new emphasis on prosecuting individual defendants who are legally responsible for wrongdoing and represents a major shift in federal enforcement policy.

"The Yates Memo set everyone's hair on fire," said Jordan at the ACLA meeting. "It's a huge deal."

The Yates memo also calls for expanded information-sharing between criminal and civil investigators during investigations, which can complicate cases. "There's not a week that goes by that I don't get a civil investigative demand or subpoena related to the lab industry," Jordan added.

Jordan advises that lab executives take compliance seriously. "The ideas that underlie the Yates memo are not new, but the government views individuals as the reason for fraud and its goal is to punish and deter by looking at those it perceives as bad actors," he tells *LE*. "Leaders of companies can start by setting a tone at the top that emphasizes and promotes a strong culture of ethical actions."

In addition, it is important to make sure that the lab has a real, functioning compliance program and not merely the "paper" program that sits on a shelf, Jordan adds. The government now routinely asks executives about what they've done to stress compliance, what resources have been provided to the program, and how the company has acted in the face of the regulatory regime in which it operates.

"The government (and whistleblowers) have been focusing most closely on kickbacks and relationships with referral sources," he notes. "A CEO can stress that these relationships must be for legitimate purposes – not for the purpose of generating referrals. This is a very complex area where consultation with counsel is very helpful in demonstrating that a company is trying to comply with the ever-changing regulatory landscape."

NEOGENOMICS REPORTS FULL-YEAR 2015 RESULTS

NeoGenomics (Fort Myers, FL) reported a net loss of $2.7 million for the full-year 2015, down from a net profit of $1.1 million in 2014. The company's overall revenue increased by 14.6% to $99.8 million in 2015, partially driven by the acquisition of Path Logic in July 2014 (more below). Looking ahead, NeoGenomics said it anticipates full-year 2016 revenues to be in the range of $240 million to $250 million.

On March 1, NeoGenomics held a conference call with analysts and investors. Here are some comments on key topics from CEO Douglas VanOort.

Molecular Testing
Molecular testing growth was strong and now accounts for about a quarter of the company's test mix, according to VanOort. He said the fastest growing subset of molecular testing is the company's custom NeoType cancer panels, which combine molecular, FISH and IHC testing, and are currently growing by roughly 75% per year.

Path Logic Acquisition
NeoGenomics acquired Path Labs LLC (doing business as Path Logic) for $5.9 million on July 14, 2014. At the time of the acquisition, Path Logic, which provides anatomic pathology services in northern California, had 65 employees and annual revenue of approximately $10 million. However, since close of the acquisition, Path Logic's revenue has fallen to approximately $7.5 million per year due to customer attrition. "PathLogic is clearly underperforming. It did experience negative gross margin, it lost a lot of money in quarter four. This has our attention, there's no quick fix….We have had some management changes at PathLogic in the fourth quarter," said VanOort.

Clarient Acquisition
NeoGenomics completed its $310 million acquisition of Clarient Inc. (Aliso Viejo, CA) on December 30. VanOort said Clarient's 75,000-square-foot facility in Aliso Viejo is being redesigned to accommodate all operations performed today in the nearby NeoGenomics Irvine lab, and he expects to complete the move by the end of this year.

NeoGenomics Financial Summary ($000)

	2015	2014	% Chg
Total revenue	$99,802	$87,069	14.6%
Operating cash flow	6,393	9,450	-32.3%
Capital expeditures	2,215	3,772	-41.3%
Free cash flow	4,178	5,678	-26.4%
Pretax income	-4,489	1,289	NA
Net income	-2,657	1,132	NA
Diluted EPS	-0.04	0.02	NA
Total number of requisitions	204,282	152,076	34.3%
Avg. revenue per requisition	489	573	-14.7%

Source: *Laboratory Economics* from NeoGenomics

He said that Clarient traditionally had accounts receivables days sales outstanding of over 100 days. "We quickly installed new leadership for Clarient's billing operations and have made billing a major focus area."

FDA SEEKS INPUT ON GENETIC TEST RESULTS, NGS PANELS

Industry stakeholders gathered in Silver Spring, MD, recently to weigh in on reporting of genetic test results and just what information might be needed to allow physicians to make effective medical decisions.

The Food and Drug Administration (FDA) solicited this information during a public workshop March 2. The agency says this input will inform its approach regarding return of genetic test results.

Elizabeth Mansfield, FDA's deputy director for personalized medicine, told participants that the agency does not want to restrict anyone from having genetic testing done but wants to determine what levels of clinical evidence and information patient and providers need to accurately interpret the test results.

The workshop focused on three different types of genetic tests, which the FDA illustrated with case studies: genetic tests in patients who are currently well to predict their risk of future disease; genetic tests for acute disease, including germline tests for inherited conditions and somatic analyses of tumor tissue; and genetic tests for chronic conditions, which mostly focused on pharmacogenomics tests to predict the response to drugs for the treatments of such diseases.

According to Rina Wolf, Vice President at XIFIN Inc. (San Diego, CA), a number of commenters noted that the average clinician will only read the first three to four lines of a report, thus "actionable" information should be presented first.

Other suggestions made by commenters:

- Information should be presented in multiple ways (i.e., text, color codes, graphics, narratively) because different people comprehend things differently;
- FAQs and data should be presented in a patient-specific manner, such as "What is my actual risk of developing Alzheimer's?" versus saying there is an increased risk of 30%;
- Electronic results are preferred, especially if they are interactive, and give clinicians the ability to drill down for more information.

Ordering physicians and genetic counselors indicated that they prefer to control the amount and type of information they receive, though Wolf notes that under the patient access regulations that took effect in October 2014, patients now have the right to have access to all of their test results.

The FDA will continue to accept comments on patient and professional perspectives on the return of genetic test results and interpretations until March 31. More information on the workshop, including a webcast archive, is available at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm478841.htm.

NGS Panels

At a separate workshop held Feb. 25, the FDA asked for stakeholder input on regulation of next-generation sequencing (NGS) cancer panels. Specifically, the agency wants to know what preanalytical, analytic and clinical validity characteristics the agency should consider in regulation of such tests when used to guide treatment decisions.

FDA officials asked experts at the workshop what requirements they believe are necessary for approving or clearing oncopanels in kit format that labs can perform in a standardized way based on

specifications included in labeling. They also asked workshop attendees to consider an "intended use" statement in which the NGS device would be characterized as a tool for detecting sequence variation using a specific platform, gauging certain mutations and assessing certain types of specimens.

The FDA will accept comments on regulation of NGS cancer panels until March 28. The agency said it will likely issue guidelines on such panels but did not specify a timeframe. Additional information, including an archived webcast of the meeting, is available at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm480046.htm

GRODMAN RESIGNS FROM BIO-REFERENCE LABS

OPKO Health has named Gregory Henderson, MD, PhD, as President of Bio-Reference Laboratories (BRL), effective immediately. Dr. Henderson succeeds Marc Grodman, MD, age 64, who is resigning, having served as Chairman, President and CEO of BRL since founding the company in 1981. OPKO acquired BRL in August 2015 for $950 million. Grodman had owned a 10% stake in Bio-Reference and reaped approximately $100 million from the sale to OPKO.

Dr. Henderson founded and sold two large clinical lab companies, including NextWave Diagnostic Laboratory (Wilmington, NC) and Pacific Pathology Partners (Seattle, WA). He has been a practicing pathologist for more than 20 years and joins BRL from the Mount Sinai Health Network, where he was the Vice Chairman of Pathology Outreach and Affiliate Laboratory Affairs.

CELLNETIX NAMES NEW CHIEF EXECUTIVE

Kathleen Fondren has been promoted to CEO at Seattle's CellNetix Pathology & Laboratories, where she has been serving as chief operating officer since September 2014. She succeeds company founder, chairman and CEO Don Howard, who resigned from CellNetix at the end of December. Fondren joined CellNetix in the COO role. From 1987 to 2014, she had worked at Highline Medical Center in Burien, where she became assistant administrator for clinical services.

THIRD LAW FIRM NOW INVESTIGATING THERANOS

The vultures are circling Theranos Inc. (Palo Alto, CA). Rosen Law Firm (New York City) has announced it is preparing a class action lawsuit to recover losses suffered by Theranos investors resulting from allegations that Theranos may have issued materially misleading business information to investors. There are now three law firms seeking potential class action lawsuits against Theranos—the two others are Kessler Topaz & Cheek LLP (Philadelphia and San Francisco) and Chimicles & Tikellis LLP (Haverford, PA).

But apparently one person that hasn't lost faith in Theranos is presidential contender Hillary Clinton. Theranos is hosting a fundraiser for Clinton's campaign on Monday morning, March 21. The event will take place at Theranos' headquarters in Palo Alto and will feature a conversation with Hillary's daughter Chelsea Clinton. Participants who pay $2,700 will get to go to a "host reception" with Chelsea.

Meanwhile, Theranos continues to advertise a job opening for Senior Litigation Counsel. This position will "Manage Theranos' overall litigation strategy at every stage of a case, including documentation collection, discovery, court filings, hearings, settlement negotiations, and trial," according to a job advertisement on the Theranos website.

LAB STOCKS DOWN 10% YTD

Sixteen lab stocks have declined by an unweighted average of 10% year to date through March 14. In comparison, the S&P 500 Index is down 5.1%. The top-performing lab stocks so far this year are Psychemedics, up 41%, and Rosetta Genomics, up 9%. Meanwhile, LabCorp is down 7% and Quest Diagnostics is down 2%.

Company (ticker)	Stock Price 3/14/16	Stock Price 12/31/15	2016 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$2.37	$3.30	-28%	$32	NA	1.5	1.0
CombiMatrix (CBMX)	5.37	10.95	-51%	5	NA	0.5	0.8
Enzo Biochem (ENZ)	4.35	4.50	-3%	200	33.7	2.1	4.3
Exact Sciences (EXAS)	6.46	9.23	-30%	622	NA	15.7	1.9
Foundation Medicine (FMI)	18.21	21.06	-14%	627	NA	6.5	2.3
Genomic Health (GHDX)	24.50	35.20	-30%	797	NA	2.8	5.8
Invitae (NVTA)	8.56	8.21	4%	273	NA	32.7	2.0
LabCorp (LH)	115.03	123.64	-7%	11,640	26.5	1.4	2.3
Myriad Genetics (MYGN)	37.07	43.16	-14%	2,640	27.9	3.6	3.5
NeoGenomics (NEO)	6.93	7.87	-12%	420	NA	4.3	6.9
Opko Health (OPK)	10.27	10.05	2%	5,600	NA	12.3	3.0
Psychemedics (PMD)	14.33	10.14	41%	78	51.1	2.8	6.6
Quest Diagnostics (DGX)	69.85	71.14	-2%	10,010	14.3	1.4	2.2
Rosetta Genomics (ROSG)	1.34	1.23	9%	24	NA	3.8	1.2
Sonic Healthcare (SHL.AX)	17.72	17.87	-1%	7,320	20.0	1.6	2.1
Veracyte (VCYT)	5.61	7.20	-22%	155	NA	3.4	2.8
Unweighted Averages			-10%		28.9	6.0	3.0

Source: Capital IQ

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